MEDIMMUNE INC /DE
Form 10-K
March 09, 2004

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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, 2003
Commission File Number: 000-19131

MEDIMMUNE, INC.

(Exact name of registrant as specified in its charter)

Delaware	**52-1555759**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

35 West Watkins Mill Road
Gaithersburg, Maryland 20878
(Address of principal executive office)
(Zip Code)

Registrant's telephone number, including area code: **(301) 417-0770**

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 ý No o

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 ý.

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

Aggregate market value of the 250,941,192 shares of voting and non-voting common equity held by non-affiliates of the registrant, based on the closing price on June 30, 2003, was $9.1 billion. Common Stock outstanding as of February 29, 2004: 248,227,030 shares.

Documents Incorporated by Reference:

Portions of the registrant's definitive proxy statement for the annual meeting of stockholders to be held May 20, 2004 (Part III).

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

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, which MedImmune cannot 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 "Risk Factors" and elsewhere in this report. MedImmune cautions that RSV disease and influenza 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, 2003. This annual report will not be updated as a result of new information or future events.

PART I

ITEM 1. BUSINESS

MedImmune, Inc. (together with its subsidiaries, "MedImmune" or the "Company") is a biotechnology company that uses advances in biological sciences to discover, develop, manufacture and commercialize products that treat or prevent infectious diseases, immune system disorders and cancer. The Company's core competencies are in the areas of monoclonal antibodies and vaccines.

Founded in 1988, MedImmune is headquartered in Gaithersburg, Maryland and has three primary operating subsidiaries: MedImmune Oncology, Inc., MedImmune Vaccines, Inc. and MedImmune Ventures, Inc. The Company promotes three main products: Synagis® (palivizumab) and FluMist (Influenza Virus Vaccine Live, Intranasal) to prevent two common respiratory infectious diseases; and Ethyol® (amifostine) to reduce undesired side effects of certain anti-cancer chemo- and radiotherapies.

MedImmune operates five facilities in the United States and Europe to manufacture one or more components of each of these products and promotes these products in the U.S. through its own sales and marketing organization. In addition, the Company has entered into agreements with other companies to manufacture certain components of these products, promote these products outside of the U.S. and support the Company's promotional efforts in the U.S.

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 and commercialization collaborations with other companies and organizations.

Products

Synagis

Synagis is a humanized monoclonal antibody 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, such as premature infants. 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 and children with chronic lung disease, also known as bronchopulmonary dysplasia ("BPD"), are at increased risk for acquiring severe RSV disease (pneumonia and bronchiolitis), often requiring hospitalization. In 2003, based on additional clinical trial data, the FDA approved expansion of the definition of high-risk patients to include children with certain heart diseases present at birth (hemodynamically significant congenital heart disease ("CHD")).

Synagis is most commonly administered by intramuscular injection once per month during anticipated periods of RSV prevalence in the community. In the northern hemisphere, the RSV season typically commences in October and lasts through April or May. As such, the sales of this product 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 by the Ross Products Division of Abbott Laboratories ("Abbott").

Outside the U.S., the International Division of Abbott ("AI") has the exclusive right to distribute Synagis. As of February 29, 2004, 49 countries outside the U.S. had approved Synagis for marketing. In July 2003, AI announced that the European Agency for the Evaluation of Medicinal Products had granted a positive opinion for the use of Synagis in young children born with CHD to prevent lower respiratory tract infection caused by RSV.

In 2003, 2002 and 2001, the Company reported $849 million, $672 million and $518 million, respectively in worldwide net revenues from Synagis representing 86%, 85% and 89% of the Company's total net revenues in 2003, 2002 and 2001, respectively.

Ethyol

Ethyol is used to prevent certain unwanted side effects of specific types of chemo- and radiotherapies that are used to treat cancer. In the U.S., Ethyol 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 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 showing that Ethyol protected against cisplatin-induced renal toxicity. The Company believed this trial would fulfill the Accelerated Approval requirement and submitted its data to the FDA for review in 2002. Early in 2003, the Company met with the FDA to discuss the their 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 is currently discussing an appropriate study design with the FDA. 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 Ethyol 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 Ethyol.

