

MEDIMMUNE INC /DE  
Form 10-K  
March 09, 2005

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D. C. 20549

## FORM 10-K

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

For the fiscal year ended December 31, 2004

Commission File Number: 0-19131

## 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, Maryland 20878

(Address of principal executive office)  
(Zip Code)

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

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

Securities Registered pursuant to Section 12(g) of the Act:

Common Stock, \$.01 par value  
(Title of Class)

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

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

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

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Aggregate market value of the 249,022,698 shares of voting and non-voting common equity held by non-affiliates of the registrant, based on the closing price on June 30, 2004, was \$5.8 billion. Common Stock outstanding as of February 25, 2005: 248,727,739 shares.

Documents Incorporated by Reference: Portions of the registrant's definitive proxy statement for the annual meeting of stockholders to be held May 19, 2005 (Part III).

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FORM 10-K  
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MedImmune, Synagis, CytoGam, Ethyol, FluMist, NeuTrexin, RespiGam and Vitaxin are registered trademarks of the Company. Numax is a trademark of the Company. Accuspray is a trademark of Becton Dickinson. BiTE is a trademark of Micromet AG.

**FORWARD-LOOKING STATEMENTS**

*The statements in this annual report that are not descriptions of historical facts may be forward-looking statements. Those statements involve substantial risks and uncertainties. You can identify those statements by the fact that they contain words such as anticipate, believe, estimate, expect, intend, project or other terms of similar meaning. Those statements reflect management's current beliefs, but are based on numerous assumptions, over which MedImmune may have little or no control and that may not develop as MedImmune expects. Consequently, actual results may differ materially from those projected in the forward-looking statements. Among the factors that could cause actual results to differ materially are the risks, uncertainties and other matters discussed below under Item 1. Business, Risk Factors, and elsewhere in this report. MedImmune cautions that RSV disease and influenza, two diseases targeted by the Company's products, occur primarily during the winter months; MedImmune believes its operating results will reflect that seasonality for the foreseeable future. MedImmune is also developing several products for potential future marketing. There can be no assurance that such development efforts will succeed, that such products will receive required regulatory clearance or that, even if such regulatory clearance is received, such products will ultimately achieve commercial success. Unless otherwise indicated, the information in this annual report is as of December 31, 2004. This annual report will not be updated as a result of new information or future events.*

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**PART I**

**ITEM 1. BUSINESS**

MedImmune is committed to advancing science to develop better medicines that help people live healthier, longer and more satisfying lives. It currently focuses its efforts on the areas of infectious disease, oncology and immunology. MedImmune markets four products: Synagis (palivizumab) and FluMist (Influenza Virus Vaccine Live, Intranasal) to help prevent two common respiratory infectious diseases; Ethyol (amifostine) to help reduce undesired side effects of certain anti-cancer chemo- and radiotherapies; and Cytogam (cytomegalovirus immune globulin intravenous (human)) to help prevent cytomegalovirus (CMV) disease associated with solid organ transplantation.

Founded in 1988 and headquartered in Gaithersburg, Maryland, MedImmune operates facilities in the United States and Europe to manufacture and distribute one or more components of each of its products. MedImmune also has clinical, research and development staff in the U.S., through which it is developing a pipeline of product candidates for potential commercialization. In addition to its internal efforts, the Company has established clinical, research, development, manufacturing and commercialization collaborations with other companies and organizations.

**Products**

**Synagis**

Synagis is a humanized monoclonal antibody ( MAb ) approved for marketing in 1998 by the U.S. Food and Drug Administration (the FDA ) for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus ( RSV ) in pediatric patients at high risk of acquiring RSV disease. RSV is the most common cause of lower respiratory tract infections in infants and children worldwide. Healthy children and individuals with adequate immune systems often acquire a benign chest cold when infected with RSV. In contrast, high-risk infants, including children born prematurely or with chronic lung disease, also known as bronchopulmonary dysplasia ( BPD ), and children with certain heart diseases present at birth (hemodynamically significant congenital heart disease ( CHD )) are at increased risk for acquiring severe RSV disease (pneumonia and bronchiolitis), often requiring hospitalization.

Synagis is administered by intramuscular injection once per month during anticipated periods of RSV prevalence in the community, which is typically during the winter months in the Northern Hemisphere. As such, the sales of Synagis reflect this seasonality and occur primarily in the first and fourth quarters of the calendar year. In the U.S., Synagis is co-promoted by MedImmune and the Ross Products Division of Abbott Laboratories ( Abbott ).

Outside the U.S., Abbott International ( AI ), an affiliate of Abbott, exclusively distributes Synagis. Synagis was originally approved by the European Medicines Agency ( EMEA ) in September 1999 for the prevention of serious lower respiratory tract disease caused by RSV, and in Japan in 2002. The indication for congenital heart disease infants was approved by the EMEA in October, 2003. As of December 31, 2004, 61 countries outside the U.S. had approved Synagis for marketing.

In 2004, the FDA approved MedImmune s supplemental Biological License Application ( BLA ) for a new liquid formulation of Synagis to be used in the United States. The liquid formulation is a product improvement over the current lyophilized (freeze-dried) version that the Company believes will enhance the convenience for physicians in administering the drug. The Company expects to switch to this new formulation of Synagis in the U.S. during the 2005/2006 RSV season.

In 2004, 2003 and 2002, the Company reported \$942 million, \$849 million, and \$672 million, respectively, in worldwide net product sales from Synagis representing 84%, 86%, and 85% of the Company s total net product sales in each of these three years.

## Ethylol

Ethylol is used to help prevent certain unwanted side effects of specific types of chemo- and radiotherapies that are used to treat cancer. In the U.S., Ethylol was initially approved by the FDA in 1995 to reduce the cumulative renal (kidney) toxicity associated with repeated administration of cisplatin (a common chemotherapy agent) to patients with advanced ovarian cancer.

In 1999, the FDA approved the use of Ethylol for the reduction of the incidence of moderate-to-severe dry mouth (xerostomia) in patients undergoing post-operative radiation treatment for head and neck cancer, when a significant portion of the parotid glands are located in the radiation treatment field. Xerostomia, both acute and chronic, is a debilitating condition in which saliva production is reduced due to damage caused to the salivary glands by therapeutic radiation. Patients with xerostomia are at increased risk of oral infection, dental cavities and loss of teeth, and often have difficulty chewing, swallowing and speaking.

In 1996, the FDA approved the Company's supplemental new drug application under the FDA's Accelerated Approval Regulations to include treatment of patients with non-small cell lung cancer ( NSCLC ). Products approved under the Accelerated Approval Regulations require further adequate and well-controlled studies to verify and describe clinical benefit. The Company completed a post-licensure clinical trial in 2001 designed to show that Ethylol helped protect against cisplatin-induced renal toxicity in patients with NSCLC. In accordance with the Accelerated Approval Requirements, the Company submitted the data to the FDA for review in 2002. Early in 2003, the Company met with the FDA to discuss the FDA's belief that the study did not meet the Accelerated Approval requirement, as well as the FDA's request that another trial be conducted. The Company has submitted a recommendation to the FDA and is awaiting a response. If no agreement can be reached on the design of such a study, there can be no assurances that the FDA will not withdraw approval of Ethylol for the NSCLC indication. MedImmune does not believe that the withdrawal of this indication, should the FDA decide to do so, will meaningfully impact the market potential for Ethylol.

MedImmune is the sole marketer of Ethylol in the U.S., and outside the U.S. the Company has various distribution and marketing arrangements for Ethylol, primarily with affiliates of Schering-Plough Corporation ( Schering ). This product has been approved for marketing in 64 countries worldwide, including the United States.

In 2004, 2003 and 2002, MedImmune reported worldwide net product sales for Ethylol of \$92 million, \$100 million, and \$81 million, respectively, which represented 8%, 10% and 10% of the Company's total net product sales in each of these three years.

## FluMist

FluMist is a vaccine approved for marketing in June 2003 by the FDA for the prevention of disease caused by influenza A and B viruses in healthy children and adolescents, 5-17 years of age, and healthy adults, 18-49 years of age. FluMist is delivered as a nasal mist and is a live, attenuated vaccine, meaning that it uses live viruses that have been modified and weakened to remove their disease-causing attributes but still stimulate the immune system and help prevent the flu. Each year in the U.S., the influenza virus infects an estimated 17 million to 50 million people, many of whom are otherwise healthy children and adults. Vaccination against the influenza virus in the Northern Hemisphere typically commences in October and may last through the peak of the season, which usually occurs in February.

In 2004, the U.S. Centers for Disease Control and Prevention's (the CDC) Advisory Committee on Immunization Practices (the ACIP) announced that FluMist will be included in the federal government's Vaccines for Children (the VFC) program as an alternative to the injectable flu vaccine beginning in the

2005/2006 influenza season. As a result, healthy children ages 5 to 18 years who meet the eligibility requirements of the VFC program may receive FluMist at no cost next season.

In 2004, MedImmune reported \$54 million in revenues for FluMist, or about 5% of the company's total revenues. This amount was composed of \$21 million in product sales of FluMist during the fourth quarter of 2004 for the 2004/2005 influenza season, and \$33 million in revenues related to vaccine sold for the 2003/2004 influenza season that were not reported as revenue until the first half of 2004. The Company did not record any product sales-related revenue for FluMist in 2003 due to the uncertainty associated with returns and discounts in the vaccine's launch season that was not determinable until the first half of 2004. In 2003, MedImmune reported \$46 million in revenues for FluMist, or about 4% of the company's total revenues. This amount was derived solely from milestone and reimbursement payments from Wyeth, the Company's former collaboration partner for FluMist.

#### **Other Products**

The Company also sold three additional products in 2004, 2003 and 2002 reporting \$41 million, \$43 million, and \$38 million in combined worldwide net product sales for each year, respectively. These amounts represent less than 5% of the Company's total reported net product sales in 2004, 2003 and 2002.

- **CytoGam** an intravenous immune globulin product enriched in antibodies against CMV, a herpesvirus. It is indicated for the prevention of CMV disease associated with solid organ transplantation.
- **NeuTrexin (trimetrexate glucuronate for injection)** a lipid-soluble analog of methotrexate, approved for use with concurrent leucovorin administration as an alternative therapy for the treatment of moderate-to-severe *Pneumocystis carinii* pneumonia in immunocompromised patients, such as AIDS patients.
- **RespiGam (respiratory syncytial virus immune globulin intravenous (human))** an intravenous immune globulin enriched in neutralizing antibodies against RSV, indicated for the prevention of serious RSV disease in children less than 24 month of age with BPD or a history of premature birth (i.e., born at 35 weeks or less gestation). RespiGam, the Company's first anti-RSV product, has been replaced in the marketplace by Synagis, and is no longer manufactured or marketed.

#### **Product Candidates**

A significant portion of MedImmune's operating expenses are related to the research and development of investigational-stage product candidates. Research and development expenses were \$327 million in 2004, \$156 million in 2003 and \$148 million in 2002. MedImmune currently focuses its research and development efforts in the therapeutic areas of infectious diseases, immunology and oncology. Any of these programs could become more significant to the Company in the future, but there can be no assurance that any of the new programs under review will generate viable marketable products. As such, the Company continually evaluates all product candidates and may, from time to time, discontinue the development of any given program and focus its attention and resources elsewhere. For example, in 2004 the Company discontinued its preclinical research relating to technology targeting the enzyme Human Aspartyl (Asparaginy)l Beta-Hydroxylase (HAAH) and PC-cell-derived growth factor (PCDGF). The Company may choose to address new opportunities for future growth in a number of ways including, but not limited to, internal discovery and development of new products, in-licensing of products and technologies, and/or acquisition of companies with products and/or technologies. Any of these activities may require substantial research and development efforts and expenditure of significant amounts of capital.

The following table summarizes the Company's current product candidate programs and each is described in greater detail below:

<b>Infectious Disease</b>	<b>Immunology</b>	<b>Oncology</b>
Numax	Anti-IL-9 MAb	Ethyol
CAIV-T	Anti-HMGB-1 MAb	Vitaxin
Human Papillomavirus vaccine	Anti-IFN-alpha MAb	Siplizumab
Epstein-Barr Virus vaccine	Anti-IFNAR MAb	MT-103
<i>S. pneumoniae</i> vaccine	Anti-chitinase MAb	Anti-EphA2 MAb and vaccine
PIV-3/RSV/hMPV combination vaccines	Anti-TIRC-7 MAb	<i>Listeria</i> -EphA2 MAb
hMPV program		Anti-EphA4 MAb

#### **Infectious Disease**

- Numax** MedImmune has been developing a second-generation anti-RSV MAb, Numax, that appears to be more potent in preclinical studies than Synagis in reducing RSV replication in both the lower and upper respiratory tract when given at the same dose. In 2004, MedImmune moved forward in a number of clinical trials with Numax, including the initiation of a pivotal Phase 3 trial to evaluate the MAb's potential to prevent serious RSV in high-risk infants. The trial is designed to assess if the increased potency seen in preclinical studies can be translated into better efficacy against lower respiratory tract illness in high-risk children and to assess the effect of Numax on upper respiratory tract disease, such as otitis media. The Company also completed a Phase 1 study in healthy adult volunteers, finished dosing and follow-up in a Phase 1 safety study in children hospitalized with RSV, made progress in a Phase 1/2 trial in high-risk infants, and initiated a Phase 3 feasibility study in full-term Native American infants. Recently accumulated epidemiological data indicate that the risks associated with RSV disease for otherwise healthy, full-term Native American infants is similar to those commonly associated with children considered to be at high-risk to the virus. In February 2005, the Company and AI amended the international distribution agreement to include the exclusive distribution of Numax, if and to the extent approved for marketing by regulatory authorities outside of the United States. Under the terms of the amended agreement, AI will be working to secure regulatory approval of Numax outside of the United States and, upon receipt of such approval, will distribute and market Numax outside of the United States.
- CAIV-T (cold adapted intranasal influenza vaccine trivalent)** CAIV-T is MedImmune's next generation, refrigerator-stable version of FluMist. In 2004, MedImmune initiated two new studies, including a pivotal Phase 3 study designed to compare CAIV-T with the injectable flu shot, and a bridging study designed to establish that CAIV-T is equivalent to the currently marketed frozen formulation, FluMist. The pivotal study enrolled 8,492 children between the ages of 6 months through 59 months at 249 sites in 16 countries in the Northern Hemisphere. The bridging study enrolled 981 healthy participants between the ages of 5 and 49 years old.
- Human Papillomavirus ( HPV ) vaccine** Since 1997, MedImmune and GlaxoSmithKline ( GSK ) have been co-developing a vaccine against HPV to prevent cervical cancer under a research collaboration. There are over 75 different types of HPV associated with a variety of clinical disorders, ranging from benign lesions to potentially lethal cancers. Two strains of HPV (HPV-16 and -18) are generally believed to cause most cervical cancers. The MedImmune/GSK vaccine candidate uses virus-like particle technology to produce a structurally identical, non-infectious form of the virus. Final data from a Phase 2 clinical trial with the HPV vaccine were presented by GSK in February 2004 at The International Papillomavirus Conference and were published in *The Lancet* in 2004. In 2004, GSK initiated a global Phase 3 clinical program expected to involve 28,000 women designed to evaluate the safety and efficacy of the vaccine in preventing cervical cancer. In 2005, MedImmune amended its agreement with GSK, permitting Merck & Co., Inc. ( Merck ), who also has an HPV vaccine in Phase 3 development, to sublicense rights to our patents. As a result, we may





receive certain milestone payments and royalties on future development and sales from both vaccines, should they be approved.

