

CHIRON CORP
Form 10-K
March 16, 2006

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark one)

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

For the fiscal year ended December 31, 2005

OR

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

For the transition period from _____ to _____

Commission File Number: 0-12798

CHIRON CORPORATION

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)
4560 Horton Street, Emeryville, California
(Address of Principal Executive Offices)

94-2754624
(I.R.S. Employer
Identification No.)
94608
(Zip Code)

Registrant's Telephone Number, Including Area Code: **(510) 655-8730**

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

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

Common Stock, \$0.01 Par Value

Warrant to Purchase Common Stock, \$0.01 Par Value

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes: No:

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes: No:

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

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

The aggregate market value of the voting and non-voting stock held by non-affiliates of the registrant, based upon the closing price of Common Stock on June 30, 2005 as reported on the NASDAQ National Market, was approximately \$2.9 billion. Shares of Common Stock held by each executive officer and director and by each shareholder whose beneficial ownership exceeds 5% of the outstanding Common Stock at June 30, 2005 have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The aggregate market value of voting and non-voting stock held by non-affiliates of the registrant as of January 31, 2006 was \$3.4 billion. The number of shares outstanding of each of the registrant's classes of common stock as of January 31, 2006:

| Title of Class | Number of shares |
|--------------------------------|------------------|
| Common Stock, \$0.01 par value | 197,154,517 |

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement to be filed in connection with the solicitation of proxies for the Annual Meeting of Stockholders to be held on June 22, 2006 are incorporated by reference into Part III of this Report.

PART I

ITEM 1. BUSINESS

Our Policy on Forward-Looking Statements

This 10-K contains forward-looking statements regarding our expectations, hopes or intentions regarding the future, including statements relating to sales growth, product development initiatives, regulatory approval, new product marketing, acquisitions, litigation, competition, and licensing activities that involve risks and uncertainties and are subject to change. The forward-looking statements contained in this 10-K reflect our current expectations on the date of this 10-K. Actual results, performance or outcomes may differ materially from current expectations. Our actual performance may differ from current expectations due to many factors, including additional adverse developments resulting from the suspension from October 5, 2004 through March 2, 2005 of Chiron's UK license to manufacture FLUVIRIN® influenza virus vaccine, the announcement of such suspension and the litigation and investigations relating to these matters, the outcome of clinical trials, regulatory review and approvals, remediation activities, manufacturing capabilities, intellectual property protections and defenses, stock price volatility and marketing effectiveness. In particular there can be no assurance that we will increase sales of existing products, successfully develop and receive approval to market new products, or achieve market acceptance for such new products. No assurances can be given that the transaction contemplated by the merger agreement with Novartis AG will be consummated. In addition, we may engage in business opportunities, the successful completion of which is subject to certain risks, including approval by Novartis, other stockholders, regulatory approvals and the integration of operations. We have discussed the important factors that we believe could cause actual results to differ from what is expressed in the forward-looking statements, in Part II, Item 7, of this 10-K, Management's Discussion and Analysis of Financial Condition and Results of Operations, under the caption Factors That May Affect Future Results. We do not undertake an obligation to update the forward-looking information contained in this 10-K.

Overview

We are a global biopharmaceutical company that participates in three healthcare markets: blood testing, vaccines, and biopharmaceuticals. Our revenues, which totaled \$1.9 billion in 2005, consist of product sales, revenues from a joint business contractual arrangement, collaborative agreement revenues, royalty and license fee revenues and other revenues, primarily consisting of contract manufacturing and grant revenues. Our research and development efforts are focused on developing products for oncology and infectious and pulmonary disease.

Blood Testing

Our Blood Testing segment is dedicated to improving blood safety through the development and sale of novel blood-screening assays and equipment that protect the world's blood supply. Our Blood Testing segment, which reported total revenues of \$555.7 million in 2005, is a world leader in nucleic acid testing, or NAT, blood screening with a leading position in the U.S. and a strong presence in Europe and Asia. The segment also generates revenues from a joint business contractual arrangement, a collaboration agreement, royalties and license fees.

Our Blood Testing segment consists of two separate collaborations: an alliance with Gen-Probe Incorporated (Gen-Probe) for NAT products, and a joint business contractual arrangement with Ortho-Clinical Diagnostics, Inc. (Ortho-Clinical Diagnostics) for immunodiagnostic products. Our collaboration with Gen-Probe was formed in 1998 and focuses on developing and commercializing NAT products to screen donated blood, plasma, organs and tissue for viral infection. We sell the collaboration's assays and instruments to blood banks under the PROCLEIX® brand name. Our joint business contractual arrangement with Ortho-Clinical Diagnostics was formed in 1989 to develop and sell immunodiagnostic

tests to detect retroviruses and hepatitis viruses in blood. Ortho-Clinical Diagnostics manufactures and sells the assays and instrument systems. Chiron shares equally in the profit of the contractual arrangement. Our Blood Testing segment also earns royalties and license fees from third parties based on their sales of immunodiagnostic and nucleic acid testing probe diagnostic products utilizing our hepatitis C virus and HIV-related patents, for use in blood screening and plasma fractionation markets.