In 1999, the FDA also approved the use of Ethyol 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.

Since 2001, MedImmune has been the sole marketer of Ethyol in the U.S. Prior to this date, Ethyol was co-promoted by MedImmune and ALZA Corporation ("ALZA"). Outside the U.S., the Company has various distribution and marketing arrangements for Ethyol, primarily with affiliates of Schering-Plough Corporation ("Schering"). This product has been approved for marketing in 60 countries worldwide, including the United States.

In 2003, 2002 and 2001, MedImmune reported worldwide net revenues for Ethyol of $100 million, $81 million and $20 million, respectively, which represented nine percent, ten percent, and three percent of the Company's total net revenues 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 stimulate the immune system to 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. In September 2003, the Advisory Committee on Immunization Practices (ACIP) of the U.S. Centers for Disease Control and Prevention ("CDC") issued a Supplemental Recommendation for the use of live, attenuated influenza vaccine to its annual Recommendations for the Prevention and Control of Influenza.

FluMist is the subject of a collaborative arrangement with Wyeth. FluMist is manufactured by MedImmune, distributed in the U.S. exclusively by Wyeth and co-promoted in the U.S. by MedImmune and Wyeth. Outside of the U.S., Wyeth has exclusive rights to FluMist worldwide, excluding Australia, New Zealand, North Korea, South Korea, and some South Pacific countries.

MedImmune's FluMist-associated revenues are dependent on payments from Wyeth for: transfer of product to Wyeth; achievement of certain milestones; royalties on net sales; and reimbursement for certain expenses. Vaccination against the influenza virus in the northern hemisphere typically commences in October and may last through January. Once the Company has gained some historical experience with respect to the impact of returns and discounting, the timing of when the Company reports revenues attributable to FluMist is expected to reflect this seasonality.

In 2003, MedImmune reported $46 million in net revenues for FluMist, or about four percent of the company's total revenues. This amount was derived solely from milestone and reimbursement payments from Wyeth. The Company did not record any sales-related revenue in 2003 due to the uncertainty associated with returns and discounts in the vaccine's launch season.

Other Products

The Company also markets the following three additional products for which it reported a total of $43 million, $38 million, and $43 million in worldwide net product sales in 2003, 2002 and 2001, respectively. These amounts represent four percent of the Company's total reported net revenues in 2003 and 2002 and seven percent of the Company's total reported net revenues in 2001.

CytoGam® (cytomegalovirus immune globulin intravenous (human)) an intravenous immune globulin product enriched in antibodies against cytomegalovirus ("CMV"), a herpesvirus, marketed to prevent CMV disease associated with kidney, lung, liver, pancreas or heart 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 months of age with BPD or a history of premature birth (i.e., born at 35 weeks or less gestation). RespiGam was the Company's first anti-RSV product and has largely been replaced by Synagis in the marketplace. The manufacturer and license holder for RespiGam is no longer producing this product and has provided the FDA with notice of intent to withdraw the Biologics License Application for this product.

Product Candidates

A large portion of MedImmune's operating expenses are related to the research and development of its product candidates. Research and development expenses were $156 million in 2003, $148 million in 2002 and $83 million in 2001. MedImmune currently focuses its research and development efforts in the therapeutic areas of infectious diseases, immunology and oncology. The Company also continues to work on feasibility studies in a number of other areas. 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. 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:

Infectious Disease	Immunology	Oncology
CAIV-T (liquid)	Vitaxin®	Ethyol
Synagis (liquid)	Anti-IL-9 antibody	HPV
Numax	HMGB-1	Vitaxin
Epstein-Barr Virus vaccine		Siplizumab
S. pneumoniae vaccine		MT-103
hMPV antibody and vaccine		EphA2

Infectious Disease	Immunology	Oncology
PIV-3/RSV/hMPV combination vaccine		PCDGF EphA4

Infectious Disease

CAIV-T (cold adapted influenza virus vaccine trivalent, liquid) CAIV-T is being developed under collaborative agreements between Wyeth and MedImmune as a liquid, refrigerator-stable version of the trivalent, live, attenuated, cold-adapted influenza virus vaccine. Liquid CAIV-T may have the potential to replace the frozen formulation of MedImmune's influenza vaccine since frozen vaccines pose additional distribution and commercial challenges. Wyeth has been conducting late-stage clinical trials with CAIV-T and has begun collecting and evaluating that data.