- **Epstein-Barr Virus ( EBV ) vaccine** MedImmune has rights to a vaccine against certain subunits of EBV, a herpesvirus that is the leading cause of infectious mononucleosis. This vaccine is based upon the major envelope glycoprotein that mediates viral absorption and penetration, and is a major target for the production of neutralizing antibodies stimulated by natural EBV infection. The vaccine is being developed with GSK under a worldwide collaboration, excluding North Korea and South Korea. Data from a 2002 GSK study in Europe showed that the formulations were both well tolerated and highly immunogenic. A Phase 1 trial in patients with cystic fibrosis awaiting lung transplants and a Phase 1 trial in patients awaiting kidney or liver transplants continued in 2004. The vaccine is currently in Phase 2 development.
- **Streptococcus pneumoniae vaccine** In 2000, MedImmune granted a worldwide exclusive license to a *Streptococcus pneumoniae* vaccine to GSK. *Streptococcus pneumoniae* is a major cause of pneumonia, middle-ear infections and meningitis worldwide, especially in very young children and in the elderly. During 2004, GSK continued the clinical development efforts with this vaccine in a Phase 1 study that was started in 2003.
- **Parainfluenza virus type 3 ( PIV-3 )/RSV/human metapneumovirus ( hMPV ) combination vaccines** Substantial preclinical research has been conducted toward the goal of combining previously independent vaccine programs against RSV and PIV-3. The Company has also begun efforts to include hMPV in a potential combined vaccine program, which, if successful, could be used to prevent disease against some combination of these three viruses. Additional preclinical research and process development to further evaluate the safety and efficacy of live, attenuated intranasal vaccine candidates targeting combinations of PIV-3 with either RSV or hMPV were conducted during 2004. Preliminary data from a preclinical study showing MedImmune's lead RSV/PIV-3 candidate vaccine elicited protective immune responses to RSV and PIV-3 were published in the *Journal of Virology* in 2004. In January 2005, MedImmune filed an investigational new drug ( IND ) application to begin clinical studies of its RSV/PIV-3 candidate vaccine. The Company plans to advance the RSV/PIV-3 vaccine program into the clinic before moving ahead with an hMPV/PIV-3 vaccine candidate.
- **hMPV program** hMPV is a respiratory virus with a high incidence of infection in children under the age of five. Early epidemiological studies indicate that outbreaks of hMPV occur on a seasonal basis, with clinical symptoms that are similar to RSV, ranging from mild respiratory problems to severe cough, bronchiolitis, and pneumonia. The very youngest children infected with hMPV often require hospitalization and mechanical ventilation. MedImmune has enrolled approximately 530 high-risk children into an preclinical epidemiology study designed to evaluate the prevalence of hMPV lower respiratory tract disease. Hospitalized children with lower respiratory tract disease will be evaluated virologically for hMPV, as well as RSV and PIV.

#### Immunology

- **Anti-interleukin-9 ( IL-9 )** IL-9 is a naturally occurring cytokine implicated in the pathogenesis of asthma and may contribute to other types of chronic obstructive pulmonary disease and cystic fibrosis. Data from preclinical studies in models of asthma suggest that IL-9 neutralizing monoclonal antibodies may help reduce airway hyper-reactivity, mucous production and inflammation. During 2004, MedImmune initiated a Phase 1 single-dose trial with an anti-IL-9 monoclonal antibody in healthy adult volunteers. The Company is evaluating this molecule as a potential new treatment for symptomatic, moderate-to-severe persistent asthma.
- **Anti-High Mobility Group Box Chromosomal Protein 1 ( HMGB-1 ) MAb** HMGB-1 is a late-acting cytokine believed to be involved in the tissue damage associated with a range of inflammatory illnesses, such as rheumatoid arthritis, sepsis and acute lung injury. Preclinical studies to date have suggested that blocking HMGB-1 may help protect against injury associated with many



chronic and acute inflammatory diseases, and may reduce sepsis-related deaths. In 2003, MedImmune entered into an agreement with Critical Therapeutics, Inc. to co-develop biological products targeting HMGB-1 to treat severe inflammatory diseases. In 2004, MedImmune continued its preclinical testing of anti-HMGB-1 antibodies.

- **Anti-Interferon alpha and anti-Type 1 Interferon Receptor MAb** During 2004, MedImmune announced a collaboration with Medarex, Inc. to develop antibodies targeting interferon-alpha and the type 1 interferon receptor 1. The collaboration will initially focus on two antibodies, MDX-1103 and MDX-1333, that are in preclinical development by Medarex for the treatment of autoimmune diseases, such as systemic lupus erythematosus.
- **Anti-Chitinase MAb** During 2004, MedImmune acquired the rights from Yale University to a family of proteins known as chitinases that may be important therapeutic targets in a number of inflammatory, oncology and other diseases. Preclinical data from the Company's collaborators at Yale was published in *Science* in 2004.
- **Anti-TIRC-7 MAb** During 2004, MedImmune acquired new technology from GenPat77 Pharmacogenetics AG targeting TIRC-7, a molecule that appears to be implicated in immune regulation, and therefore may be useful in the treatment of rheumatoid arthritis, multiple sclerosis and other immunological diseases.

#### **Oncology**

- **Ethyol** During 2004, MedImmune continued enrollment in two clinical studies to possibly expand the use of Ethyol in new indications. The first trial is a Phase 2 study using subcutaneous administration of Ethyol to evaluate its ability to reduce the incidence or severity of radiation-induced esophagitis and pneumonitis in patients with NSCLC. The second trial is a Phase 1/2 clinical study evaluating the effectiveness of Ethyol in preventing toxicity associated with dose escalation of chemotherapy in elderly patients with newly diagnosed, previously untreated, acute myelogenous leukemia, the most common type of leukemia reported in adults.
- **Vitaxin** Vitaxin functions by blocking the function of alpha-v beta-3 integrin, which is frequently found on newly-forming blood vessels and certain tumor cells (for example, melanoma, prostate cancer, and tumors with bone metastases). During 2004, MedImmune fully enrolled a Phase 2 trial in patients with metastatic melanoma and continued to track the patients through the planned analysis of data from the study. The study evaluated objective response rates and progression-free survival. MedImmune continued enrollment under an amended protocol in a second Phase 2 trial in patients with hormone refractory prostate cancer. In 2004, MedImmune discontinued its efforts with Vitaxin in rheumatoid arthritis and psoriasis based on preliminary data suggesting a lack of clinical benefit in these inflammatory diseases.
- **Siplizumab** Siplizumab is a humanized MAb that targets CD2, a molecule expressed on certain white blood cells, and appears to have the effect of depleting T-cells and natural killer (NK) cells. These properties suggest that siplizumab could provide a treatment for patients with T-cell lymphoproliferative disorders. Animal studies of T-cell leukemia have indicated that siplizumab can help increase survival. In 2004, a Phase 1 trial was initiated at the National Cancer Institute to examine the clinical safety of siplizumab in individuals with T-cell lymphoma and leukemia. In 2005, MedImmune anticipates starting another Phase 1 trial in patients with CD2-positive lymphoproliferative disease.

- **MT-103** In June 2003, MedImmune licensed the North American rights from Micromet AG to MT-103, a bi-specific T-cell engager (BiTE ) molecule that binds to B-cell lymphomas expressing the CD19 surface molecule. With its second binding arm, MT-103 recruits and activates T-cells to kill the cancerous B-cells. The Phase 1 dose-escalation trial involving continuous infusion of MT-103 in patients with non-Hodgkin's lymphoma is ongoing in Europe. MedImmune is also evaluating the broader application of Micromet's BiTE technology to other targets of interest.
- **Anti-EphA2 MAbs and vaccines** EphA2 is normally expressed at very low levels on normal epithelial cells, but many different cancers over-express EphA2, including metastatic melanoma, breast, prostate, colon, lung, ovarian and esophageal carcinomas. Further, when over-expressed, EphA2 appears to promote metastases. Based on its studies to date, MedImmune believes that targeting EphA2 in animal models may selectively inhibit the growth and survival of malignant cells, without altering the function or survival of corresponding normal cells. In April of 2004, MedImmune licensed the worldwide rights to the *Listeria* vaccine technologies from Cerus Corporation to target EphA2-expressing tumors. In 2004, the Company continued its preclinical testing in these areas, applying monoclonal antibody and vaccine research against EphA2.
- **Anti-EphA4 MAbs** MedImmune has identified EphA4 as a potential new target on certain cancer cells. Preclinical studies indicate that high levels of EphA4 are found on many different cancers, including breast and pancreatic carcinomas, and that targeted intervention against EphA4 may decrease the proliferation and metastatic behavior of these malignant cells. In 2004, MedImmune continued its preclinical testing of EphA4 antibodies.

#### *Collaborations, Alliances and Investments*

To build, advance and promote its product portfolio, MedImmune often seeks to augment its own internal programs and capabilities with collaborative projects with a number of outside partners. For its marketed products, the Company has established certain license agreements, co-promotion arrangements, manufacturing, supply and co-development alliances with pharmaceutical and other biotechnology companies, academic institutions and government laboratories to which the Company currently pays royalties. For more information on these collaborations, please see Note 15, Collaborative Arrangements to MedImmune's Consolidated Financial Statements. Similarly, for product candidates now in development, the Company has secured licenses to certain intellectual property and entered into strategic alliances with outside parties for various aspects of research, development, manufacturing and commercialization, pursuant to which the Company will owe future royalties if the product candidates are licensed and commercialized.

The Company also believes that investing in early stage biotechnology companies allows the Company to benefit from other innovations in the industry. Accordingly, the Company has established a wholly owned venture capital subsidiary, MedImmune Ventures, Inc., which makes minority interest investments in biotechnology companies that the Company believes have promising technology. Occasionally, the Company will make these investments in connection with strategic alliances as it has done with Critical Therapeutics, Inc., Micromet AG and GenPat77 Pharmacogenetics AG. In 2004, the Company also invested in: Arriva Pharmaceuticals, Inc., a biopharmaceutical company focused on the discovery and development of novel protease inhibitors for the treatment of human diseases; Collective Therapeutics, Inc., a company developing B-cell directed monoclonal antibody therapies for autoimmune disorders and B-cell cancers; Inotek Pharmaceuticals Corporation, a company focused on the discovery, research and development of novel pharmaceutical technologies with potential applications in critical care, surgery, trauma, transplantation and autoimmune diseases; Receptor BioLogix, Inc., a seed stage biopharmaceutical company developing a potential treatment for breast cancer; and Vanda Pharmaceuticals, Inc., a drug development company that repositions compounds that either failed in Phase

2 or 3 due to undifferentiated efficacy or were discontinued due to low research and development prioritization at larger pharmaceutical firms.

As of February 25, 2005, MedImmune Ventures has invested approximately \$77 million of the \$100 million it was originally funded in 2002, and in February 2005, the Board of Directors voted to increase its funding by an additional \$100 million.

### ***Sales and Marketing***

The Company has developed an extensive sales and marketing organization that focuses on target healthcare providers, managed healthcare organizations, specialty distribution companies, chain pharmacies, government purchasers and payers. Approximately 70 sales and managed care representatives cover approximately 650 hospitals, managed care organizations, and clinics in the U.S., which specialize in pediatric/neonatal care or transplantation for the promotion of Synagis, FluMist and CytoGam. Approximately 170 biotech sales specialists cover approximately 12,000 pediatric practices in the U.S. for the promotion and detailing of Synagis and FluMist. In addition, approximately 60 oncology/immunology specialists are devoted to the sales and marketing of Ethyol to oncologists practicing in cancer treatment centers, large hospitals and private medical practices. In total, the Company now employs approximately 420 sales and marketing personnel in the United States.

For the promotion of Synagis in the U.S., the Company has a co-promotion agreement with Abbott. Through its 500 sales representatives, Abbott details Synagis to approximately 27,000 office-based pediatricians and 6,000 birth hospitals.

In the U.S., the Company also relies upon specialty distributors and wholesalers to deliver Synagis to its customers, including physicians, hospitals and pharmacies. During 2003, MedImmune launched the Synagis Distribution Network ( SDN ), which significantly reduced the number of distributors and wholesalers involved in the distribution of Synagis to ensure high-quality and consistent services for patients. In 2004, the SDN was not altered significantly from its original structure in 2003. There are a relatively small number of specialty distributors who provide such services. There can be no assurances that these distributors will adequately provide their services to either the end users or to the Company, nor can there be any guarantee that these service providers remain solvent.

As discussed in Note 4, Segment, Geographic and Product Information, of the Company's Consolidated Financial Statements, the Company has three major customers who individually provided over 15% of its total revenue during 2004. Note 4 also contains information concerning the geographic areas in which the Company operates. The Company faces risks related to foreign currency exchange rates, as discussed under the caption Risk Factors Changes in foreign currency exchange rates or interest rates could result in losses.

### ***Manufacturing and Supply***

MedImmune operates commercial manufacturing facilities and distribution facilities in the U.S. and Europe. In addition, the Company has entered into manufacturing, supply and purchase agreements with other companies to provide certain portions of its production capacity for all of its marketed products and to produce clinical supplies for its development-stage products. Certain materials necessary for the Company's commercial manufacturing of its products are proprietary products of other companies, and in some cases, such proprietary products are specifically cited in the Company's drug application with the FDA such that they must be obtained from that specific, sole source. In addition, certain materials necessary for the Company's commercial manufacturing of its products are only available through one approved single source supplier though it is available from more than one supplier. The Company currently attempts to manage the risk associated with such sole-sourced and single-sourced materials by active inventory management and, where feasible, alternate source development. MedImmune monitors

the financial condition of its suppliers, their ability to supply the Company's needs and the market conditions for these raw materials. Also, certain materials required in the commercial manufacturing of the Company's products are derived from biological sources. The Company maintains screening procedures with respect to certain biological sources, where appropriate, and is investigating alternatives to them.

**Synagis** The primary manufacturing facility for Synagis bulk drug substance is the Company's Frederick, Md. manufacturing center ( FMC ). The FMC is a biologics facility with cell culture production and associated downstream processing equipment for recombinant products. Filling and packaging of the lyophilized formulation of Synagis bulk produced at the FMC is performed by Boehringer Ingelheim Pharma GmbH & Co. KG ( BI ). Filling of the liquid formulation of Synagis bulk produced at the FMC is performed by Sicor Pharmaceuticals, Inc. and packaging is performed by Cardinal Health PTS, LLC.

Supplemental supply of Synagis for the U.S. market is manufactured by BI under a manufacturing and supply agreement. BI also fills and packages Synagis produced at its German facility. As the sole supplier of Synagis for all territories outside the U.S. and supplemental supplier for the U.S. market, BI is responsible for obtaining and maintaining licensure and approval for making the product at its facility from all appropriate regulatory authorities including the FDA. The Company plans to continue to rely upon BI for production of additional quantities of Synagis to meet expected worldwide demand for the product.

**Ethiol** All bulk drug substance for Ethiol is produced by a contract manufacturer. In 2004, filling and finishing of all product was completed at the Company's manufacturing facility in Nijmegen, the Netherlands. To backup its own filling and finishing capabilities, the Company has an agreement with Ben Venue Laboratories, Inc, a subsidiary of BI, to fill and finish Ethiol for sale in the United States.

**FluMist** FluMist is produced at several facilities either owned or leased by the Company. The master virus seeds are prepared at the Company's Mountain View, California facility. The bulk monovalents and diluent are produced at leased facilities in Speke, the United Kingdom. Blending of FluMist into its trivalent formulation and filling of the final vaccine into the AccuSpray applicators, the non-invasive nasal spray delivery system developed and supplied by Becton Dickinson, takes place at the Company's Philadelphia, Pennsylvania facilities. In addition to these manufacturing facilities, the Company owns a distribution facility in Louisville, Kentucky from which FluMist is distributed to physicians, pharmacies and government agencies.

#### *Patents, Licenses and Proprietary Rights*

The products and product candidates currently being developed or considered for development by the Company are in the area of biotechnology, an area in which there are extensive patent filings. The Company relies on patent protection against use of its proprietary products and technologies by competitors. The patent positions of biotechnology firms generally are highly uncertain and involve complex legal and factual questions. To date, no consistent policy has emerged regarding the breadth of claims allowed in biotechnology patents. Accordingly, there can be no assurance that patent applications owned or licensed by the Company will result in patents being issued or that, if issued, such patents will afford meaningful protection against competitors with similar technology. The Company currently owns or in-licenses significant intellectual property related to its products or product candidates and owns or in-licenses additional applications for patents currently pending. A list of the U.S. patents the Company owns or in-licenses is filed as an exhibit hereto as Exhibit 99.1 and is incorporated by reference into this document.

#### *Government Regulation*

The research, development, manufacture and sale of the Company's products are subject to numerous complex laws and statutes as well as regulations promulgated by the applicable governmental authorities, principally the FDA in the U.S. and similar authorities in other countries. While there is considerable time

and expense associated with complying with these requirements, knowledge of and experience with these matters also yields benefits to the Company. For example, the more knowledgeable the Company is about these matters, the more the Company is able to design its research, development and manufacturing strategies in a manner that is calculated to obtain regulatory approval to market its products in the applicable countries. Moreover, the complexity of these matters can have the effect of delaying or limiting the number of competing products that can successfully be brought to market. In addition, certain regulatory approval pathways, for example, orphan drug designation in the U.S. for marketing products applicable to rare diseases or small populations, can also have the effect of limiting the number of competing products available in the market.