Research and development is focused on programs to improve blood safety, including the development of an enzyme conversion system that converts groups A, B and AB red blood cells to enzyme-converted universal blood group O, and the development of a blood-screening assay for variant Creutzfeldt-Jakob disease (vCJD).

Vaccines

Our vaccines segment is the fifth largest vaccines business in the world with total revenues of \$602.1 million in 2005. We offer approximately 20 pediatric and adult vaccines including influenza, meningococcal, travel and pediatric vaccines. These vaccines have protected millions of people globally from potentially fatal diseases such as influenza, polio, rabies and meningococcal disease. We market our vaccines primarily in the United States, Germany, Italy and the United Kingdom.

Our heritage in vaccines is traced to the three European manufacturers we acquired over the past two decades, all of which were originally founded 100 or more years ago: Italy-based Sclavo was acquired in 1992, Germany-based Behring was acquired in 1998 and United Kingdom-based PowderJect Pharmaceutical plc, or PowderJect, was acquired in July 2003. We acquired FLUVIRIN® influenza virus vaccine as part of our acquisition of PowderJect.

Our vaccines segment research and development is focused on developing next generation influenza manufacturing capability, including our cell culture derived influenza vaccine, developing new vaccines for pandemic preparedness, and broadening our meningococcal franchise.

Biopharmaceuticals

Our biopharmaceuticals segment researches, develops, manufactures and markets a range of therapeutic products for cancer and infectious and pulmonary disease. The biopharmaceutical segment, which includes both product sales and royalties, reported total revenues of \$629.0 million for the year 2005. Our marketed products include TOBI® tobramycin solution for inhalation, USP for pseudomonal lung infections in cystic fibrosis patients; PROLEUKIN® (aldesleukin) for injection for metastatic melanoma and renal cell carcinoma; and BETASERON® (interferon beta-1b) for subcutaneous injection for multiple sclerosis. In January 2006, the European Commission granted marketing approval to Chiron for CUBICIN® (daptomycin), a first-in-class IV antibiotic, adding another commercial product to our portfolio. The marketing approval was granted in the 25 member states of the European Union, Iceland, Liechtenstein and Norway. Under the approval, CUBICIN® is indicated for the treatment of complicated skin and soft-tissue infections (cSSTI) caused by Gram-positive bacteria. Research and development efforts are focused in the areas of oncology and infectious and pulmonary disease including the development of tobramycin inhalation powder, or TIP, a new tobramycin product with an enhanced method of delivery and the clinical advancement of tifacogin for the treatment of severe community-acquired pneumonia. Our oncology pipeline includes CHIR-258, a growth factor kinase inhibitor, CHIR-12.12, an anti CD-40 monoclonal antibody and CHIR-265, a Raf kinase inhibitor.

Royalties and License Fee Revenue

We earn royalty and license fee revenue in all three segments by licensing some of our key intellectual property in areas such as hepatitis C and HIV. In addition, we generate royalties through agreements with development and marketing partners, including royalties from Schering AG's sales of BETA FERON®

(interferon beta-1b) for SC injection in Europe. Some royalties and license fees are not considered to be associated with any particular business segment and are recorded separately in the segment data as Other Royalty and License Fee Revenues. Financial information for the reportable segments is included in Note 18, Segment Information of Notes to Consolidated Financial Statements.

We were incorporated in California in 1981 and merged into a Delaware corporation in November 1986. Our principal executive offices are located at 4560 Horton Street, Emeryville, California 94608, and our main telephone number is (510) 655-8730.

Product Descriptions

Blood Testing

Our collaboration with Gen-Probe is focused on developing and commercializing NAT products using transcription-mediated amplification, or TMA, technology to screen donated blood, plasma, organs and tissue for viral infection. Compared to immunodiagnostic testing, where infection is determined by the presence of antibodies, testing directly for the presence of viral nucleic acids improves the sensitivity of testing and enables infection to be detected earlier than with previously approved technologies.

We sell assays and instrumentation under the PROCLEIX® brand name, and Gen-Probe receives a percentage of our sales revenues. Under the terms of the collaboration agreement, Gen-Probe performs certain product development and manufacturing functions, while Chiron and Gen-Probe jointly participate in new assay and instrument research and development.