Synagis (liquid) MedImmune is developing a liquid formulation of Synagis to improve the product's ease-of-use. Currently, Synagis is a lyophilized (freeze dried) product that requires a waiting period following reconstitution with water prior to use. In 2003, MedImmune completed clinical and biochemical comparability studies and began preparing to submit a supplement to its biologics license application for Synagis to the FDA for this liquid formulation.

Numax MedImmune has been developing a third generation anti-RSV antibody product, Numax that appears to be more potent in preclinical studies than Synagis. In 2003, MedImmune submitted an Investigational New Drug ("IND") application to the FDA and initiated a Phase 1 clinical program for Numax.

Epstein-Barr Virus Subunit Vaccine MedImmune has rights to a vaccine against certain subunits of Epstein-Barr virus ("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 under a collaboration with GlaxoSmithKline ("GSK"). Data from a 2002 GSK study in Europe showed that the formulations were both well tolerated and highly immunogenic. Although the study was not specifically designed to assess vaccine efficacy, none of the volunteers developed symptoms of infectious mononucleosis during the study period. A Phase 2 feasibility trial, initiated and fully enrolled in 2002 by GSK, continued in 2003.

***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 the very young and

elderly. During 2003, GSK continued its preclinical research efforts with vaccine candidates and initiated a Phase 1 clinical study.

Human Metapneumovirus Program The human metapneumovirus ("hMPV") is a newly identified respiratory virus with a high incidence of infection in young children under the age of five. Early epidemiological studies indicate that outbreaks of hMPV occur on a seasonal basis, with clinical symptoms that are largely similar to RSV, ranging from mild respiratory problems to severe cough, bronchiolitis, and pneumonia, with the very youngest children often requiring hospitalization and mechanical ventilation. In 2003, MedImmune continued its epidemiological study of hMPV and conducted preclinical tests assessing the potential to develop antibodies and/or vaccines to prevent or treat infection by this new virus.

Parainfluenza Virus Type 3/RSV/hMPV Combination Vaccine Substantial preclinical research has been conducted toward the goal of combining previously independent vaccine programs against parainfluenza virus type 3 ("PIV-3") and RSV. 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 and RSV or PIV-3 and hMPV were conducted during 2003.

Immunology

Vitaxin Vitaxin is a monoclonal antibody in development for both immunological disorders and certain types of cancer. Vitaxin targets alpha-v beta-3, an integrin, which is a particular receptor protein, expressed on a number of cell types, including those found in newly forming blood vessels, certain white blood cells and bone cells, and on the surface of certain types of solid tumors. In 2003, the Company completed its initial Phase 1 development with Vitaxin and initiated two Phase 2 trials in autoimmune diseases (rheumatoid arthritis and psoriasis) to assess the antibody's ability to be used safely and effectively in treating patients with either of these diseases.

Anti-IL-9 Antibody 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. During 2003, MedImmune selected its lead candidate molecule and submitted an IND to the FDA.

High Mobility Group Box Chromosomal Protein 1 (HMGB-1) 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. The companies plan to focus on developing drug products with the potential to block HMGB-1 that, if successful, could help reduce the injury and death associated with severe inflammatory diseases and infections.

Oncology

Ethyol During 2003, MedImmune began enrollment in two new 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 new trial is a Phase 1/2 clinical study evaluating Ethyol's effectiveness 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.

Human Papillomavirus Vaccine MedImmune and GSK are developing a vaccine against human papillomavirus ("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. MedImmune and GSK's vaccine candidate uses virus-like particle technology to produce a structurally identical, non-infectious form of the virus. In April 2003, preliminary data from a Phase 2 HPV vaccine clinical trial was presented by GSK at the European Research Organization on Genital Infection and Neoplasia EUROGIN Meeting in Paris. Final data were presented on the HPV vaccine by GSK in February 2004 at The International Papillomavirus Conference. We expect GSK to publish additional data on this vaccine in the near future.