### *Competition*

The biotechnology and pharmaceutical industries are characterized by rapidly evolving technology and intense competition. The Company's competitors include pharmaceutical, chemical and biotechnology companies, many of which have financial, technical and marketing resources significantly greater than those of the Company. In addition, many specialized biotechnology companies have formed collaborations with large, established companies to support research, development and commercialization of products that may be competitive with those of the Company. Academic institutions, governmental agencies and other public and private research organizations are also conducting research activities and seeking patent protection and may commercialize products on their own or through joint venture arrangements.

The Company expects its products to compete primarily on the basis of product efficacy, safety, patient convenience, reliability and patent position. In addition, the first product to reach the market in a therapeutic or preventive area is often at a significant competitive advantage relative to later entrants to the market. The Company's competitive position will also depend on its ability to attract and retain qualified scientific and other personnel, develop effective proprietary products, implement product and marketing plans, obtain patent protection and secure adequate capital resources.

The Company believes that Synagis is the only product currently available for the prevention of RSV disease. However, the Company is aware of one product, ribavirin, which is indicated for the treatment of RSV disease in the U.S. The existence of this product, or other products or treatments of which the Company is not aware, or products or treatments that may be developed in the future, may adversely affect the marketability of products developed by the Company.

In relation to influenza vaccines, in the past, the Company has been aware of two main manufacturers of trivalent inactivated influenza vaccines (TIV). From these two manufacturers, approximately 80 million doses of these inactivated vaccines have traditionally been sold annually in the United States. The Company is also aware that Merck has licensed a Russian live virus intranasal vaccine, currently available in Russia, and that ID Biomedical Corporation is developing an intranasal, inactivated flu vaccine that the Company understands is in the early stages of clinical testing. The 2004/2005 influenza season was impacted by a significant market reduction in the number of TIV doses available in the U.S. to approximately 50 million doses due to contamination problems experienced by one of the principal TIV manufacturers. In an effort to prevent future shortages, the FDA is considering allowing other manufacturers of TIV into the U.S. market. If the FDA decides to allow additional manufacturers into the market, it will create additional competition in the influenza vaccine market. Any of the products listed here, as well as other products of which the Company is not aware, may adversely affect the marketability of FluMist.

Many companies, including well-known pharmaceutical companies, are marketing anticancer drugs and drugs to ameliorate or treat the side effects of cancer therapies. These companies, and many others, are also seeking to develop new drugs and technologies for various cancer applications. Many of these drugs, products and technologies are, or in the future may be, competitive with the Company's oncology



products. In the U.S., the Company believes that Sanofi-Aventis holds the largest share of the chemotherapy market in terms of both approved products and annual sales. To the Company's knowledge, other companies maintaining a significant active oncology marketing and sales presence include Amgen, Inc., AstraZeneca, Bristol-Myers Squibb Company, Chiron Corporation, Eli Lilly and Company, Genentech, GSK, Hoffmann-La Roche, Inc., Johnson & Johnson, Pfizer, and Schering-Plough Corporation. Many of these companies have greater financial, technical, manufacturing, marketing and other resources than the Company and may be better equipped than the Company to develop, market and manufacture these therapies. No assurance can be given that the oncology drugs developed by the Company will be able to compete successfully against therapies already established in the marketplace or against new therapies that may result from advances in biotechnology or other fields that may render the Company's oncology drugs less competitive or obsolete. In addition, the Company's oncology drugs may become subject to generic competition in the future.

On June 29, 2004, the Company received a Paragraph IV certification for Ethyol from a generic challenger (Sun Pharmaceutical Industries, Ltd.). The Company evaluated all options available to it including filing a lawsuit against the generic company under the Hatch-Waxman Act. On August 10, 2004, MedImmune filed a patent infringement case against Sun Pharmaceutical in the U.S. District Court for the District of Maryland. For additional information see Note 17, Legal Proceedings, of the Company's Consolidated Financial Statements.

#### *Officers and Key Employees of the Company*

<b>Name</b>	<b>Age</b>	<b>Position</b>	<b>Since</b>
Wayne T. Hockmeyer, Ph.D.	60	Chairman of the Board; President, MedImmune Ventures, Inc.	1988
David M. Mott	39	Chief Executive Officer, President and Vice Chairman of the Board	1992
James F. Young, Ph.D.	52	President, Research and Development	1989
Armando Anido, R.Ph.	47	Executive Vice President, Sales and Marketing	1999
Edward M. Connor, M.D.	52	Executive Vice President and Chief Medical Officer	1999
Peter A. Kiener, D.Phil.	52	Senior Vice President, Research	2005
Bernardus N. Machielse, Drs.	44	Senior Vice President, Operations	2003
Edward T. Mathers	44	Senior Vice President, Corporate Development	2005
Linda J. Peters	39	Senior Vice President, Regulatory Affairs	2005
Gail Folena-Wasserman, Ph.D.	50	Senior Vice President, Development	2002
Lota S. Zoth, C.P.A.	45	Senior Vice President and Chief Financial Officer	2004

**Wayne T. Hockmeyer, Ph.D.** founded MedImmune, Inc. in April 1988 as President and Chief Executive Officer and was elected to serve on the Board of Directors in May 1988. Dr. Hockmeyer became Chairman of the Board of Directors in May 1993. He relinquished his position as Chief Executive Officer in October 2000 and now serves as the Chairman of the Board of Directors and President of MedImmune Ventures, Inc. Dr. Hockmeyer earned his bachelor's degree from Purdue University and his Ph.D. from the University of Florida in 1972. In 2002, Dr. Hockmeyer was awarded a doctor of science honoris causa from Purdue University. Dr. Hockmeyer is a member of the Maryland Economic Development Commission. He is also a member of the Board of Directors of Advancis Pharmaceutical Corp., Collective Therapeutics, GenVec, Inc., Idenix Pharmaceuticals, Inc., Tercica, Inc., TolerRx Inc., and Vanda Pharmaceuticals, Inc.

**David M. Mott** Mr. Mott was appointed Chief Executive Officer and Vice Chairman in October 2000 and was also appointed President in February 2004. He joined the Company in April 1992 as Vice President with responsibility for business development, strategic planning and investor relations. In 1994, Mr. Mott assumed additional responsibility for the medical and regulatory groups, and in March 1995 was appointed Executive Vice President and Chief Financial Officer. In November 1995, Mr. Mott was appointed to the position of President and Chief Operating Officer and was elected to the Board of Directors. In October 1998, Mr. Mott was appointed Vice Chairman. Mr. Mott is Chairman of the Board of Directors of Conceptis Technologies, a member of the board of the Biotechnology Industry Organization (BIO), and also serves on the Board of Trustees of St. James School and on the Board of Governors of Beauvoir, the National Cathedral Elementary School. He holds a bachelor of arts degree from Dartmouth College.

**James F. Young, Ph.D.** Dr. Young was promoted to the position of President, Research and Development, in December 2000. Dr. Young joined MedImmune in 1989 as Vice President, Research and Development. In 1995, he was promoted to Senior Vice President and in 1999 he was promoted to Executive Vice President, Research and Development. Dr. Young received his doctorate in microbiology and immunology from Baylor College of Medicine in Houston, Texas, and bachelor of science degrees in biology and general science from Villanova University. Dr. Young is a member of the Board of Directors of Arriva Pharmaceuticals, Inc., and Iomai Corporation.

**Armando Anido, R.Ph.** Mr. Anido was promoted to Executive Vice President, Sales & Marketing in February 2005. He joined the Company in 1999 as Senior Vice President, Sales and Marketing and was appointed to Senior Vice President, Commercial Operations in February 2004. Prior to joining the Company, Mr. Anido was Vice President of CNS Marketing at Glaxo Wellcome, Inc. from 1996 to 1999. Prior to this time, Mr. Anido served in various positions at Lederle Laboratories from 1989 to 1995, culminating in his service as the Vice President of Anti-Infectives Marketing. Mr. Anido is a registered pharmacist, and holds a bachelor of science in pharmacy and a master of business administration degree from West Virginia University. Mr. Anido is a member of the Board of Directors of Adolor, Inc.

**Edward M. Connor, M.D.** Dr. Edward Connor was promoted to Executive Vice President, Chief Medical Officer in September 2004. He joined the Company in 1994 as the Director of Clinical Studies and was promoted in 1995 to Vice President of Clinical Development, in 1999 to Senior Vice President, Clinical Development, and in February 2004 to Senior Vice President, Chief Medical Officer. Dr. Connor holds a bachelor's degree in biology from Villanova University and a medical degree from University of Pennsylvania School of Medicine. He is board certified in pediatrics and is a consultant in pediatric infectious diseases.

**Peter A. Kiener, D.Phil.** Dr. Kiener was promoted to Senior Vice President, Research, in February 2005. He joined MedImmune in 2001 and was named Vice President, Research, in 2003. Prior to joining MedImmune, Dr. Kiener spent 18 years with Bristol-Myers Squibb's (BMS) Pharmaceutical Research Division, finally holding the position of Director, Immunology, Inflammation, Pulmonary and Oncology Drug Discovery. Previously, Dr. Kiener worked in academia at the University of North Texas/Texas College of Osteopathic Medicine's Department of Anatomy, the Department of Biochemistry at the University of Massachusetts (Amherst), and at the Medical Research Council at Sir William Dunn School of Pathology, University of Oxford in the United Kingdom. Dr. Kiener holds a bachelor of science degree with honors in chemistry from Lancaster University, Lancaster, UK, and a doctorate of philosophy in biochemistry from the Sir William Dunn School of Pathology.

**Bernardus N. Machielse, Drs.** Drs. Ben Machielse was appointed Senior Vice President, Operations, in January 2005. Drs. Machielse joined MedImmune in May 1999 as Vice President, Quality and was named Senior Vice President, Quality, in September 2003. Prior to joining MedImmune, Drs. Machielse was Vice President of Quality Control and Quality Assurance for Xoma Corporation of



Berkeley, California. He also spent several years in various manufacturing and quality positions at Centocor BV of the Netherlands. Drs. Machielse holds a bachelor of science degree in medical biology and a master of science degree in biochemistry from the University of Utrecht, The Netherlands.

**Edward T. Mathers** Mr. Mathers was named Senior Vice President, Corporate Development, in February 2005. He joined MedImmune as Vice President, Corporate Development, in 2002. Prior to MedImmune, Mr. Mathers was Vice President of Marketing and Corporate Licensing and Acquisitions at Inhale Therapeutic Systems. Previously, he held a number of increasingly responsible positions in sales and marketing at Glaxo Wellcome, Inc. (GlaxoSmithKline). Mr. Mathers started his career at Ortho Pharmaceuticals Corporation (a division of Johnson & Johnson). He holds a bachelor's degree in chemistry from North Carolina State University.

**Linda J. Peters** Ms. Peters joined MedImmune as Senior Vice President, Regulatory Affairs, in February 2005. Prior to joining MedImmune, Ms. Peters was Vice President of Global Regulatory Affairs for Baxter Healthcare's BioScience and Renal businesses. Previously she served as Director of Regulatory Affairs at Takeda Pharmaceuticals North America and held positions of increasing responsibility at TAP Pharmaceuticals. Ms. Peters earned her bachelor of science and master of science degrees in animal science from Southern Illinois University, and a master of business administration degree from the J.L. Kellogg School of Management at Northwestern University.

**Gail Folena-Wasserman, Ph.D** Dr. Wasserman was promoted to Senior Vice President, Development in February 2002. She joined MedImmune in 1991 as Director, Development, and was promoted to Vice President, Development, in October 1995. Prior to joining the Company, she worked at SmithKline Beecham Pharmaceuticals. Dr. Folena-Wasserman holds a bachelor's degree in biology and chemistry from Montclair State University in New Jersey, and received a master's degree in biochemistry and a doctorate in chemistry from The Pennsylvania State University.

**Lota S. Zoth, C.P.A.** Ms. Zoth was promoted to Senior Vice President and Chief Financial Officer in April 2004. From January 2004 through April 2004, Ms. Zoth was acting as Chief Financial Officer in addition to her role as Vice President and Controller, a position she held since joining the Company in August 2002. Prior to joining MedImmune, Ms. Zoth was Senior Vice President and Corporate Controller for PSINet, Inc, who filed a petition for bankruptcy on May 31, 2001. Between 1998 and 2000, Ms. Zoth was Vice President, Corporate Controller and Chief Accounting Officer of Sodexho Marriott Services, Inc. Prior to Sodexho Marriott, Ms. Zoth was Vice President, Financial Analysis, for Marriott International, Inc.'s food and management services division. Ms. Zoth is a CPA, and holds a bachelor of business administration in accounting from Texas Tech University.

### *Employees*

The Company considers relations with its employees to be good. As of December 31, 2004, the Company had 1,823 full-time permanent employees and 153 full-time temporary employees.

Approximately 80 of the Company's employees in the United Kingdom are members of a labor union, with which the Company renegotiates employment terms annually. There can be no guarantee that the annual negotiations will lead to an outcome that is favorable to the Company. If negotiations were to break down between the Company and the union, there can be no guarantee that the Company would be able to manufacture an adequate supply of FluMist.

***Risk Factors***

The Company's business faces many risks. The risks described below may not be the only risks the Company faces. Additional risks that the Company does not yet know of or that the Company currently believes are immaterial may also impair the Company's business operations. If any of the events or circumstances described in the following risks actually occur, the Company's business, financial condition or results of operations could suffer, and the trading price of the Company's common stock could decline. You should consider the following risks, together with all of the other information in this Annual Report on Form 10-K, before deciding to invest in the Company's securities.

**The Company's revenues are largely dependent on sales of Synagis.**

Sales of Synagis accounted for approximately 84% of the Company's total product sales in 2004 and the Company's 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 impact on the Company. 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 or marketing strategies and any change in the reimbursement rate 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 impact on the Company. The Company has also created an exclusive network for distribution of Synagis in the U.S., which will have the effect of preventing certain entities from obtaining Synagis and may have the effect of changing the reimbursement rate 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 the Company's direct control and any negative impact on AI's sales of Synagis could affect the Company's revenues related to those sales. In addition, actions of AI related to the regulatory approval or commercialization of Synagis could negatively impact the Company's sales of Synagis in the U.S.

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

Sales of two of the Company's 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 fourth quarter 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 the Company's revenues of any manufacturing or supply delays, any sudden loss of inventory, any inability to satisfy product demand, the inability to estimate the impact of returns and rebates, or of any unsuccessful sales or marketing strategies during the applicable sales season. Furthermore, the Company's current product base limits its ability to offset in the second and third quarters any lower-than-expected sales of Synagis during the first and fourth quarters.

**The Company may not be able to successfully commercialize FluMist.**

There can be no assurance that FluMist will achieve commercial success. There are a number of factors which make the commercialization of FluMist difficult. These factors include, but are not limited to, significant competition in the marketplace by other influenza virus vaccines, the higher cost of

manufacturing FluMist relative to competing vaccines, perceived or actual risks related to the use of a live virus vaccine, lack of acceptance by the targeted patient population of the need for vaccination against influenza, lack of reimbursement coverage by private or public insurance carriers or programs, lack of product accessibility by potential consumers, an inability to develop alternative channels for sales, such as pharmacies, due to state or federal regulations or for other reasons and difficult storage requirements for the transport and storage of the product. Furthermore, commercialization is dependent upon successful manufacturing of the product, which may be adversely affected if the Company is unable to perform the complex annual update of the FluMist formulation for new influenza strains, if there are problems or difficulties in the complex manufacturing process or if there is a sudden loss of inventory. There can also be no assurance that the Company could successfully manufacture a quadravalent vaccine, should such a vaccine ever be required. There can be no assurance that the Company's cost of goods will not exceed its revenues for this product. If the Company is unable to successfully commercialize FluMist, the anticipated benefits of the termination of the collaboration with Wyeth or the acquisition of Aviron may not be realized, and the Company's results of operations would be negatively impacted by impairment charges for the write-down of manufacturing and intangible assets related to FluMist.

**The Company may not be able to bring its product candidates to market.**

Research and development activities are costly and may not be successful, and there can be no assurance that any of the Company's 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 the Company's 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 the Company will be able to generate additional product candidates for its 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 the Company will be able to successfully manufacture the product on a commercial scale or effectively commercialize the product.

**A significant portion of the Company's business is dependent on third parties.**

The Company licenses a significant portion of the technology necessary for its business from third parties and relies on third parties for a significant portion of the clinical development, supply of components, manufacturing, distribution, and promotion of the Company's products. The actions of these third parties are outside of the Company's control and the failure of these third parties to act in accordance with their obligations to the Company would have a material adverse effect on the Company's business. Even if the Company is legally entitled to damages for a failure of a third party to fulfill its obligations to the Company, there can be no assurance that such damages will adequately compensate the Company for indirect or consequential losses such as the damage to a product brand or the Company's reputation. If a third party does not fulfill its obligations to the Company, the Company may have to incur substantial additional costs, which could have a material adverse effect on the Company's business.