Assays developed with Gen-Probe, and their status in the United States and the rest of world include:

| | U.S. | Ex-U.S. |
|--|-------------------------------------|----------|
| PROCLEIX® HIV-1/HCV Assay | Marketed | Marketed |
| PROCLEIX® WNV Assay (West Nile Virus) | Marketed | N/A |
| PROCLEIX® ULTRIO® Assay (HIV-1, HCV, and HBV) | Biologics License Application filed | Marketed |

The PROCLEIX® HIV-1/HCV Assay is a NAT product that was co-developed with Gen-Probe for the simultaneous detection of HIV-1 and hepatitis C virus (HCV) in plasma, whole blood, organs and tissue donations. The global need for HIV-1 and HCV testing continues to increase. Last year, approximately 5 million people acquired HIV, bringing the number of people in the world living with HIV to 39 million, the highest level ever. Annually, approximately 3 million people die from AIDS, the disease caused by HIV infection. HCV is a major cause of acute hepatitis and chronic liver disease, including cirrhosis and liver cancer. Globally, an estimated 170 million persons are chronically infected with HCV and 3 to 4 million persons are newly infected each year. The major causes of HCV infection worldwide are use of unscreened blood transfusions, and re-use of needles and syringes that have not been adequately sterilized. The PROCLEIX® HIV-1/HCV Assay received FDA approval in February 2002 and CE (Conformité Européenne) Mark in Europe in January 2003 for use on the semi-automated PROCLEIX® System. The PROCLEIX® HIV-1/HCV Assay and System are commercially available in the United States and throughout Europe, Asia, Australia and New Zealand and are under evaluation in Latin America and several Asian countries.

The PROCLEIX® ULTRIO® Assay is a premium NAT product offering that adds the direct detection of hepatitis B virus (HBV) to the approved PROCLEIX® HIV-1/HCV Assay, allowing for three results to be obtained in the same amount of time using the same instrumentation. Over 350 million people worldwide are chronic carriers of HBV, with over 2 billion infected. HBV is the leading cause of liver

cancer in the world and is at its highest prevalence in Southeast Asia, Southern Europe, India and Africa. The PROCLEIX® ULTRIO® Assay received CE Mark Registration in Europe on the semi-automated PROCLEIX® System in January 2004 and on the fully automated, high-throughput PROCLEIX® TIGRIS® System in December 2004. We filed a Biologics License Application (BLA) in September 2004 in the United States for use of the PROCLEIX® ULTRIO® Assay on the PROCLEIX® System and the PROCLEIX® TIGRIS® System. On October 3, 2005, the FDA notified Gen-Probe that it considers the PROCLEIX® TIGRIS® System not substantially equivalent to the PROCLEIX® System for screening donated blood with the PROCLEIX® ULTRIO® Assay. Gen-Probe expects to file an amended BLA to respond to the FDA's questions contained in this complete review letter.

The PROCLEIX® WNV (West Nile Virus) Assay, a NAT product co-developed with Gen-Probe for the detection of WNV in plasma, whole blood, organs and tissue has been available for sale in the United States, under an Investigational New Drug, or IND, protocol and labeled For Investigational Use Only since June 2003. In December 2005, we received marketing approval for the PROCLEIX® WNV Assay on the semi-automated PROCLEIX® System. Since testing began under the IND application through December 2005, the PROCLEIX® WNV Assay has detected more than 1,500 West Nile virus contaminated units of donated blood, potentially preventing over 4,500 transfusion transmissions of the virus. The current market for this product is North America (the United States & Canada), although European and Latin American medical authorities have expressed interest in conducting epidemiological studies.

In addition to assays, we also sell equipment under the Gen-Probe collaboration. Blood Testing equipment includes:

- PROCLEIX® System;
- PROCLEIX® TIGRIS® System; and
- PROCLEIX® OPTIVA System

The PROCLEIX® System is a semi-automated instrument platform that is manufactured by Gen-Probe and marketed by Chiron and which has been commercially available since receiving FDA clearance in February 2002. The PROCLEIX® OPTIVA System, is a set of modular components that automate several of the steps performed manually with the PROCLEIX® System. A portion of the PROCLEIX® OPTIVA System, the Front-End Pipetor (FEP), received European CE Marking in June 2004. Another component, the PROCLEIX® OPTIVA Reagent Addition Station (RAS), received CE Marking in April 2005. The PROCLEIX® TIGRIS® System, a next generation, fully automated, high-throughput instrument platform, was launched in Europe in December 2004. It is also available under IND for use with the PROCLEIX® WNV Assay in the United States. The PROCLEIX® TIGRIS® System is manufactured for Gen-Probe and marketed by Chiron. By increasing throughput and automation, the PROCLEIX® TIGRIS® System is designed to allow smaller pool sizes and to enable individual donor testing (IDT) on a large scale, which is important for the detection of diseases with low viremic levels such as West Nile Virus and hepatitis B.