Vitaxin As described above, the Company has been developing Vitaxin for use in both cancer and immunological disorders. 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). MedImmune initiated two Phase 2 trials during 2003 in patients diagnosed with melanoma and prostate cancer.

Siplizumab Siplizumab is a humanized monoclonal antibody 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 increase survival. In 2003, MedImmune filed an IND for siplizumab with the intention of initiating a Phase 1 trial to examine the clinical safety of siplizumab in individuals with CD2-positive lymphoproliferative disorders and to determine the maximum tolerated dose of the antibody in these patients.

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 that express the CD19 surface molecule. With its second binding arm, MT-103 recruits and activates T-cells to kill the cancerous B-cells. MedImmune is also evaluating the broader application of Micromet's BiTE technology to other targets of interest.

EphA2 EphA2 is normally expressed at very low levels on normal epithelial cells, but many different cancers significantly 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 antibodies targeting EphA2 in animal models may selectively inhibit the growth and survival of malignant cells, but do not alter the function or survival of corresponding normal cells. In 2003, MedImmune continued its preclinical testing of EphA2 antibodies.

PCDGF PC-cell-derived growth factor ("PCDGF") is over expressed by many different types of cancer, for example breast cancers that have become refractory to conventional hormone therapies. Preclinical studies indicate that inhibition of PCDGF expression decreases the growth and survival of aggressive, hormone-refractory breast cancer cells. Additionally, studies by MedImmune investigators and others have linked high levels of PCDGF with ovarian and prostate carcinomas as well as multiple myeloma. In 2003, the Company continued its preclinical investigation potentially therapeutic antibodies.

EphA4 In 2003, MedImmune 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.

Collaborations, Alliances and Investments

To build, advance and promote its product portfolio, MedImmune 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 a number of 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 to which the Company will owe future royalties if the product candidates are licensed and commercialized. These entities and outside parties are described in the preceding "Product Candidates" section.

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., that makes minority 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 did previously with Genaera Corporation and A&G Pharmaceuticals, Inc. and in 2003 with Micromet AG and Critical Therapeutics, Inc. In 2003, the Company also invested in: Tercica, Inc., a biopharmaceutical company focused on the development and commercialization of therapies to treat disorders of the endocrine system, including human growth and diabetes; Applied Genetic Technologies Corporation, a drug research company developing novel human therapeutics, principally a gene therapy treatment for Alpha-One Antitrypsin Deficiency (A_1AD), a form of emphysema; and VaxInnate Corporation, an early stage company engaged in the development of immunostimulating agents, including vaccines and immunosuppressive agents. In connection with such investments, the Company will sometimes be entitled to appoint a member of the board of directors of these portfolio companies, and in such cases, a Company employee is generally appointed to serve in that role.

Marketing and Sales

The Company has developed a sales and marketing organization that it believes is responsive to the increased importance of managed care and the needs of the healthcare industry to provide higher quality care at lower costs. 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, respectively. Approximately 110 biologic sales specialists cover approximately 10,000 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 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 320 people devoted to sales and marketing of its products in the United States.

The Company has also entered into co-promotion agreements for its products. For the promotion of Synagis in the U.S., the Company has a co-promotion agreement with the Ross Products division of Abbott. Through its 500 sales representatives, the Ross Products division 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 involved in the distribution of Synagis to attempt to ensure high-quality and consistent services for patients. 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. The Company also reduced the number of wholesalers involved with Synagis to properly manage the SDN.

For FluMist, the Company has a co-promotion agreement with Wyeth to market the vaccine in the United States. Through approximately 450 sales representatives, sales managers, and managed care specialists, the Wyeth sales team details FluMist to office-based pediatricians and primary care physicians, while MedImmune's representatives detail the product to pediatric infectious disease/respiratory thought leaders, pharmacies and employers. FluMist is distributed directly to physician's offices, pharmacies, and vaccination clinics by Wyeth.