**Defending product liability claims could be costly and divert focus from the Company's business operations and product recalls may be necessary.**

The Company's products contain biologically active agents that can have the effect of altering the physiology of the person using the product. Accordingly, as a developer, tester, manufacturer, marketer and seller of biological products, the Company 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 the Company's insurance coverage. 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 the Company or damage to the product brand. Any of these occurrences could have a material adverse effect on the Company's 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.

**The Company may not be able to meet the market demand for its products.**

The Company generally does not have or contract for redundant supply, production, packaging or other resources to manufacture its products. As a result, the Company is at risk for business interruption if there is any disruption in the manufacturing chain. Difficulties or delays in the Company's or the Company's contractors' manufacturing of existing or new products could increase the Company's costs, cause the Company to lose revenue or market share and damage the Company's reputation. In addition, because the Company's various manufacturing processes and those of its 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.

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

The Company's manufacturing operations expose it 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, the Company collaborates and has arrangements with other companies related to the manufacture of its products and, accordingly, certain aspects of the manufacturing process are not within the Company's direct control. In addition, MedImmune has not produced FluMist for commercial use for a sustained period and may encounter additional unforeseeable risks as the Company develops additional commercial manufacturing experience with this product. In addition, the Company's facilities in the United Kingdom are unionized and may be subject to manufacturing interruptions due to labor action.

**Contamination of our raw materials could adversely affect the Company.**

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 impact 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 payers is critical for the success of the Company's products.**

The cost to individual consumers for purchase of the Company's products can be significant. Accordingly, sales of Company products are dependent to a large extent on the insurance reimbursement available for the Company's 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 the Company products. 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 the Company's products and have a material adverse effect on the Company's business.

**The Company relies upon a limited number of pharmaceutical wholesalers and distributors that could impact the ability to sell the Company's products.**

The Company relies largely upon specialty pharmaceutical distributors and wholesalers to deliver its 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 the Company's 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, the Company could experience a significant loss if one of its top customers were to declare bankruptcy or otherwise become unable to pay its obligations to MedImmune.

**Obtaining and maintaining regulatory approvals to develop, manufacture and market the Company's products is costly and time consuming.**

The development, manufacturing and marketing of all of the Company's 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 subject to numerous delays, which are generally not in the Company's 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, the Company 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, even if the Company has 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 the consent of the Company. If the Company fails to comply with applicable requirements, it 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 the Company's ability to enter into supply contracts; and criminal prosecution. If the Company is unable to obtain approvals on a timely basis or at all, if the scope of approval is more limited than expected by the Company or if the Company is unable to maintain approvals, its ability to successfully market products and to generate revenues will be impaired.

**Patent protection for the Company's products may be inadequate or costly to enforce.**

The Company may not be able to obtain effective patent protection for its 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 the Company's 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 MedImmune's intellectual property rights. Any such litigation will involve substantial cost and significant diversion of the Company's attention and resources and there can be no assurance that any of the Company's litigation matters will result in an outcome that is beneficial to the Company. The Company is 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. The Company is uncertain as to when, or if, any such process may be adopted or how such a process would relate to the Company's intellectual property rights, but any such process could have a material impact on the prospects of the Company's products.



**If the Company fails to obtain and maintain any required intellectual property licenses from third parties, its 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 the Company's products or product candidates. These patents (including any patents issuing from pending patent applications), if valid and enforceable, would preclude the Company's ability to manufacture, use or sell these products unless the Company obtains a license from the applicable third party. These third parties are not generally required to provide the Company with a license and, as such, obtaining any such licenses may not be possible or could be costly and impose significant royalty burdens on the Company. There can be no assurance that a license will be available on terms acceptable to the Company or at all, which could have a material adverse effect on the Company's business. In addition, there can be no assurance that the Company 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 those of the Company. 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 the Company.

**Technological developments by competitors may render the Company's products obsolete.**

If competitors were to develop superior products or technologies, the Company's 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, the Company's products or technologies could be rendered obsolete, resulting in decreased product sales and a material adverse effect to the Company's business. Even if a competitor creates a product that is not technologically superior, the Company's products may not be able to compete with such products, decreasing the Company's sales.

**The Company is 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 the Company. Many of the laws and regulations administered by these agencies are complex and compliance requires substantial time, effort and consultation with outside advisors by the Company. Because of this complexity, there can be no assurance that the Company's efforts will be sufficient to ensure compliance or to ensure that it is in technical compliance with all such laws and regulations at any given time. In addition, the Company is 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 impact on the Company's business, even if the Company is found to have been in compliance or the extent of the Company's non-compliance is deemed immaterial. If the Company is found to not be in compliance with any of these laws and regulations, the Company and, in some cases its officers, may be subject to fines, penalties, criminal sanctions and other liability, any of which could have a material adverse effect on the Company's business.

**The Company cannot control the use of its products.**

The product labeling for each of the Company's 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 the Company's products are being used for unapproved uses and may subject the Company to regulatory scrutiny, sanctions or product liability, any of which could have a material adverse effect on the Company's business.

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

The success of the Company's business depends, in large part, on its 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, the Company's Chief Executive Officer, President and Vice Chairman and Dr. James F. Young, the Company's President, Research and Development. In addition, the Company relies on its 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 the Company's inability to attract or retain such employees and relationships could have a material effect on its business. The Company does not maintain or intend to purchase key man life insurance on any of its personnel and, accordingly, the Company's business may be subject to disruption upon the sudden or unexpected loss of a key employee.

**If the Company fails to manage its growth properly, the business will suffer.**

The Company has expanded significantly in recent years due to both acquisition and internal growth. To accommodate its rapid growth and compete effectively, the Company will need to continue to improve its 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 maintain adequate 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 MedImmune's common stock price over time could cause stockholders to lose investment value.**

The market price of MedImmune's common stock has fluctuated significantly over time, and it is likely that the price will fluctuate in the future. During 2004, the daily closing price of MedImmune common stock on the Nasdaq stock market ranged from a high of \$28.42 to a low of \$21.40. Investors and analysts have been, and will continue to be, interested in the Company's reported earnings, as well as how the Company performs compared to their expectations. Announcements by the Company 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 the Company's common stock. In addition, the stock market has experienced extreme price and volume fluctuations that have particularly 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 MedImmune common stock.

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

The Company has 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, the Company 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 impact on the Company's financial results. In addition, expenditures relating to the Company's manufacturing operations in the United Kingdom and the Netherlands are paid in local currency. MedImmune has not hedged its 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 the Company's distribution agreements outside the U.S. provide for it to be paid based upon sales in local currency. As a result, changes in foreign currency exchange rates could adversely affect the amount the Company expects to collect under these agreements.

***Investor Information***

MedImmune files annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission (SEC). You can inspect, read and copy these reports, proxy statements and other information at the SEC's Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549.

You can also obtain copies of these materials at prescribed rates by writing to the Public Reference Section of the SEC at 450 Fifth Street, N.W., Washington, D.C. 20549. You can obtain information on the operation of the public reference facilities by calling the SEC at 1-800-SEC-0330. The SEC also maintains a web site ([www.sec.gov](http://www.sec.gov)) that makes available reports, proxy statements and other information regarding issuers that file electronically with it.

MedImmune makes available free of charge on or through its internet website its annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports as soon as reasonable practicable after such material is electronically filed with or furnished to the SEC. MedImmune's internet address is [www.medimmune.com](http://www.medimmune.com). The information on MedImmune's website is not incorporated by reference into this report.

**ITEM 2. PROPERTIES**

The Company's principal executive and administrative offices and research and development facilities are located in Gaithersburg, Maryland. During March 2004, the Company took occupancy of its new headquarters facility, a complex totaling 219,000 square feet consisting of a research and development facility and administrative offices on approximately 22.8 acres of land. The Company owns the facility and land, which will also serve as the site for the Company's pilot plant, which will total 90,000 square feet and is currently under construction, and additional administrative space totaling 142,000 square feet which is scheduled to break ground during the second quarter of 2005. The Company continues to occupy facilities consisting of approximately 119,000 square feet in Gaithersburg, which are leased until 2006. The Company subleases a small portion of these facilities.

The Company also owns 56,000 square feet of administrative and warehouse space and a 91,000 square foot biologics facility in Frederick, Maryland. The biologics facility includes a cell culture production area used to manufacture Synagis and development-stage projects. Until December 2002, this facility was also used for the manufacture of immune globulins and by-products from human plasma. In addition, in Nijmegen, the Netherlands, the Company owns a 21,000 square foot manufacturing facility on

36,000 square feet of land and leases approximately 12,600 square feet of warehouse space. This lease runs through December 2010.

MedImmune operates a number of facilities related to research and development, manufacture and distribution of FluMist and CAIV-T, including: 104,000 square feet of office and laboratory space in Mountain View, California, which is leased through October 2008 with two options to extend for successive three-year periods; approximately 55,000 square feet of space in Philadelphia, Pennsylvania, pursuant to a lease agreement through December 2007, with an option to extend for two terms of three years; approximately 72,000 square feet of office, laboratory and warehouse space in Bensalem, Pennsylvania, pursuant to a lease agreement through June 2008; approximately 72,000 square feet of office, laboratory and manufacturing space in Santa Clara, California, pursuant to a lease agreement through January 2019, with an option to renew for seven years; a fully owned 86,000 square foot distribution facility in Louisville, Kentucky on 19 acres; an 8,900 square foot manufacturing facility in Speke, the United Kingdom, pursuant to a sublease expiring in June 2006; and 94,000 square feet of manufacturing and laboratory space on approximately eight acres of land in Speke pursuant to a lease agreement through 2024.

The Company believes that its current facilities and anticipated additions are adequate to meet its research and development, commercial production, and administrative needs for the foreseeable future.

**ITEM 3. LEGAL PROCEEDINGS**

Information with respect to legal proceedings is included in Note 17 of Item 8 Consolidated Financial Statements and Supplementary Data and is incorporated herein by reference.

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

Not Applicable

**PART II****ITEM 5. MARKET FOR MEDIMMUNE S COMMON STOCK, RELATED SHAREHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES**

The Company's common stock trades on the Nasdaq National Market under the symbol MEDI. As of February 25, 2005, the Company had 2,018 common stockholders of record. This figure does not represent the actual number of beneficial owners of common stock because shares are generally held in street name by securities dealers and others for the benefit of individual owners who may vote the shares.

The following table shows the range of high and low prices and year-end closing prices for the common stock for the two most recent fiscal years.

	<b>2004</b>		<b>2003</b>	
	<b>High</b>	<b>Low</b>	<b>High</b>	<b>Low</b>
First Quarter	\$ 26.41	\$ 20.77	\$ 34.60	\$ 26.80
Second Quarter	25.95	22.91	42.09	31.52
Third Quarter	25.15	21.70	40.88	31.69
Fourth Quarter	28.70	23.62	35.00	22.79
Year End Close	\$ 27.11		\$ 25.38	

The Company has never declared or paid any cash dividends on its common stock and does not anticipate paying any cash dividends in the foreseeable future. The Company currently intends to retain any earnings to fund future growth, product development, investments, collaborations and operations.

**Issuer Purchases of Equity Securities(1)**

<b>Period</b>	<b>Total Number of Shares Purchased</b>	<b>Average Price Paid per Share</b>	<b>Total Number of Shares Purchased as Part of Publicly Announced Plans</b>	<b>Approximate Dollar Value that May Yet Be Purchased Under the Plans</b>
October 1, 2004 through October 31, 2004	45,000	\$ 24.49	45,000	\$ 254,079,000
November 1, 2004 through November 30, 2004	150,000	\$ 26.66	150,000	\$ 250,079,000
December 1, 2004 through December 31, 2004	371,800	\$ 26.65	371,800	\$ 240,169,000

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

**ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA***(in millions, except per share data)*

	2004(1)	2003	2002(2),(3)	2001(3)	2000(3)
<b>RESULTS FOR THE YEAR</b>					
Total revenues	\$ 1,141.1	\$ 1,054.4	852.7	\$ 620.7	\$ 542.0
Gross profit	757.6	702.8	589.1	442.8	369.9
(Loss) earnings before cumulative effect of a change in accounting principle	(3.8)	183.2	(1,098.0)	) 149.0	145.0
Net (loss) earnings	(3.8)	183.2	(1,098.0)	) 149.0	111.2
Basic (loss) earnings per share:					
(Loss) earnings before cumulative effect of a change in accounting principle	(0.02)	0.73	(4.40)	) 0.70	0.69
Net (loss) earnings	(0.02)	0.73	(4.40)	) 0.70	0.53
Diluted (loss) earnings per share:					
(Loss) earnings before cumulative effect of a change in accounting principle	(0.02)	0.72	(4.40)	) 0.68	0.66
Net (loss) earnings	(0.02)	0.72	(4.40)	) 0.68	0.50
<b>YEAR END POSITION</b>					
Cash and marketable securities	\$ 1,706.1	\$ 1,900.1	\$ 1,423.1	\$ 777.7	\$ 526.3
Total assets	2,564.4	2,794.6	2,188.3	1,236.9	1,016.6
Long-term debt	507.1	682.1	218.4	9.5	10.3
Shareholders' equity	1,674.6	1,699.2	1,677.2	1,044.3	843.6

**PRO FORMA RESULTS**

The following data represents the Company's pro forma financial results assuming retroactive adoption of the change in accounting principle (SAB 101):

	2000(3)
Total revenues	\$ 542.0
Net earnings	145.0
Earnings per share	
Basic	0.69
Diluted	0.66

(1) Includes charges related to the dissolution of the collaboration with Wyeth and reacquisition of full rights to the influenza vaccines franchise.

(2) Includes a charge for acquired in-process research and development (IPR&D), in connection with the Company's acquisition of Aviron on January 10, 2002.

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

**QUARTERLY FINANCIAL DATA (UNAUDITED)***(in millions, except per share data)***2004 Quarter Ended**

	<b>Dec. 31</b>	<b>Sept. 30</b>	<b>June 30</b>	<b>Mar. 31</b>
Net product sales	\$ 457.8	\$ 92.3	\$ 90.7	\$ 483.2
Gross profit	327.3	51.9	53.4	325.0
Net earnings (loss)	50.5	(65.0 )	(100.3 )	111.0
Net earnings (loss) per share:				
Basic	\$ 0.20	\$ (0.26 )	\$ (0.40 )	\$ 0.45
Diluted(2)	\$ 0.20	\$ (0.26 )	\$ (0.40 )	\$ 0.43

**2003 Quarter Ended**

	<b>Dec. 31(1)</b>	<b>Sept. 30(1)</b>	<b>June 30(1)</b>	<b>Mar. 31(1)</b>
Net product sales	\$ 398.6	\$ 82.3	\$ 80.6	\$ 431.1
Gross profit	266.3	51.8	56.9	327.8
Net earnings (loss)	76.6	(16.4 )	13.5	109.5
Net earnings (loss) per share:				
Basic	\$ 0.31	\$ (0.07 )	\$ 0.05	\$ 0.44
Diluted(2)	\$ 0.30	\$ (0.07 )	\$ 0.05	\$ 0.43

(1) Certain amounts have been reclassified to conform to the current presentation.

(2) In accordance with EITF No. 04-8, "The Effect of Contingently Convertible Debt on Diluted Earnings per Share," which became effective during 2004, our 1% Convertible Notes are now included in diluted earnings per share using the if-converted method, regardless if the market price trigger has been met, unless the effect is anti-dilutive. As required, prior period diluted earnings per share have been restated for comparative purposes. The table below presents a reconciliation of historical and restated diluted earnings per share for those quarters in which the 1% Notes were dilutive:

	<b>Net Income (numerator)</b>	<b>Weighted Average Shares (denominator)</b>	<b>Per Share Amount</b>
<b>Quarter ended March 31, 2004</b>			
Historical diluted earnings	\$ 111.0	250.9	\$ 0.44
Assuming conversion of 1% Notes	1.2	7.3	
Restated diluted earnings	\$ 112.2	258.2	\$ 0.43
<b>Quarter ended December 31, 2003</b>			
Historical diluted earnings	\$ 76.6	251.2	\$ 0.30
Assuming conversion of 1% Notes	1.4	7.3	
Restated diluted earnings	\$ 78.0	258.6	\$ 0.30

**ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*This Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements regarding future events and our future results that are based on current expectations, estimates, forecasts, and the beliefs, assumptions and judgments of our management. Readers are cautioned that these forward-looking statements are only predictions and are subject to risks and uncertainties that are difficult to predict. Readers are referred to the Forward-Looking Statements and Risk Factors sections in Part I, Item 1 of this document.*

**INTRODUCTION**

MedImmune is committed to advancing science to develop better medicines that help people live healthier, longer and more satisfying lives. MedImmune currently focuses its efforts on using biotechnology to produce innovative products for prevention and treatment in the therapeutic areas of infectious disease, autoimmune disease and cancer. MedImmune's scientific expertise is largely in the areas of monoclonal antibodies and vaccines. MedImmune markets four products, Synagis, FluMist, Ethyol and CytoGam and has a diverse pipeline of development-stage products. In January 2002, we acquired Aviron, a California-based vaccine company (the Acquisition).

**OVERVIEW**

During 2004, product sales surpassed \$1 billion for the first time in corporate history, increasing 13% as compared to 2003, reflecting growth in Synagis sales and recognition of FluMist product sales revenues related to the 2003/2004 and 2004/2005 flu seasons. We recorded a net loss of \$0.02 per share in 2004 compared to diluted net earnings per share of \$0.72 in 2003. The decline in net income was primarily attributable to charges incurred in 2004 for the reacquisition of the influenza vaccines franchise from Wyeth, and increased research and development spending due to higher levels of clinical activity. Our 2003 earnings also included milestones and other payments we received from Wyeth for FDA approval of FluMist and achievement of other goals totaling \$45.9 million.

Following the disappointing launch of FluMist in 2003, we completed a thorough assessment of: (1) the approved product, FluMist; (2) the live attenuated, nasally delivered influenza technology and subsequent products (collectively, the influenza vaccines franchise); and (3) the influenza market. Based on this assessment, we maintain our belief that FluMist is a significant advance in the prevention of influenza disease, and reiterated our commitment to the future of vaccine and related technology. Notwithstanding this commitment, we do not expect the vaccine to be a meaningful contributor to revenue growth before 2007, when we hope to launch CAIV-T, the refrigerator-stable version of FluMist, in the United States. From 2004 to 2006, we expect to focus our efforts on developing FluMist into a superior influenza vaccine preferred by pediatricians, with particular attention toward developing CAIV-T (now in Phase 3 development) and seeking approval to extend the indicated population to include individuals below the age of five years and above the age of 49 years.

Toward this goal, in April 2004, we entered into agreements with Wyeth to dissolve our collaboration for the influenza vaccines franchise. As a result of the dissolution and in exchange for an upfront fee, future milestones and royalties, we reacquired the full rights to this technology. We also assumed full responsibility for the manufacturing, marketing, and selling of FluMist and any subsequent related products. During 2004, we substantially completed the transition of all research, development, clinical, regulatory, and sales and marketing activities related to the influenza vaccines franchise from Wyeth to us.

For the 2004/2005 flu season, we introduced a substantially lower price structure for FluMist and refocused our selling efforts on the same pediatricians who are our Synagis customers. In early October 2004, regulatory actions in the United Kingdom caused a significant portion of the injectable



influenza vaccine supply for the U.S. to be withheld from the market. Subsequently, we increased the quantity of filled FluMist doses for the 2004/2005 season to approximately three million, of which approximately 1.7 million doses were sold through December 31, 2004.

We continued developing our product candidates during 2004 with the advancement of three programs into Phase 3 development, including Numax, CAIV-T, and our human papillomavirus vaccine partnered with GSK. We continued to advance our oncology program for Vitaxin, with Phase 2 trials currently being conducted in melanoma and prostate cancer. During 2004, we decided to terminate Phase 2 testing of Vitaxin in patients with rheumatoid arthritis and psoriasis, based on preliminary data suggesting lack of clinical benefit in these inflammatory diseases. We also received approval for a supplemental biologics license application for a liquid formulation of Synagis in July 2004.

As we look to the future, we intend to continue commercializing our core products, advance our product candidates in the clinic, and develop our pipeline through our own internal discovery and development efforts and by gaining access to new technologies through acquisition and in-licensing arrangements. Our product development objectives include targeting a total of eight new INDs by the end of 2006. We anticipate that we will have four product candidates in Phase 3 studies by the end of 2005, and will be attempting to introduce at least three new products to market by 2009.

Our cash and marketable securities at December 31, 2004 were \$1.7 billion as compared to \$1.9 billion at December 31, 2003. In addition to our research and development activities, we utilized cash during 2004 for two significant transactions: the redemption and payment of the remaining 5¼% Convertible Subordinated Notes and the payments associated with the reacquisition and transition of the influenza vaccines franchise from Wyeth.

We have the following expectations for 2005:

*Product sales* For 2005, we expect product sales to grow by approximately 10 percent, driven by worldwide reported revenues from Synagis that are expected to top the \$1 billion mark for the first time. We expect that the product mix on a percentage basis in 2005 will be comparable to that in 2004. Owing to the fact that for the foreseeable future Synagis is expected to continue to comprise a majority of our product sales, we believe our revenues and operating results will reflect the seasonality of that product's use to prevent RSV disease, which occurs primarily during the winter months. As noted above, we do not expect FluMist to be a meaningful contributor to revenue growth before 2007, when we hope to launch in the United States an improved formulation of this influenza vaccine with a label including a broader age indication. As such, we expect only a modest increase in sales of FluMist in 2005 compared to 2004.

*Gross margin* Excluding gross margins on FluMist, we expect that our annual gross margin percentage for 2005 will be consistent with our historical rate. We anticipate that FluMist will continue to exert downward pressure on gross margins until we successfully launch an improved formulation with a broader label. We expect that gross margins may vary significantly from quarter to quarter, based on the product mix and reflecting the seasonality of Synagis and FluMist.

*Research and development expense* We expect research and development expenses to increase in 2005 compared to 2004, and comprise approximately 25 to 30 percent of product sales. This is largely due to the initiation of several Phase 3 trials for Numax and CAIV-T during the fourth quarter of 2004, which will continue throughout 2005.

Throughout 2005, we believe our financial position will remain strong with cash flow from operations funding capital expansion, strategic investments, research and development expenditures, and repurchases of common stock.

## DISSOLUTION OF THE COLLABORATION WITH WYETH

In April 2004, we entered into agreements to dissolve the collaboration with Wyeth for FluMist, CAIV-T and all related technology. As a result of the dissolution and in exchange for an upfront fee and future milestones and sales-related royalties, MedImmune reacquired the influenza vaccines franchise, and assumed full responsibility for the manufacturing, marketing and sale of FluMist and any subsequent related product. As part of the dissolution, we acquired Wyeth's distribution facility in Louisville, Kentucky. Wyeth has provided bulk manufacturing materials, transferred clinical trial data, as well as provided manufacturing support services, during a transition that was substantially completed during 2004. In connection with the dissolution of the collaboration, we made payments during 2004 totaling \$79.9 million under the terms of the agreement, representing: (1) the final reconciliation of the amounts owed between parties related to the 2003/2004 influenza season; (2) the settlement of commercialization and development expenses owed between parties through the date of the agreement; (3) the purchase of the distribution center; (4) the transfer of other assets from Wyeth; and (5) the payment of milestones for achieving certain goals for transition activities. An additional \$4.1 million due to Wyeth as of December 31, 2004 for technology transfer and transition activities is included in accrued expenses on our consolidated balance sheet.

The notable impacts of the transaction during 2004 are as follows:

**Revenue** Beginning with the 2004/2005 flu season and beyond, all FluMist product sales are recorded as the sales price to our distributor less customary sales allowances. We no longer receive any reimbursement from Wyeth for development and commercialization costs, nor do we receive milestone payments.

**Research and Development** Our research and development charges increased significantly in 2004 compared to 2003 as we completed the transition of research and development activities from Wyeth and increased our resources and infrastructure to assume full responsibility for the continued development and regulatory approval of the influenza vaccine franchise.

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

**Acquired In-Process Research and Development (IPR&D)** We recorded charges for IPR&D of \$29.2 million during 2004, representing the relative fair value of purchased in-process technologies at the purchase date, as determined by an independent valuation. A portion of the charges that occurred in 2004 relate to milestone payments to Wyeth for the achievement of certain contractual deliverables. See further explanation of the calculation of the IPR&D charge in the Critical Accounting Estimates section.

**Income Taxes** Our effective tax rate for 2004 was approximately 59%, as compared to our 2003 effective rate of approximately 37%, reflecting the impact of the portion of IPR&D expensed during the second quarter that is not deductible for tax purposes. Excluding the impact of the dissolution of the Wyeth agreements, the 2004 effective tax rate was approximately 33%. See further discussion of income taxes in the Critical Accounting Estimates section.

## NEW ACCOUNTING STANDARDS

In January 2003, the Financial Accounting Standards Board ( FASB ) issued FIN No. 46, Consolidation of Variable Interest Entities, an interpretation of Accounting Research Bulletin No. 51. FIN No. 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the

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

In December 2004, the FASB issued Statement of Financial Accounting Standards ( SFAS ) No.123R, a revision of SFAS 123, Accounting for Stock-based Compensation. SFAS 123R requires public companies to recognize expense associated with share-based compensation arrangements, including employee stock options, using a fair value-based option pricing model, and eliminates the alternative to use Accounting Principles Board Opinion 25's intrinsic value method of accounting for share-based payments. In accordance with the new pronouncement, we plan to begin recognizing the expense associated with share-based payments, as determined using a fair value-based method, in our statements of operations beginning on July 1, 2005. We expect that adoption of the expense provisions of the Statement will have a material impact on our results of operations. The standard allows three alternative transition methods for public companies: modified prospective application without restatement of prior interim periods in the year of adoption; modified retrospective application with restatement of prior interim periods in the year of adoption; and modified retrospective application with restatement of prior financial statements to include the same amounts that were previously included in pro forma disclosures. We have not determined which transition method we will adopt.

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

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

In December 2004, the FASB issued SFAS 151, Inventory Costs An Amendment of ARB No. 43, Chapter 4. SFAS 151 amends the guidance in ARB No. 43, Chapter 4 to require that idle facility expense, freight, handling costs and wasted material (spoilage) be recognized as current-period charges regardless of whether they meet the criterion of so abnormal. In addition, the Statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. We will adopt SFAS 151 for inventory costs incurred beginning January 1, 2006 as required by the Standard. We expect that adoption of the Standard will have an immaterial impact on our consolidated financial position and results of operations.

#### **CRITICAL ACCOUNTING ESTIMATES**

The preparation of consolidated financial statements requires management to make estimates and judgments with respect to the selection and application of accounting policies that affect the reported

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

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

During 2004, we recorded a charge of \$29.2 million for acquired IPR&D in conjunction with our reacquisition of influenza vaccine franchise rights from Wyeth in May 2004. The charge represents the estimated relative fair value, as of the purchase date, of the acquired in-process technologies and certain IPR&D projects, primarily CAIV-T, calculated utilizing the income approach. CAIV-T is not expected to have the logistical and distribution issues associated with the frozen formulation and is expected to have an expanded label. We do not believe that there will be any alternative future use for the in-process technologies that were expensed as of the reacquisition date. In valuing the purchased in-process technologies, we estimated cash inflows based on extensive market research performed on the U.S. marketplace and cash outflows for product costs, milestones and royalties to be paid over a 10-year period assuming approval and U.S. launch in the 2007/2008 timeframe using probability-of-success-adjusted scenarios and a discount rate of 11.3%. Based on current information, management believes that the projections underlying the analysis are reasonable; however, the actual cash inflows or outflows cannot be predicted with certainty. To achieve these projections, we are required to complete certain Phase 3 clinical trials over the next several years. The estimated total cost of these worldwide Phase 3 clinical trials, which is dependent upon several factors including the ultimate design of the trials, the number of patients to be enrolled, and the number of sites needed to complete enrollment, is estimated to range between \$110 million and \$160 million.

As with all biotechnology products, the probability of commercial success for any one research and development project is highly uncertain. If we fail to successfully complete the clinical trials or if CAIV-T is not approved by the FDA as a safe and effective vaccine for our targeted populations, the launch may be delayed or terminated, resulting in a diminished or no return on the purchase price of the Acquisition, payments made to Wyeth in connection with dissolution of the collaboration and development costs incurred to date. In addition, as of December 31, 2004, none of the existing manufacturing facilities involved in the production of CAIV-T have been licensed to manufacture CAIV-T by any regulatory agency, nor has CAIV-T been manufactured on a sustained commercial scale. There can be no assurance that these facilities can achieve licensure by the FDA or any other regulatory agency, nor can there be any assurances that if licensed, commercial scale production could be achieved or sustained. If we fail to obtain FDA approval for the marketing and manufacture of CAIV-T, we will not achieve the currently anticipated return on any investment we have made or will make in CAIV-T.

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

As a result of multiple factors, which were unforeseen at the time of the Acquisition, FluMist did not achieve the level of initial commercial success that we had projected for the first season. After a thorough analysis of the product subsequent to the first season, we are focused on attempting to change the formulation from frozen to refrigerator-stable and to expand the label to 6 months through 64 years of age. As such, we do not presently believe that the FluMist product will be a meaningful contributor to revenue growth before 2007, when we hope to launch CAIV-T. Had we known at the time of the Acquisition that we would have a more narrow indication (the June 2003 approval was for healthy people from 5 years to 49 years of age) than expected or that our sales volumes would be much lower than expected, the value assigned to the purchased IPR&D would likely have been approximately half of the original valuation.

**Revenue Recognition** We recognize revenue from product sales when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed or determinable and collectibility is reasonably assured.

We receive royalties from licensees, based on third-party sales of licensed products or technologies. Royalties are recorded as earned in accordance with the contract terms when third-party results can be reliably measured and collectibility is reasonably assured.

Revenue from certain guaranteed payments where we continue involvement through a development collaboration or an obligation to supply product is recognized ratably over the development or supply period.

We may record deferred revenues related to milestone payments and other up front payments. Deferred revenue for manufacturing obligations is recognized as product is delivered. Deferred revenue associated with performance milestones is recognized based upon the achievement of the milestones, as defined in the respective agreements, as long as the milestones are substantive and at risk. Revenue under research and development cost reimbursement contracts is recognized as the related costs are incurred.

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

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 is recovered through further processing or receipt of specification waiver from regulatory agencies, and becomes available and is used for commercial sale.

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

product's pricing is such that we may not fully recover the cost of inventory, we must consider that in our judgments as well. In the context of reflecting inventory at the lower of cost or market, we will record permanent inventory write-downs as soon as a need for such a write-down is determined. Such write-downs in inventory are permanent in nature, and will not be reversed in future periods.

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

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

For all inventory components on hand as of December 31, 2004, we reviewed the following assumptions to determine the amount of any necessary reserves: expected production levels and estimated cost per dose; sales volume projections that are subject to variability; the expected price to be received for the product and anticipated distribution costs; 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 December 31, 2004 at net realizable value was consistent with the methodology used for the valuations from approval in June 2003 through and as of December 31, 2004.

The December 31, 2003 valuation of FluMist inventories considered the disappointing sales results of our initial launch of FluMist, which became available in late 2003, and our revised sales estimates of FluMist for both the 2003/2004 and 2004/2005 flu seasons. As a result, we revised our sales volume estimates and decreased the estimated price expected to be received per dose for the 2004/2005 flu season. In addition, we decreased our estimated production levels based on our anticipated decrease in sales volumes, which increased the per unit cost to produce FluMist. Using these assumptions, we compared the amount of expected FluMist sales with the expected production cost to estimate the net realizable value of FluMist inventories to be produced throughout the season. Sales and production estimates for the 2004/2005 season incorporated into the inventory valuations performed as of December 31, 2003 and the first half of 2004 were generally consistent. The valuation as of September 30, 2004 incorporated management's estimates of sales and production levels that were adjusted to take into account anticipated increased demand due to the shortage of injectable influenza vaccine in the U.S. for the 2004/2005 season. The valuation of inventory as of December 31, 2004 is based on sales volume and price estimates for the 2005/2006 season that are largely based on our actual experience for the 2004/2005 season.