As discussed in Note 4, "Segment, Significant Customer and Geographic Information," of the Company's Consolidated Financial Statements, the Company has four major customers who individually provided over 10% of its total revenue during the last three years. 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 five commercial manufacturing 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 attempts to remain apprised of 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. Raw materials may be subject to contamination and/or recall. A material shortage, contamination, and/or recall could adversely impact or disrupt MedImmune's commercial manufacturing of its products.

Synagis The primary manufacturing facility for supply of Synagis in the U.S. is the Company's Frederick Manufacturing Center ("FMC"). The FMC is a biologics facility containing a cell culture production area for the manufacture of recombinant products. Filling and packaging of final Synagis product is completed by two vendors: Sicor, Inc. and Boehringer Ingleheim Pharma KG ("BI").

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. To provide adequate backup for international supply of Synagis, MedImmune will seek to obtain approval from the appropriate international regulatory agencies to sell Synagis made at FMC outside the U.S. The Company plans to continue to rely upon BI for production of additional quantities of Synagis to meet expected worldwide demand for the product and to reduce its reliance for supply of Synagis outside the U.S. to any one manufacturing site.

Ethyol All bulk drug substance for Ethyol is produced by contract manufacturers. In 2003, 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 to fill and finish Ethyol for sale in the U.S.

CytoGam CytoGam is produced from human plasma collected from donors who have been screened to have high concentrations of antibodies against cytomegalovirus or respiratory syncytial virus, respectively. The collected human plasma is converted into an intermediate raw material known as Fraction II+III paste. This step was completed at MedImmune's FMC for CytoGam from 2000 until 2002, when the Company made the decision to outsource the process to Precision Pharma Services, Inc. The intermediate paste is processed into bulk product, filled and packaged by the Massachusetts Biologic Laboratories. The Company is exploring opportunities to use its plasma production suite, formerly involved in the manufacture of CytoGam, in a manner that would support the production of its other marketed and developmental-stage recombinant products.

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 facilities leased from Evans Vaccines, a wholly owned subsidiary of Chiron Corporation 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 facility. The Company has begun the initial stages of commercial manufacturing of FluMist for the 2004-2005 influenza season.

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 is extensive patent filings. The Company relies on patent protection against use of its proprietary products and technologies by competitors. The patent position of biotechnology firms generally is highly uncertain and involves 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 over 100 patents worldwide related to its products or product candidates. The Company also owns or in-licenses at least 100 additional applications for patents currently pending in the U.S. 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.

The Company believes that there are other patents issued to third parties and/or patent applications filed by third parties that could relate to each of the Company's products and product candidates and could adversely affect the Company's freedom to make, have made, use, have used, sell, or have sold such products or use certain processes for their manufacture. Some of these third parties have contacted the Company claiming patent infringement by the Company. The Company is unable to predict whether it will ultimately be necessary to seek licenses from such third parties or, if such

licenses were necessary, whether such licenses would be available on terms acceptable to the Company. The necessity for such licenses could have a material adverse effect on the Company's business.

There has been substantial litigation regarding patent and other intellectual property rights in the biotechnology industry. Litigation may be necessary to enforce certain intellectual property rights of the Company, or to defend against asserted intellectual property rights of third parties. Any such litigation could result in substantial cost to and diversion of effort by the Company. As described in Note 17 to the Consolidated Financial Statements, the Company has chosen to file litigation to challenge certain intellectual property rights of third parties.

Government Regulation

The production and marketing of the Company's products and research and development activities are subject to regulation for safety and efficacy by numerous governmental authorities in the U.S. and other countries. In the U.S., vaccines, biologics, drugs and certain diagnostic products are subject to FDA licensure. The federal Food, Drug and Cosmetics Act, the Public Health Service Act and other federal statutes and regulations govern or influence the testing, manufacture, safety, labeling, storage, record keeping, licensure, advertising and promotion of such products. No assurances can be given that any products under development will be licensed for marketing by the FDA or, if approved, that the product would be successfully commercialized or maintained in the marketplace. Noncompliance with applicable requirements could result in fines, recall or seizure of products, total or partial suspension of production, refusal of the government to approve product license applications, restrictions on the Company's ability to enter into supply contracts and criminal prosecution. The FDA also has the authority to revoke product licenses and establishment licenses previously granted.