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

	Gross Inventory	Reserves	Net Inventory
<b>FluMist Details</b>			
As of December 31, 2003	\$ 122.1	\$ (85.8 )	\$ 36.3
Raw materials, net	5.0	0.5	5.5
Production, net	62.0	(47.4 )	14.6
Disposals and scrap	(85.6 )	77.9	(7.7 )
Cost of goods sold recognized on 2003/2004 inventory during Q1 of 2004	(34.2 )	5.0	(29.2 )
Cost of goods sold recognized on 2004/2005 inventory during Q4 of 2004	(18.6 )	14.1	(4.5 )
As of December 31, 2004	\$ 50.7	\$ (35.7 )	\$ 15.0

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

For our other products, we periodically assess our inventory balances to determine whether net realizable value is below recorded cost. Factors we consider include expected sales volume, production capacity and expiration dates. We plan to replace the current lyophilized formulation of Synagis with the newly approved liquid formulation during the 2005/2006 RSV season pending final FDA approval of the manufacturing facilities and processes. As of December 31, 2004, we analyzed inventory quantities, including pending future commitments, and projected sales levels of the current formulation of Synagis in connection with this conversion plan. Based on our review, we recorded a permanent inventory write-down for excess inventories of \$5.5 million. No other significant inventory adjustments were recorded during 2004.

#### Sales Allowances and Other Sales Related Estimates

##### *Reductions to Gross Product Sales*

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

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

We update these factors for any known changes in facts or circumstances as soon as the changes are known. If our historical trends are not indicative of the future, or our actual sales are materially different

from the projected amounts, or if our assessments prove to be materially different than actual occurrence, our results could be affected. The estimation process for determining reserves for sales allowances inherently results in adjustments each year. Additionally, because of the varying lags and the seasonal nature of our largest product, Synagis, our sales discounts, returns, chargebacks and rebates fluctuate throughout the year. If our estimate of the percentage of gross sales to be recorded for sales allowances for Synagis were to increase by 1%, our revenues for the 2003/2004 Synagis sales season (which runs from July 2003 to June 2004) would have been reduced by approximately \$9 million. A decrease of 1% in the sales allowances for Synagis during the same period would have increased our revenues by approximately \$9 million.

We estimate the amount of rebates due to government purchasers quarterly based on historical experience, along with updates, and based on our best estimate of the proportion of sales that will be subject to this reimbursement, largely comprised of Medicaid payments to state governments. During the first quarter of 2003, we lowered our estimate of rebates due to government purchasers to reflect favorable historical experience and a change in our estimate of the proportion of the sales that are subject to reimbursement. During the fourth quarter of 2003, we became aware of efforts by several states to collect rebates for product administered in certain settings for which reimbursement was not sought in the past. After analyzing the situation, we determined that the new facts and circumstances warranted an increase in our estimate of rebates due to government purchasers. As such, we recorded additional reserves for rebates due to government purchasers of approximately \$13.7 million during the fourth quarter of 2003, and increased our estimate of the proportion of current sales that will be subject to reimbursement, given the change in circumstance. For the years ended December 31, 2004, 2003 and 2002, allowances for discounts, returns, chargebacks and rebates due to government purchasers resulted in a net reduction to gross product sales of approximately 10%, 9% and 9%, respectively. The increase in 2004 is attributable to FluMist sales, which experience higher discount and return rates than our other products, and higher levels of Medicaid reporting compliance for reimbursement.

Allowances for discounts, returns, and chargebacks, which are netted against accounts receivable, totaled \$14.5 million and \$9.0 million at December 31, 2004 and 2003, respectively. Allowances for government reimbursements were \$52.5 million and \$42.4 million as of December 31, 2004 and 2003, respectively, and are included in accrued expenses in the accompanying balance sheets.

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

We estimate our co-promotion expense and sales commissions by applying an estimated rate that is based upon an estimate of projected sales for the season to our actual sales for the period. We decreased co-promotion expense by \$2.0 million in 2003 and increased co-promotion expense by \$2.1 million in 2002, resulting from the final reconciliation of net sales for the 2002/2003 and 2001/2002 contract years. No significant adjustments to co-promotion expense were made during 2004.

We estimate the level of bad debts as a percentage of gross trade accounts receivable balances outstanding at the end of the period, based upon our assessment of the concentration of credit risk, the financial condition and environment of our customers, and the level of credit insurance, if any, we obtain on our customers' balances. Because of the seasonal nature of our largest product, Synagis, our accounts receivable balances fluctuate significantly. Accordingly, our allowance for doubtful accounts also fluctuates. Our accounts receivable balances tend to be highest at the end of December and March, while the September balances are somewhat lower as our selling season is just beginning, and the June balances are significantly lower, reflecting the close-out of the prior season. For the years ended December 31, 2004 and 2003, we recorded \$2.0 million and \$3.8 million in reductions to bad debt expense, largely based on our current assessment of the factors above. Bad debt expense is classified as selling, general and administrative expense in our consolidated statements of operations.



**Income Taxes** We record valuation allowances to reduce our deferred tax assets to the amounts that are anticipated to be realized. We consider future taxable income and ongoing tax planning strategies in assessing the need for valuation allowances. In general, should we determine that we are able to realize more than the recorded amounts of net deferred tax assets in the future, our net income will increase in the period such determination was made. Likewise, should we determine that we would not be able to realize all or part of the net deferred tax asset in the future, our net income would decrease in the period such determination was made. Reversals of valuation allowance related to acquired deferred tax assets, however, would first be applied against goodwill and other intangibles before impacting net income. A tax reserve is recorded when we cannot assert that it is probable that a tax position claimed on a return will be sustained upon challenge by the tax authority. Any change in the balance of a tax reserve during the year is treated as an adjustment to current year tax expense.

During 2004, we reached a state tax settlement that enabled us to release a tax contingency reserve of \$1.5 million, resulting in a benefit to our consolidated statement of operations. In addition, our U.K. subsidiary recognized income in 2004 for U.K. tax purposes, which enabled us to release a valuation allowance for net operating losses of approximately \$2.4 million, resulting in a favorable impact to the consolidated statement of operations.

**Goodwill and Intangible Assets** We have recorded and valued significant intangible assets that we acquired as a result of the Acquisition. We engaged independent valuation experts who reviewed our critical assumptions and assisted us in determining a value for the identifiable intangibles. Of the \$129.4 million of acquired intangible assets, \$90.0 million was assigned to the worldwide collaborative agreement with Wyeth for the development, manufacture, distribution, marketing, promotion, and sale of FluMist. We estimated the fair value of the Wyeth agreement using the sum of the probability-adjusted scenarios under the income approach. In applying this method, we relied on revenue assumptions, profitability assumptions and anticipated approval dates. The remaining \$39.0 million was assigned to a contract manufacturing agreement with Evans Vaccines Limited. We estimated the fair value of the Evans agreement using the cost approach, which is based on the theory that a prudent investor would pay no more for an asset than the amount for which the asset could be replaced. In our analysis, we reduced replacement cost for such factors as physical deterioration and functional or economic obsolescence. We review intangible assets for impairment when an event that could result in an impairment occurs. As a result of the dissolution of the collaboration with Wyeth during 2004, we recorded a permanent impairment loss of \$73.0 million that represented the remaining unamortized cost of the related intangible asset. As of December 31, 2004, there was no further impairment of our intangible assets, of which \$13.1 million remains unamortized.

During 2004 and 2003, we made adjustments to goodwill recorded in the Acquisition of \$11.2 million and (\$2.4) million, respectively, reflecting adjustments to deferred tax assets relating to the resolution of income tax related uncertainties. We review goodwill for impairment at least annually (during the fourth quarter) and during interim periods if an event that could result in an impairment occurs. As of December 31, 2004, we have not identified any impairment of goodwill, of which \$24.8 million remains on the consolidated balance sheet.

**Investments in Debt and Equity Securities** Our short-term and long-term investments are subject to adjustment for other-than-temporary impairments. Impairment charges are recognized in the consolidated statements of operations when a decline in the fair value of an investment falls below its cost value and is judged to be other than temporary. We consider various factors in determining whether an impairment charge is required, including: the length of time and extent to which the fair value has been less than the cost basis; the financial condition and near-term prospects of the issuer; fundamental changes to the business prospects of the issuer; share prices of subsequent offerings; and our intent and ability to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value. During 2004, 2003 and 2002, we recorded impairment losses of \$13.7 million, \$1.7 million and \$14.0 million,

respectively, based on the duration and magnitude of the declines in the fair value of certain of our investments, as well as the financial condition and near-term prospects of the investee companies.

## RESULTS OF OPERATIONS

### Comparison of 2004 to 2003

#### Revenues Product Sales

	2004 (In Millions)	2003	Growth
Synagis	\$ 942.3	\$ 849.3	11 %
Ethyol	92.4	100.2	(8 )%
FluMist	48.0		n/a
Other Products	41.3	43.1	(4 )%
	\$ 1,124.0	\$ 992.6	13 %

During 2004, product sales grew 13% to \$1.1 billion as compared to \$1.0 billion during 2003, primarily due to an 11% increase in sales of Synagis to \$942.3 million. Of the overall 13% increase in product sales, approximately five percentage points were due to the recognition of FluMist product sales for the first time in 2004. Domestic price increases accounted for five growth points, and an additional two percentage points were due to increases in domestic sales volume, but were largely negated by higher sales allowances that reduced sales by two percentage points. International sales added three points of growth.

**Synagis** Synagis accounted for approximately 84% and 86% of our product sales for 2004 and 2003, respectively. We achieved a 7% increase in domestic Synagis sales to \$833.6 million for 2004, up from \$777.1 million in 2003. Of the 7% growth year over year, five percentage points resulted from price increases and four percentage points were due to higher sales volumes, which were partially offset by higher sales allowances that caused a reduction of two percentage points. Our reported international sales of Synagis increased to \$108.7 million in 2004 compared to \$72.2 million in 2003, largely due to a 33% increase in units sold to Abbott International ( AI ), our exclusive distributor of Synagis outside of the United States. We believe this growth is primarily due to increased product demand by our end users, including physicians, hospitals, and pharmacies. Also contributing to international sales growth was an increase in the sales price caused by a change in the mix of countries to which we sell Synagis internationally that favorably impacted the average sales price, and the favorable currency translation impact of a weakened U.S. dollar. We record Synagis international product sales based on AI 's sales price to customers, as contractually defined.

**Ethyol** Ethyol accounted for approximately 8% and 10% of our product sales for 2004 and 2003, respectively. Worldwide Ethyol sales declined 8% to \$92.4 million in 2004, as compared to \$100.2 million in 2003. Domestic sales of Ethyol declined 6% from prior year, driven by an eight percentage point decline due to volume and an additional four points due to an increase in sales allowances, offset by six growth points due to price increases. We believe that the lower domestic sales volumes for 2004 are largely due to the depletion of wholesaler inventories from December 31, 2003 levels to accommodate end-user demand and the impact, which we believe is temporary, of the adoption of a relatively new form of radiation treatment in the head and neck cancer market. International sales of Ethyol declined over the prior year, primarily due to a 58% decrease in unit volume to our international distribution partner, Schering. We record Ethyol international product sales based on a percentage of Schering 's end-user sales, as contractually defined.

**FluMist** Our 2004 product sales of FluMist amounted to \$48.0 million, including product sales for the 2004/2005 flu season of \$20.9 million, representing estimated net doses of approximately 1.7 million.



2004 sales also include transfer price revenues of \$27.1 million for product shipped to Wyeth, our former partner, during 2003 related to the 2003/2004 season. At December 31, 2003, we concluded that the variables associated with FluMist product revenues were not determinable, largely due to low sales volume and the lack of returns history and comparable rebate redemption rates for the new product. As a result, no product revenues were recognized during 2003 associated with the 4.1 million doses that were shipped to Wyeth during 2003.

**Other Products** Sales of other products include sales of CytoGam, RespiGam, NeuTrexin and by-products that result from the CytoGam manufacturing process and amounted to \$41.3 million in 2004 as compared to \$43.1 million in 2003. The slight decrease is primarily due to the decline in sales of RespiGam, which has been replaced in the marketplace by our second-generation RSV product, Synagis, and is no longer manufactured.

#### **Revenues Other Revenues**

Other revenues of \$17.1 million for 2004 are lower than 2003 other revenues of \$61.8 million largely due to decreased revenues under collaborative agreements. During 2004, we recognized \$7.5 million of milestone revenue under our international distribution agreement with AI upon the achievement of end-user sales of Synagis outside the U.S. in excess of \$150 million in a single RSV season. Other revenues in 2004 also include contractual payments received from Wyeth prior to dissolution of our collaboration, including royalties related to the 2003/2004 influenza season, supply goal payments, and corporate funding for clinical development and sales and marketing programs. During 2003, we recognized \$45.9 million of revenues under the collaboration with Wyeth related to milestone payments, supply goal payments, and funding for clinical development and marketing programs. Also during 2003, we recognized \$7.5 million of milestone revenue for achieving in excess of \$100 million in end-user sales of Synagis outside the U.S. during a single RSV season.

#### **Cost of Sales**

Cost of sales for 2004 increased 26% to \$366.4 million from \$289.8 million for 2003. Gross margins on product sales were 67% for 2004, down four percentage points from gross margins of 71% for 2003. Gross margins for all products, excluding FluMist, aggregated to 75% of product sales for both 2004 and 2003. The negative impact of FluMist on gross margins was less in 2003 than 2004 largely due to the shift in costs of FluMist manufacturing that are included in inventory and cost of goods sold during 2004, but were expensed as other operating costs during the first quarter of 2003, prior to FDA approval of the product.

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

Total research and development expenses more than doubled during 2004 to \$327.3 million from \$156.3 million in 2003. Research and development expenses, as reported in the accompanying statements of operations, include both our ongoing expenses of drug discovery and development efforts, as well as costs related to the technology transfer and transition activities associated with reacquisition of the influenza vaccines franchise from Wyeth during 2004. The technology transfer and transition costs, totaling approximately \$27.8 million, are largely amounts paid to Wyeth for collection and analysis of data from five late-stage CAIV-T studies conducted by Wyeth over the last several years, including assistance in documenting study reports, closing and locking databases for clinical trials, and transition of clinical study results to our clinical databases. The costs also include payments for the maintenance of the CAIV-T development facility and production of CAIV-T clinical trial material, as well as assistance with internal technology transfer of manufacturing operations for CAIV-T.

The increase in our ongoing expenses of drug discovery and development efforts is related to a large number of new and ongoing clinical and preclinical studies, particularly for Numax, CAIV-T and Vitaxin,

as well as costs associated with the expansion of infrastructure to support these studies. During November 2004, we advanced the Numax program into Phase 3 clinical trials, with a pivotal head-to-head trial with Synagis, and a second trial designed to assess whether Numax can reduce the incidence of RSV hospitalization in Native American infants. We are also completing a Phase 1/2 trial with Numax. During October, we initiated a Phase 3 trial that will compare CAIV-T to the traditional injectible flu vaccine in children from 6 months to 59 months of age, and a Phase 3 bridging study designed to compare CAIV-T with frozen FluMist. We also progressed with two ongoing Phase 2 trials for Vitaxin targeting melanoma and prostate cancer, while we discontinued two trials for Vitaxin targeting rheumatoid arthritis and psoriasis based on preliminary data suggesting lack of clinical benefit in these inflammatory diseases. Also during 2004, we began a Phase 1 clinical trial with an anti-interleukin-9 (IL-9) monoclonal antibody to evaluate the molecule as a potential treatment for symptomatic, moderate to severe persistent asthma. During 2004, we also made a \$15.0 million payment to Medarex, Inc. as part of a new collaboration to co-develop antibodies targeting interferon-alpha and the type 1 interferon receptor for the treatment of autoimmune diseases.

We have several programs in clinical and pre-clinical development, but a summary of our more significant current internal research and development efforts is as follows:

Product Candidates	Description	Stage of Development
Numax	Second-generation anti-RSV monoclonal antibody	Phase 3
CAIV-T	Refrigerator-stable version of intranasal influenza vaccine, live	Phase 3
Vitaxin	Monoclonal antibody for the treatment of melanoma and prostate cancer	Phase 2
FluMist	Intranasally delivered virus vaccine to prevent influenza infection	Phase 4
Ethiol	Subcutaneous administration in non-small cell lung cancer patients-reduction of esophagitis and pneumonitis	Phase 2

#### Selling, General and Administrative Expenses

Selling, general and administrative ( SG&A ) expenses increased 17% to \$400.2 million in 2004 compared to \$340.9 million in 2003. The increase is largely attributable to costs associated with expanding the pediatric commercial organization, increased co-promotion expense, and increased marketing activities and professional services. Excluding the amounts incurred during 2004 for Wyeth-related transition activities and the favorable impact in both years of adjustments to the bad debt provision based upon changes in our assessment of credit risk, SG&A expense as a percentage of product sales was 36% and 35% in 2004 and 2003, respectively.

#### Other Operating Expenses

Other operating expenses, which reflect manufacturing start-up costs and other manufacturing related costs, decreased to \$8.6 million in 2004 from \$26.1 million in 2003. The decrease is due to the shift in the costs of FluMist manufacturing that are in inventory and cost of goods sold this year, but were expensed as other operating costs in the prior year prior to the June 2003 approval of FluMist. Other operating expenses in both periods also include excess capacity charges associated with the plasma production portion of the Frederick Manufacturing Center.

### **Impairment of Intangible Asset**

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

### **Acquired IPR&D**

We recorded a charge of \$29.2 million for acquired IPR&D for 2004 in conjunction with our reacquisition of the influenza vaccines franchise from Wyeth. The charge represents the relative fair value of purchased in-process technologies at the acquisition date, calculated utilizing the income approach, of certain IPR&D projects, primarily CAIV-T. See further discussion of IPR&D in the Critical Accounting Estimates section of this Management's Discussion and Analysis.

### **Interest Income and Expense**

We earned interest income of \$65.5 million for 2004, compared to \$56.8 million in 2003, reflecting higher average investment balances and higher average rates. Interest expense for 2004, net of amounts capitalized, was \$8.4 million, down from \$10.3 million in 2003. The decline is due to the retirement of the 5¼% convertible subordinated notes in March 2004, partially offset by a decrease in the amount of interest cost capitalized in 2004 versus the prior period, due to the completion of several large construction projects in 2004, including the new R&D facility and corporate headquarters in Maryland.

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

We incurred a \$2.7 million loss on investment activities for 2004, compared to a gain of \$3.4 million in 2003. The 2004 loss consists of impairment write-downs of \$13.7 million due to the decline in fair value of certain of our investments in private companies below their cost basis that were determined to be other-than-temporary, partially offset by net realized gains on sales of common stock and other investments totaling \$11.0 million. During 2003, we recognized gains on the sale of common stock and other investments of \$5.9 million, partially offset by impairment write-downs and charges to record our portion of our minority investees' operating results as required by the equity method of accounting.

### **Income Taxes**

We recorded an income tax benefit of \$5.4 million for 2004, resulting in an effective tax rate of 59%. Comparatively, we recorded income tax expense of \$108.0 million for 2003, which resulted in an effective tax rate of 37%.

The year-over-year change in our estimated effective tax rate is due in part due to \$6.9 million of non-deductible charges for IPR&D during the second quarter of 2004. Our effective tax rate in 2004 was also favorably impacted by the increase in credits available for research and development activities, including credits earned for orphan drug status of certain research and experimentation activities, corresponding to the overall growth in research and experimentation activity over 2003. These credits will vary from year to year depending on our activities and the enactment of tax legislation. Also during 2004, we reached a state tax settlement and our U.K. subsidiary recognized income for U.K. tax purposes, enabling us to release valuation allowance and tax contingency reserves, resulting in a favorable impact to the consolidated statement of operations.

### **Net (Loss) Earnings**

We reported a net loss for 2004 of \$3.8 million, or \$0.02 per share compared to net earnings for 2003 of \$183.2 million or \$0.72 per diluted share.

Shares used in computing loss per share for 2004 were 248.6 million, while shares used for computing basic and diluted earnings per share for 2003 were 250.1 million and 257.2 million, respectively. The decrease in share count is primarily attributable to our stock repurchase program that we implemented in July 2003.

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

## Comparison of 2003 to 2002

### Revenues Product Sales

	2003 (In Millions)	2002	Growth
Synagis	\$ 849.3	\$ 671.7	26 %
Ethyol	100.2	81.2	23 %
FluMist			
Other Products	43.1	38.0	13 %
	\$ 992.6	\$ 790.9	25 %

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

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

**Ethyol** Ethyol accounted for approximately 10% of our product sales in both 2003 and 2002. Domestic Ethyol sales increased 25% to \$94.4 million in 2003, up from \$75.5 million in 2002. This 25% increase was the result of a 15% increase in domestic units sold in 2003 compared to 2002 and a price increase which occurred in August 2003. Our 2003 international sales of Ethyol to our distribution partner, Schering, were consistent with 2002 sales of \$5.7 million.

**FluMist** During 2003, we received payments totaling \$51.9 million upon the shipment of 4.1 million doses of FluMist to Wyeth, our former partner who was contractually responsible for distributing the product to third parties. The final selling price for the doses shipped to Wyeth was largely dependent on Wyeth's net sales to end users. As of December 31, 2003, we concluded that the variables associated with the product transfer price were not determinable, largely due to low sales volume and the lack of returns history and comparable redemption rates for rebates for FluMist in its launch season. As a result, we did not recognize the revenue associated with the 4.1 million doses shipped to Wyeth during 2003. Product sales for these shipments were recognized during the first quarter of 2004, once the influenza season was substantially over and Wyeth's ultimate net sales to end users were determinable.





**Other Products** Sales of other products in 2003, which include sales of CytoGam, NeuTrexin, RespiGam, and by-products that result from the CytoGam manufacturing process, increased \$5.1 million, or 13% compared to 2002. The increase was largely due to a 10% increase in our sales of CytoGam.

#### **Revenues Other Revenues**

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

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

#### **Cost of Sales**

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

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

Research and development expenses of \$156.3 million in 2003 increased 6% from \$148.0 million in 2002. The increase was due largely to payments made in 2003 associated with gaining access to new data and technologies, net of a decrease in clinical trials expense and a decrease in stock compensation expense for unvested stock options assumed in the Acquisition and in retention payments and stock compensation expense for acceleration of stock options for certain of Aviron's executives. During 2003, we made a \$10.0 million payment to Critical Therapeutics, Inc. as part of a new collaboration to co-develop biologic products to treat severe inflammatory diseases. Additionally in 2003, we initiated four Phase 2 studies for Vitaxin and agreed to pay \$10.0 million for data from the completed international Phase 3 studies for a liquid formulation of FluMist.

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

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

SG&A expenses increased 14% to \$340.9 million in 2003 compared to \$299.6 million for the 2002 period, largely due to increased co-promotion expense, reflective of the increase in Synagis sales. As a percentage of product sales, SG&A expense decreased to 34% of product sales in the 2003 period from 38% in the 2002 period, due to product sales growing at a faster rate than expenses.

### **Other Operating Expenses**

Other operating expenses, which reflect manufacturing start-up costs and other manufacturing-related costs, were \$26.1 million in 2003 compared to \$100.0 million in 2002. The decrease in other operating expenses was principally due to the shift in the costs of FluMist manufacturing that are capitalized in inventory and expensed as cost of goods sold beginning in the second quarter of 2003, but were expensed as other operating costs in the prior year. Additionally, 2002 other operating expenses included impairment charges of \$12.9 million relating to the write-off of certain plasma manufacturing assets, as we outsourced production of CytoGam during 2002. We also experienced decreases in stock compensation expense for unvested stock options assumed in the Acquisition and in retention payments and stock compensation expense for acceleration of stock options for certain of Aviron's executives.

### **In-Process Research and Development**

We incurred charges of \$1,179.3 million in the first quarter of 2002 for the write-off of purchased in-process research and development in conjunction with the Acquisition. The write-off represented the fair value of purchased in-process technologies at the acquisition date, calculated as the sum of probability-adjusted commercial scenarios. This method was based upon management's estimates of the probability of FDA approval and commercial success for FluMist.

### **Interest Income and Expense**

We earned interest income of \$56.8 million for 2003, compared to \$49.4 million in 2002, reflecting higher cash balances available for investment, partially offset by a decrease in interest rates, which lowered the overall portfolio yield. Interest expense for 2003, net of amounts capitalized, was \$10.3 million, up from \$9.1 million for 2002, principally due to interest expense generated by the 1% Notes issued in July 2003.

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

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

### **Income Taxes**

We recorded income tax expense of \$108.0 million for the year ended December 31, 2003, based on an effective tax rate of 37.1%. We recorded income tax expense of \$48.2 million for the year ended December 31, 2002. Excluding items not deductible for tax purposes, principally the write-off of purchased in-process research and development, the resulting effective tax rate for 2002 was 37.2%.

### **Net Earnings (Loss)**

Net earnings for 2003 were \$183.2 million, or \$0.73 per share basic and \$0.72 per share diluted, compared to a net loss for 2002 of \$1.1 billion or \$4.40 per share. Shares used in computing basic and diluted earnings per share in 2003 were 250.1 and 257.2, respectively. Shares used in computing net loss per share for 2002 were 249.6 million.

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

## LIQUIDITY AND CAPITAL RESOURCES

### Sources and Uses of Cash

Our capital requirements have been funded from operations, cash and investments on hand, and issuance of common stock and convertible debt. Cash and marketable securities were \$1.7 billion at December 31, 2004 as compared to \$1.9 billion at December 31, 2003, a decrease of \$194.0 million. This decrease in cash and marketable securities is primarily due to the combined impact of the retirement of the 5¼% convertible subordinated notes in March 2004 and payments made to Wyeth in conjunction with our reacquisition of full rights to the influenza vaccines franchise. Working capital decreased to \$330.0 million at December 31, 2004 from \$712.0 million at December 31, 2003, also due to the retirement of the 5¼% Notes and the payments made to Wyeth, as well as a shift in our fixed income portfolio mix to longer-term maturities.

*Operating Activities* Net cash provided by operating activities decreased to \$144.7 million in the year ended December 31, 2004 as compared to \$357.5 million in the comparable 2003 period, primarily the result of the decrease in net earnings in 2004, excluding the noncash charge for the impairment of an intangible asset, and the final settlement of advances from Wyeth and payments made to Wyeth for technology transfer and transition activities related to the dissolution of our collaboration.

*Investing Activities* Cash used for investing activities during 2004 was \$300.9 million, as compared to \$238.3 million in 2003. Cash used for investing activities in 2004 included net additions to our investment portfolio of \$162.0 million; capital expenditures of \$79.8 million, primarily for the construction of our new R&D facility and corporate headquarters in Gaithersburg, Maryland, the expansion of our FluMist manufacturing facilities in Speke, England, and construction of our new pilot plant in Gaithersburg, Maryland, which began in 2004; \$34.8 million paid to Wyeth for certain in-process technologies and IPR&D projects, primarily CAIV-T, and the distribution facility in Louisville; and minority interest investments in strategic partners totaling \$24.3 million through our venture capital subsidiary.

*Financing Activities* Financing activities in 2004 used \$187.9 million in cash, as compared to cash generated of \$266.2 million in 2003. During 2004, we used \$172.7 million in cash to repurchase and retire the balance of the 5¼% Notes, and an additional \$30.0 million to repurchase shares of our common stock as authorized under our share repurchase program. Approximately \$19.5 million was received upon the issuance of common stock relating primarily to the exercise of employee stock options in 2004, compared to \$44.4 million received in 2003. During 2003, we received net cash proceeds of \$489.4 million in connection with the issuance of the 1% Notes, which was partially offset by treasury stock repurchases of \$229.8 million.

Our primary source of liquidity is operating cash flow. Management continues to believe that such internally generated cash flow as well as its existing funds will be adequate to service its existing debt and other cash requirements. We expend cash to finance our research and development and clinical trial programs; to obtain access to new technologies through collaborative research and development agreements with strategic partners, through our venture capital subsidiary, or through other means; to fund capital projects; and to finance the production of inventories. In February 2005, our Board of Directors increased the approved funding for our venture capital subsidiary from \$100 million to \$200 million. During 2004, we received a BBB rating on our outstanding indebtedness by Standard & Poor's. This rating is considered to be investment grade and we believe the rating will contribute to our ability to access capital markets, should we desire or need to do so. We may raise additional capital in the future to take advantage of favorable conditions in the market or in connection with our development activities.

Our Board of Directors has authorized the repurchase of up to \$500 million of the Company's common stock during the period from July 2003 through June 2006 in the open market or in privately negotiated transactions, pursuant to terms management deems appropriate and at such times it may

designate. During 2004, we repurchased 1.2 million shares of our common stock under the stock repurchase program at a total cost of \$30.0 million, or an average cost of \$24.33 per share. During 2003, we repurchased 6.2 million shares at a total cost of \$229.8 million, or an average cost of \$36.83 per share. From January 1, 2005 through February 25, 2005, we purchased an additional 0.6 million shares for approximately \$15.0 million, or an average cost of \$24.63 per share. 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.

In 2005, we will continue construction of the FluMist manufacturing facilities in Speke, the United Kingdom, and our new pilot plant in Gaithersburg, Maryland, and will break ground on additional administrative offices at the headquarters site in Gaithersburg, Maryland. We expect our capital expenditures to approximate \$150 million in 2005. We anticipate these projects will be funded from cash generated from operations and investments on hand.

**Contractual Obligations and Commitments** The following table summarizes our contractual obligations and commitments as of December 31, 2004 that we anticipate will require significant cash outlays in the future (in millions):

<b>Contractual Obligations</b>	<b>Total</b>	<b>2005</b>	<b>2006</b>	<b>2007</b>	<b>2008</b>	<b>2009</b>	<b>Beyond</b>
Long-term debt	\$ 507.1	\$ 0.9	\$ 1.0	\$ 1.1	\$ 0.6	\$ 0.4	\$ 503.1 (1)
Facilities leases	51.8	7.8	6.4	4.7	3.0	2.4	27.5
Purchase obligations	171.5	44.2	21.8	18.9	17.3	17.3	52.0
Obligations to Evans(2)	22.9	3.9	19.0				
<b>Total contractual obligations</b>	<b>\$ 753.3</b>	<b>\$ 56.8</b>	<b>\$ 48.2</b>	<b>\$ 24.7</b>	<b>\$ 20.9</b>	<b>\$ 20.1</b>	<b>\$ 582.6</b>
<i>Other Commercial Commitments</i>							
Standby letters of credit(3)	\$ 2.6	\$ 2.6	\$	\$	\$	\$	\$
Obligations under Collaborative Agreements(4)	23.4	11.7	4.7	1.8	1.0	0.4	3.8
<b>Total other commercial commitments</b>	<b>\$ 26.0</b>	<b>\$ 14.3</b>	<b>\$ 4.7</b>	<b>\$ 1.8</b>	<b>\$ 1.0</b>	<b>\$ 0.4</b>	<b>\$ 3.8</b>

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

(2) Represents amounts due to Evans Vaccines Limited pursuant to a sublease arrangement.

(3) We have guaranteed performance under certain agreements related to our construction projects. The undiscounted maximum potential amount of future payments that we could be required to make under such guarantees, in the aggregate, is approximately \$2.6 million.

(4) We participate in a number of research and development collaborations to develop and market certain technologies and products. The amounts indicated as obligations under collaborative agreements represent committed funding obligations to our collaborative partners under our various development programs. The amounts do not include developmental and sales milestone payments totaling \$600 million or royalties on potential future product sales related to these collaborations since the amount, timing, and likelihood of the payments is unknown as they are dependent on the occurrence of future events that may or may not occur.

#### **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

The following discussion about our risk-management activities includes forward-looking statements that involve risks and uncertainties. Actual results could differ materially from those projected in the forward-looking statements.

Our primary market risks as of December 31, 2004 are our exposures to loss resulting from changes in interest rates, foreign currency exchange rates and equity prices.

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As of December 31, 2004, our excess cash balances are primarily invested in marketable debt securities with investment grade credit ratings. Substantially all of our cash and cash equivalents and short-term and long-term investments are held in custody by three major U.S. financial institutions. Deposits held with banks may exceed the amount of insurance provided on such deposits. Generally, these deposits may be redeemed upon demand and, therefore, bear minimal risk. Our investments consist principally of U.S. government and agency securities and corporate notes and bonds. The maturities range from one month to seven years. Our investment guidelines are intended to limit the amount of investment exposure as to issuer, maturity, and investment type. The fair value of these investments is sensitive to changes in interest rates. Further, interest income earned on variable rate debt securities is exposed to changes in the general level of interest rates.

The following table presents principal cash flows and weighted average interest rates by expected maturity dates for each class of debt security with similar characteristics (in millions):

	2005	2006	2007	2008	2009	2010	2011	Total	Fair Value
U.S. Gov t and Agencies	\$	\$ 187.4	\$ 15.0	\$ 26.9	\$ 50.0	\$ 10.0	\$ 27.5	\$ 316.8	\$ 323.5
Interest Rate		3.9	% 4.8	% 4.5	% 4.1	% 4.2	% 4.9	%	
Corp. Notes and Bonds	\$ 118.6	\$ 240.2	\$ 198.5	\$ 279.7	\$ 225.6	\$ 19.8	\$ 41.4	\$ 1,123.8	\$ 1,178.4
Interest Rate	7.0	% 6.1	% 5.6	% 4.0	% 5.5	% 4.9	% 5.6	%	

We are exposed to equity price risks and risk of impairment related to our minority interest investments. MedImmune Ventures, Inc., the Company's wholly-owned venture capital subsidiary, manages the Company's current portfolio of minority interest investments and endeavors to make additional investments in public or private biotechnology companies focused on discovering and developing human therapeutics. The Company has approved funding to MedImmune Ventures for up to \$200 million in investments, of which \$77 million has been invested as of February 25, 2005. MedImmune Ventures will invest primarily in areas of strategic interest to the Company, including infectious disease, immunology and oncology. The cost basis of MedImmune Ventures' investment holdings, net of impairment writedowns, was \$47.9 million as of December 31, 2004.