Orphan Drug Designation

The Orphan Drug Act was established to encourage development of drugs for rare diseases and conditions affecting a small patient population (generally fewer than 200,000 people). Orphan drug designation of a product can potentially provide a company with seven years of market exclusivity if the company is the first to receive FDA product marketing approval for the orphan drug in the designated indication. Additionally, this designation provides a company with tax credits of 50 percent for qualified clinical research expenses and the opportunity for clinical research grants. CytoGam and Ethyol currently qualify as orphan drugs for the following indications: (1) CytoGam has market exclusivity for use in lung, liver, pancreas and heart transplants until December 2005; and (2) Ethyol has market exclusivity for its currently licensed radioprotective indication through June 2006. Ethyol, NeuTrexin and siplizumab have all been designated as orphan drugs for potential use in indications that have not yet been approved by the FDA as follows:

(1) Ethyol as a chemoprotective agent for use with cyclophosphamide in the treatment of advanced ovarian carcinoma, as a chemoprotective agent for use with cisplatin in the treatment of metastatic melanoma, for the treatment of myelodysplastic syndromes, and for the reduction of the incidence and severity of cisplatin-induced toxicities;

(2) NeuTrexin for the treatment of metastatic colorectal adenocarcinoma, metastatic carcinoma of the head and neck, pharynx and larynx, pancreatic adenocarcinoma and advanced non-small cell carcinoma of the lung and osteogenic sarcoma; and

(3) Siplizumab for the treatment of graft versus host disease and T-cell lymphoma.

If approved for any of the designated orphan indications, each of these products would have market exclusivity for seven years from the date of FDA approval if it is the first product approved by the FDA for treatment of the designated orphan indication. Orphan drug designations for the use of

Ethyol to prevent side effects of cisplatin in ovarian cancer patients, and the use of RespiGam to prevent RSV disease in high-risk infants expired in 2002 and 2003, respectively.

Environmental and Safety Regulations

The Company is also subject to regulation by the Occupational Safety and Health Administration ("OSHA") and the Environmental Protection Agency ("EPA") and to regulation under the Toxic Substances Control Act, the Resources Conservation and Recovery Act and other regulatory statutes, and may in the future be subject to other federal, state or local regulations. OSHA and/or the EPA may promulgate regulations concerning biotechnology that may affect the Company's research and development programs. At any time, any agency may adopt regulations that would have a material adverse effect on the Company's operations and the Company is unable to predict when or whether this might happen. The Company voluntarily attempts to comply with guidelines of the National Institutes of Health regarding research involving recombinant DNA molecules. Such guidelines, among other things, restrict or prohibit certain recombinant DNA experiments and establish levels of biological and physical containment that must be met for various types of research.

Foreign Regulation

Sales of pharmaceutical and biopharmaceutical products outside the U.S. are subject to foreign regulatory requirements that vary from country to country. Whether or not FDA licensure has been obtained, licensure of a product by comparable regulatory authorities of other countries must be obtained before marketing the product in those countries. The time required to obtain such licensure may be longer or shorter than that required for FDA approval, and no assurance can be given that such approval will be obtained.

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 is aware of certain potentially competitive products targeting areas of medical interest to the Company, including influenza, RSV, psoriasis, HPV infections, influenza infections, and organ graft rejection. In the prevention of CMV disease, CytoGam competes with several products including other antiviral drugs, such as intravenous and oral ganciclovir and standard immune globulin preparations. The Company is aware that a number of physicians have prescribed CytoGam in combination with ganciclovir for the prevention of CMV disease in certain patients.

The Company believes that Synagis and RespiGam are the only products currently available for the prevention of RSV disease. However, the Company is aware of one product in the U.S., ribavirin, which is indicated for the treatment of RSV disease. 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 flu vaccines, in the past, the Company has been aware of three main distributors of inactivated, injectable vaccines. From these three distributors, approximately 80 million doses of these inactivated vaccines have traditionally been sold annually in the U.S. In 2002, Wyeth announced its

intent to no longer produce the inactivated, injectable vaccine after the completion of the 2002-2003 influenza season. 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 is in the early stages of clinical testing. 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, and are seeking to develop new products and technologies for these 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 Aventis SA holds the largest share of the chemotherapy market both in terms of approved products and annual sales, and therefore dominates the marketplace. 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 substantially 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 which 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.

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.

Officers and Key Employees of the Company

Name	Age	Position	Officer/Key Employee Since
Wayne T. Hockmeyer, Ph.D.	59	Chairman of the Board; President, MedImmune Ventures, Inc.	1988
David M. Mott	38	Chief Executive Officer, President and Vice Chairman of the Board	1992
James F. Young, Ph.D.	51	President, Research and Development	1989
Armando Anido, R.Ph.	46	Senior Vice President, Commercial Operations	1999
Edward J. Arcuri, Ph.D.	53	Senior Vice President, Manufacturing Operations	2002
Edward M. Connor, M.D.	51	Senior Vice President, Chief Medical Officer	1999
Gail Folena-Wasserman, Ph.D.	49	Senior Vice President, Development	2002
Bernardus N. Machielse, Drs.	43	Senior Vice President, Quality	2003
Lota S. Zoth, C.P.A.	44	Vice President and Controller, Acting Chief Financial Officer	2004

Wayne T. Hockmeyer, Ph.D. Dr. Hockmeyer 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., Diversa Corporation, GenVec, Inc., InterMune Pharmaceuticals, Inc., Idenix Pharmaceuticals, Inc., Tercica, Inc., and TolerRx Inc. Dr. Hockmeyer does not intend to seek re-election to the Board of Directors of InterMune Pharmaceuticals, Inc. or Diversa Corporation when his current term on those boards expires in May 2004.

David M. Mott Mr. Mott was appointed Chief Executive Officer 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 Iomai Corporation.

Armando Anido, R.Ph. Mr. Anido was appointed Senior Vice President, Commercial Operations in February 2004. He joined the Company in 1999 as Senior Vice President, Sales and Marketing. 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.

Edward J. Arcuri, Ph.D. Dr. Arcuri was promoted to the position Senior Vice President, Manufacturing Operations in September 2003. Previously, Dr. Arcuri served as Senior Vice President, Manufacturing, MedImmune Vaccines, since joining MedImmune as a part of the Company's acquisition of Aviron in January 2002. Dr. Arcuri was Senior Vice President, Operations, of Aviron since May 2000. He joined Aviron as Vice President, Manufacturing, in July 1999. Prior to joining Aviron, Dr. Arcuri served as Vice President, Manufacturing Operations and Process Development for North American Vaccine, Inc., or NAVA, from January 1995 to July 1999. Prior to joining NAVA, Dr. Arcuri served as Senior Director, Biological Manufacturing, at Merck & Co., Inc. from 1991 to 1994. Dr. Arcuri holds a B.S. degree in Biology from the State University of New York at Albany and a master's degree and Ph.D. in Biology from Rensselaer Polytechnic Institute.

Edward M. Connor, M.D. Dr. Connor was appointed Senior Vice President, Chief Medical Officer in February 2004. He joined the Company in 1994 as the Director of Clinical Studies and was promoted in 1995 to Vice President of Clinical Development and in 1999 to Senior Vice President, Clinical Development. 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.

Gail Folena-Wasserman, Ph.D. Dr. Folena-Wasserman was promoted to Senior Vice President, Development in February 2002. She joined the Company in 1991 as Director, Development and was promoted to Vice President, Development in October 1995. Prior to joining the Company, she spent nine years in natural products isolation and biopharmaceutical process development at SmithKline Beecham Pharmaceuticals. Dr. Folena-Wasserman holds a bachelor's degree in biology and chemistry from Montclair State College in New Jersey, and has a master's degree in biochemistry and a doctorate in chemistry from Pennsylvania State University.

Bernardus N. Machielse, Drs. Drs. Machielse was appointed Senior Vice President, Quality, in September 2003. Drs. Machielse joined MedImmune in May 1999 as Vice President, Quality. 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.