Our minority interest investments are subject to adjustment for other-than-temporary impairments. We recognize impairment charges in the consolidated statements of operations when a decline in the fair value of an investment falls below its cost value and is judged to be other than temporary. We consider various factors in determining whether we should recognize an impairment charge, including: the length of time and extent to which the fair value has been less than our cost basis; the financial condition and near-term prospects of the issuer; fundamental changes to the business prospects of the investee; share prices of subsequent offerings; and our intent and ability to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value. During 2004, 2003 and 2002, the Company recorded impairment losses of \$13.7 million, \$1.7 million and \$14.0 million, respectively, based on the duration and magnitude of the declines in fair value, as well as the financial condition and near-term prospects of the investee companies. We expect the volatility in the fair value of our minority investments to continue and, thus, the value assigned to the investments could change significantly from period to period.

As of December 31, 2004, MedImmune Ventures' portfolio included approximately 3.9 million shares of common stock of two publicly traded companies with a cost basis of \$20.0 million and fair value of \$32.9 million. During 2004 and 2003, MedImmune Ventures liquidated its equity holdings in two public companies over a period of approximately one year, in accordance with our investment strategy, resulting in realized gains of \$9.7 million and \$5.7 million, respectively.

The remainder of MedImmune Ventures portfolio as of December 31, 2004 consists primarily of minority interest investments in privately held biotechnology companies. The investments are maintained on the cost or equity method of accounting, according to the facts and circumstances of the individual investment. For investments carried on the equity method, the Company records its proportionate share of the investees gains or losses on a quarterly basis, which was immaterial during 2004, 2003 and 2002. As of December 31, 2004, the investments had a cost basis of \$27.9 million, net of permanent writedowns.

During July 2003, we issued \$500 million of convertible notes due 2023. These notes bear interest at 1.0% per annum payable semi-annually in arrears. Beginning with the six-month interest period commencing July 15, 2006, if the average trading price of these notes during specified periods equals or exceeds 120% of the principal amount of such notes, we will pay contingent interest equal to 0.175% per six-month period of the average trading price per \$1,000 of the principal amount during such periods. As a result, if the market value of these notes appreciates significantly in the future, we could be obligated to pay amounts of contingent interest beginning in 2006. The estimated fair value of the notes at December 31, 2004, based on quoted market prices, was \$481.1 million.

Our remaining outstanding indebtedness of \$7.1 million at December 31, 2004 is in the form of notes that bear interest primarily at fixed rates. The estimated fair value of the remaining long-term debt at December 31, 2004, based on quoted market prices or discounted cash flows at currently available borrowing rates, was \$7.5 million. Maturities for all long-term debt for the next five years are as follows: 2005, \$0.9 million; 2006, \$1.0 million; 2007, \$1.1 million; 2008, \$0.6 million; and 2009, \$0.4 million.

Expenditures relating to our manufacturing operations in the United Kingdom and the Netherlands are paid in local currency. We have not hedged our expenditures relating to these manufacturing operations; 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 United States 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.

We have entered into a supplemental manufacturing contract with Boehringer Ingelheim Pharma GmbH & Co. KG ( BI ) denominated in Euros for the supplemental manufacturing of Synagis. Fluctuations in the Euro to U.S. Dollar exchange rate may lead to changes in our U.S. Dollar cost of manufacturing. To reduce the risk of unpredictable changes in these costs, the Company may, from time to time, enter into forward foreign exchange contracts. As of December 31, 2004, the Company did not have any open foreign exchange forward contracts. Currently, we have firm commitments with BI for planned production and fill/finish through 2012 for approximately 108 million Euros (\$147.5 million using the exchange rate as of December 31, 2004).

**ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and  
Shareholders of MedImmune, Inc.:

We have completed an integrated audit of MedImmune Inc.'s 2004 consolidated financial statements and of its internal control over financial reporting as of December 31, 2004 and audits of its 2003 and 2002 consolidated financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Our opinions, based on our audits, are presented below.

*Consolidated financial statements and financial statement schedule*

In our opinion, the consolidated financial statements listed in the index appearing under Item 15(a)(1) present fairly, in all material respects, the financial position of MedImmune, Inc. and its subsidiaries at December 31, 2004 and 2003, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2004 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the index appearing under Item 15(a)(2) presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit of financial statements includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

*Internal control over financial reporting*

Also, in our opinion, management's assessment, included in Management's Report on Internal Control over Financial Reporting appearing under Item 9A, that the Company maintained effective internal control over financial reporting as of December 31, 2004 based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), is fairly stated, in all material respects, based on those criteria. Furthermore, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on criteria established in *Internal Control - Integrated Framework* issued by the COSO. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express opinions on management's assessment and on the effectiveness of the Company's internal control over financial reporting based on our audit. We conducted our audit of internal control over financial reporting in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. An audit of internal control over financial reporting includes obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we consider necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

PricewaterhouseCoopers LLP  
McLean, Virginia  
March 7, 2005



**MedImmune, Inc.**  
**Consolidated Balance Sheets**  
(in millions)

	December 31, 2004	December 31, 2003
<b>ASSETS:</b>		
Cash and cash equivalents	\$ 171.3	\$ 515.5
Marketable securities	172.6	272.7
Trade receivables, net	203.3	161.2
Inventory, net	64.1	91.7
Deferred tax assets	50.6	29.3
Other current assets	31.9	32.3
Total Current Assets	693.8	1,102.7
Marketable securities	1,362.2	1,111.9
Property and equipment, net	310.9	273.6
Deferred tax assets, net	127.3	151.3
Intangible assets, net	13.1	96.7
Goodwill	24.8	13.6
Other assets	32.3	44.8
Total Assets	\$ 2,564.4	\$ 2,794.6
<b>LIABILITIES AND SHAREHOLDERS EQUITY:</b>		
Accounts payable	\$ 15.1	\$ 22.1
Accrued expenses	251.4	218.0
Product royalties payable	85.9	81.8
Advances from Wyeth		51.9
Other current liabilities	11.4	16.9
Total Current Liabilities	363.8	390.7
Long-term debt	506.2	681.2
Other liabilities	19.8	23.5
Total Liabilities	889.8	1,095.4
Commitments and Contingencies		
<b>SHAREHOLDERS EQUITY:</b>		
Preferred stock, \$.01 par value; authorized 5.5 shares; none issued or outstanding		-
Common stock, \$.01 par value; authorized 420.0 shares; issued 255.4 at December 31, 2004 and 254.3 at December 31, 2003	2.6	2.5
Paid-in capital	2,690.0	2,673.1
Deferred compensation	(0.1 )	(1.4 )
Accumulated deficit	(788.5 )	(772.9 )
Accumulated other comprehensive income	11.1	27.7
	1,915.1	1,929.0
Less: Treasury stock at cost; 6.9 shares as of December 31, 2004 and 6.2 shares at December 31, 2003	(240.5 )	(229.8 )
Total Shareholders Equity	1,674.6	1,699.2
Total Liabilities and Shareholders Equity	\$ 2,564.4	\$ 2,794.6

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

**MedImmune, Inc.**  
**Consolidated Statements of Operations**  
(in millions, except per share data)

	<b>For the year ended December 31,</b>		
	<b>2004</b>	<b>2003</b>	<b>2002</b>
<b>Revenues</b>			
Product sales	\$ 1,124.0	\$ 992.6	\$ 790.9
Other revenue	17.1	61.8	61.8
Total revenues	1,141.1	1,054.4	852.7
<b>Costs and Expenses</b>			
Cost of sales	366.4	289.8	201.8
Research and development	327.3	156.3	148.0
Selling, general, and administrative	400.2	340.9	299.6
Other operating expenses	8.6	26.1	100.0
Impairment of intangible asset	73.0		
Acquired in-process research and development	29.2		1,179.3
Total expenses	1,204.7	813.1	1,928.7
Operating (loss) income	(63.6 )	241.3	(1,076.0 )
Interest income	65.5	56.8	49.4
Interest expense	(8.4 )	(10.3 )	(9.1 )
(Loss) gain on investment activities	(2.7 )	3.4	(14.1 )
(Loss) earnings before income taxes	(9.2 )	291.2	(1,049.8 )
(Benefit) provision for income taxes	(5.4 )	108.0	48.2
<b>Net (loss) earnings</b>	<b>\$ (3.8 )</b>	<b>\$ 183.2</b>	<b>\$ (1,098.0 )</b>
<b>Basic (loss) earnings per share</b>	<b>\$ (0.02 )</b>	<b>\$ 0.73</b>	<b>\$ (4.40 )</b>
Shares used in calculation of basic (loss) earnings per share	248.6	250.1	249.6
<b>Diluted (loss) earnings per share</b>	<b>\$ (0.02 )</b>	<b>\$ 0.72</b>	<b>\$ (4.40 )</b>
Shares used in calculation of diluted (loss) earnings per share	248.6	257.2	249.6

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

**MedImmune, Inc.**  
**Consolidated Statements of Cash Flows**  
(in millions)

	<b>For the year ended December 31,</b>		
	<b>2004</b>	<b>2003</b>	<b>2002</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>			
Net (loss) earnings	\$ (3.8 )	\$ 183.2	\$ (1,098.0 )
Adjustments to reconcile net (loss) earnings to net cash provided by operating activities:			
Impairment of intangible asset	73.0		
Write-down of acquired in-process research and development	29.2		1,179.3
Deferred taxes	9.5	87.0	50.8
Deferred revenue	(0.4 )	(6.0 )	(7.1 )
Depreciation and amortization	41.1	37.7	36.8
Advances from Wyeth	(51.9 )	51.9	
Amortization of premium (discount) on marketable securities	14.2	14.8	9.8
Amortization of deferred compensation	1.1	4.0	19.2
Realized (gain) loss on investments	2.7	(3.4 )	14.1
Impairment of long-lived assets			14.1
Increase in sales allowances	13.5	10.9	17.4
Losses on write-downs of inventory	70.9	59.0	48.6
Other	1.4	(0.1 )	(6.1 )
Increase (decrease) in cash due to changes in assets and liabilities:			
Trade receivables	(45.6 )	(36.7 )	3.9
Inventory	(43.1 )	(86.6 )	(47.9 )
Other assets	(2.9 )	(14.7 )	(2.2 )
Accounts payable and accrued expenses	33.3	45.3	4.6
Product royalties payable	4.1	7.8	26.3
Other liabilities	(1.6 )	3.4	(0.1 )
Net cash provided by operating activities	144.7	357.5	263.5
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>			
Investments in securities available for sale	(652.9 )	(659.9 )	(1,008.9 )
Maturities of securities available for sale	182.9	345.6	467.2
Proceeds from sales of securities available for sale	308.0	219.3	137.4
Net cash acquired in acquisition of Aviron			146.9
Capital expenditures	(79.8 )	(112.9 )	(80.9 )
Purchase of assets from Wyeth	(34.8 )		
Investments in strategic alliances	(24.3 )	(30.4 )	(8.7 )
Net cash used in investing activities	(300.9 )	(238.3 )	(347.0 )
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>			
Proceeds from issuance of common stock	19.5	44.4	46.7
Share repurchases	(30.0 )	(229.8 )	
Proceeds of 1% Notes, net of issuance costs		489.4	
Debt prepayments	(172.7 )	(33.1 )	
Repayments on long-term obligations	(4.7 )	(4.7 )	(4.7 )
Net cash (used in) provided by financing activities	(187.9 )	266.2	42.0
Effect of exchange rate changes on cash	(0.1 )		0.3
Net increase (decrease) in cash and cash equivalents	(344.2 )	385.4	(41.2 )
Cash and cash equivalents at beginning of year	515.5	130.1	171.3
Cash and cash equivalents at end of year	\$ 171.3	\$ 515.5	\$ 130.1
Supplemental cash flow data:			
Cash paid during the year for interest, net of amounts capitalized	\$ 9.7	\$ 8.4	\$ 11.0
Cash paid (received) during the year for income tax payments (refunds)	\$ 3.1	\$ 32.7	\$ (2.3 )

The accompanying notes are an integral part of these financial statements

**Supplemental schedule of noncash investing and financing activities:**

During January 2002, the Company acquired 100% of the outstanding capital stock of Aviron through an exchange offer and merger transaction. The Company exchanged approximately 34.0 million of its common shares for all of the outstanding shares of Aviron common stock and assumed Aviron's outstanding options and warrants, for which approximately 7.0 million additional shares of the Company's common stock were issuable. The estimated fair value of the net assets acquired was \$1,635.1 million, and included \$1,179.3 million of acquired research and development assets that were charged to current period results at the date of acquisition and \$211.4 million of 5¼% notes due in 2008.

The accompanying notes are an integral part of these financial statements

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**MedImmune, Inc.**  
**Consolidated Statements of Shareholders Equity**  
(in millions)

	Common Stock, \$01 par		Paid-in Capital	Deferred Compensation	Accumulated Earnings (Deficit)	Accumulated Other Comprehensive Income (Loss)	Treasury Stock Shares	Treasury Stock Amount	Total
<b>Balance, December 31, 2001</b>	214.5	\$ 2.2	\$ 891.6		\$ 141.9	\$ 8.6			\$ 1,044.3
Net loss					(1,098.0 )				(1,098.0 )
Change in foreign currency translation adjustment.						0.8			0.8
Change in unrealized gain on investments, net of tax						15.1			15.1
Unrealized gain on hedged inventory purchases, net of tax						0.1			0.1
Comprehensive loss									(1,082.0 )
Common stock options exercised	2.7		42.7						42.7
Issuance of common stock under the employee stock purchase plan	0.2		4.0						4.0
Tax benefit associated with the exercise of stock options.			14.7						14.7
Shares issued related to the acquisition of Aviron	33.9	0.3	1,664.4	(39.4 )					1,625.3
Amortization of deferred compensation for the vesting of stock				19.2					19.2
Reversal of deferred compensation for cancellation of stock			(4.4 )	4.4					
Decrease in restructuring liability for amortization of deferred compensation for the vesting of stock options				9.0					9.0
<b>Balance, December 31, 2002</b>	251.3	2.5	2,613.0	(6.8 )	(956.1 )	24.6			1,677.2
Net earnings					183.2				183.2
Change in foreign currency translation adjustment						1.6			1.6
Change in unrealized gain/loss on investments, net of tax						3.7			3.7
Change in unrealized gain/loss on cash flow hedges, net of tax						(2.2 )			(2.2 )
Comprehensive income									186.3
Common stock options exercised	2.8		39.9						39.9
Issuance of common stock under the employee stock purchase plan	0.2		4.8						4.8
Repurchases of common stock							(6.2 )	(229.8 )	(229.8 )
Tax benefit associated with the exercise of stock options.			16.1						16.1
Amortization of deferred compensation for the vesting of stock options				4.7					4.7
Reversal of deferred compensation for cancellation of stock options			(0.7 )	0.7					

**MedImmune, Inc.**  
**Consolidated Statements of Shareholders Equity (Continued)**  
(in millions)

	Common Stock,		Paid-in Capital	Deferred Compensation	Accumulated Earnings (Deficit)	Accumulated Other Comprehensive Income (Loss)	Treasury Stock		Total
	Shares	Amount					Shares	Amount	
<b>Balance, December 31, 2003</b>	254.3	2.5	2,673.1	(1.4 )	(772.9 )	27.7	(6.2 )	(229.8 )	1,699.2
Net loss					(3.8 )				(3.8 )
Change in foreign currency translation adjustment						0.5			0.5
Change in unrealized gain/loss on investments, net of tax						(19.2 )			(19.2 )
Change in unrealized gain/loss on cash flow hedges, net of tax						2.1			2.1
Comprehensive loss									(20.4 )
Common stock options and warrants exercised	0.9	0.1	7.3		(11.8 )		0.5	19.3	14.9
Issuance of common stock under the employee stock purchase plan	0.2		4.6						4.6
Repurchases of common stock							(1.2 )	(30.0 )	(30.0 )
Tax benefit associated with the exercise of stock options			5.2						5.2
Amortization of deferred compensation for the vesting of stock options				1.1					1.1
Reversal of deferred compensation for cancellation of stock options			(0.2 )	0.2					