Lota S. Zoth, C.P.A. Ms. Zoth became Acting Chief Financial Officer of MedImmune in January 2004. She joined the Company in August 2002 as Vice President and Controller. 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 B.B.A. in accounting from Texas Tech University.

Employees

The Company considers relations with its employees to be good. As of December 31, 2003, the Company had approximately 1,650 full-time permanent employees.

Approximately 100 of the Company's employees in The United Kingdom are members of a labor union, with which the Company renegotiates employment terms periodically. 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

In addition to the other information included in this report, you should consider the following risk factors. This report contains forward-looking statements covered by the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements involve risks and uncertainties that may affect the Company's business and prospects. MedImmune's results may differ significantly from the results discussed in the forward-looking statements as a result of certain factors that are listed below or discussed elsewhere in this report and the Company's other filings with the Securities and Exchange Commission.

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

Sales of Synagis accounted for approximately 86% of the Company's total product sales in 2003 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 an 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, 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.

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

Sales of three of the Company's products, Synagis, FluMist, and RespiGam, are seasonal in nature. Synagis and RespiGam 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 would limit 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. The Company's FluMist product sales revenues are dependent to a large extent on the price at which doses are sold (which is set by Wyeth) and the number of returned doses (which is governed by Wyeth's return goods policy). Since these values are not within the Company's control, 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 its 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 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 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. 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, 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, 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 adverse event information about a product becomes available, 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 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.

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 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 sublicencees 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. For example, the master virus donor strain used to create FluMist is not protected by patents and is, instead, protected by trade secrets associated with the technology of creating cold-adapted, temperature sensitive live influenza virus vaccines. There can be no assurance that a competitor will not create a competing influenza virus vaccine based upon similar technologies. 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 & Health Administration, the Centers for Medicare and Medicaid Services and the U.S. Department of Veteran's 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 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 2003, the daily closing price of MedImmune common stock on the Nasdaq stock market ranged from a high of $40.30 to a low of $23.30. 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 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 (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 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. The facilities occupy approximately 119,000 square feet (including the facilities on West Watkins Mill Road and at the Wind River facility) and are leased until 2006. As of February 29, 2004, the Company has substantially completed construction of the first phase of a new headquarters facility, a complex totaling 220,000 square feet consisting of a research and development facility and administrative offices. The Company owns the land and facility, and expects to take occupancy in March 2004. At that time, the Company may sublease some portion of its current facilities. The Company has also purchased 11.9 additional acres of land at the headquarters site for its anticipated future expansion of the headquarters facility.

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 for manufacture of 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 an 18,000 square foot manufacturing facility on 36,000 square feet of land and leases approximately 9,000 square feet of warehouse space through December 2005.

MedImmune Vaccines operates a number of facilities, including: 102,000 square feet of office and laboratory space in Mountain View, California, which is leased through October 2005 with two options to extend for successive five-year periods; approximately 55,000 square feet of space in Philadelphia, Pennsylvania, pursuant to a lease agreement through December 2004, with options to extend for up to two terms of three years each; 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 and approximately 22,500 square feet of office space, expiring in October 2004; approximately 8,900 square feet of a manufacturing facility in Speke, the United Kingdom, pursuant to a sublease expiring in June 2006. In Speke, MedImmune Vaccines also leases approximately eight acres of land near its existing site, which includes a 60,700 square foot structure, through 2025. In addition, MedImmune Vaccines leases approximately 5,100 square feet of office space in Speke under short-term leases.

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 near term.

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, INC.'S COMMON STOCK AND RELATED SHAREHOLDER MATTERS

The Company's common stock trades on The Nasdaq National Market under the symbol "MEDI." At February 29, 2004, the Company had 1,975 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.

	2003		2002	
	High	Low	High	Low
First Quarter	$ 34.60	$ 26.80	$ 48.35	$ 37.30
Second Quarter	42.09	31.52	41.05	24.80
Third Quarter	40.88	31.69	30.43	20.37
Fourth Quarter	35.00			