Through its joint business contractual arrangement with us, Ortho-Clinical Diagnostics sells a full line of immunodiagnostic tests for hepatitis viruses and retroviruses and provides supplemental tests and microplate and chemiluminescent instrument systems to automate test performance and data collection. We manufacture, and perform research on, viral antigens used by Ortho-Clinical Diagnostics to manufacture immunodiagnostic testing assays and supplemental hepatitis and HIV tests. Ortho-Clinical Diagnostics manufactures and sells the assays and instrument systems. Commercial products sold under the joint business contractual arrangement include RIBA® tests, which are immunodiagnostic

supplemental confirmatory tests for HIV and HCV developed and manufactured by us, and a line of immunodiagnostics screening tests for infectious diseases. We share equally in the pretax operating earnings generated under the contractual arrangement. The joint business contractual arrangement holds the immunodiagnostic rights to our hepatitis and retrovirus patents and receives royalties from hepatitis C virus and HIV tests sold by Abbott Laboratories, Inc. and from hepatitis C virus tests sold by Bio-Rad Laboratories, Inc. and certain other licensees.

Sales of nucleic acid testing products accounted for 14%, 14% and 11% of our consolidated total revenues in 2005, 2004 and 2003, respectively. Revenues related to our arrangement with Ortho-Clinical Diagnostics, including the joint business contractual arrangement, accounted for approximately 9%, 9% and 8% of our consolidated total revenues in 2005, 2004 and 2003, respectively.

Vaccines

Our vaccines segment offers approximately 20 influenza, meningococcal, travel, and pediatric and other vaccines. In our influenza franchise, our established brands include FLUVIRIN® vaccine, AGRIPPAL® vaccine, BEGRIVAC vaccine, and FLUAD® vaccine. Influenza, a contagious disease caused by the influenza virus, affects the respiratory tract, and can cause mild to severe illness, and sometimes death. Each year in the United States, on average 5% to 20% of the population get influenza, more than 200,000 people are hospitalized from influenza complications, and about 36,000 people die.

In July 2003, we acquired United Kingdom based PowderJect and commenced sales of FLUVIRIN® vaccine, a trivalent influenza vaccine. The vast majority of FLUVIRIN® vaccine production has been supplied to the U.S. market.

We manufacture AGRIPPAL® S1 and BEGRIVAC trivalent influenza vaccines and FLUAD® MF59 adjuvanted influenza vaccine in our Italian and German facilities and market them outside of the United States, largely in Europe. In 2005, we also distributed ENZIRA® influenza virus vaccine in the United Kingdom. ENZIRA® vaccine is manufactured by CSL Ltd. In July 2005, Chiron reported that it would be unable to supply any BEGRIVAC vaccine doses for the 2005-2006 influenza season due to a product sterility issue and wrote off its existing product inventory. Investigation of the product sterility issue has been completed and implementation of remedial measures and facility modifications is underway. In addition to our approved influenza virus vaccines, subsequent to December 31, 2005, we began to manufacture H5N1-strain candidate influenza virus vaccines under contract for various government pandemic stockpile programs.

In our meningococcal franchise, we sell MENJUGATE® vaccine, a conjugate vaccine against meningococcal disease caused by the bacterium *N. meningitidis* serogroup C, and MENZB, a meningococcal B vaccine developed to protect against a specific meningococcus B strain responsible for a 13-year epidemic in New Zealand. Invasive infection with the bacteria *N. meningitidis* can lead to meningococcal meningitis and septicemia (blood poisoning). Meningococcal meningitis can be caused by multiple serogroups (A, B, C, W, Y and others) and is associated with both mortality and morbidity. We have sold MENJUGATE® vaccine under a tender system to national governments and health systems in a variety of countries including various European countries, Canada, Argentina and Australia. We have sold MENZB in New Zealand.

Our travel vaccines franchise includes RABAVERT® and RABIPUR® rabies vaccines and ENCEPUR, a preservative-free tick-borne encephalitis vaccine.

Our pediatric and other vaccines include DTP, a diphtheria, tetanus and pertussis (whooping cough) vaccine; oral polio vaccine; and Vaxem Hib, glycoconjugate *Haemophilus Influenzae* vaccine. In 2000, we entered into agreements with Sanofi-Aventis (previously Aventis Pasteur MSD) for the distribution of FLUAD® vaccine and MENJUGATE® vaccine. Under the agreements, we market FLUAD® vaccine alone and we co-promote MENJUGATE® vaccine with Sanofi-Aventis in the United Kingdom and

Ireland. In the rest of Europe, Sanofi-Aventis distributes, co-markets and sells FLUAD® vaccine and MENJUGATE® vaccine under its own labels, ADIUGRIP and MENINVACT respectively. Our primary manufacturing facilities for vaccines are located in: Siena, Italy; Marburg, Germany; Liverpool, UK; and Ankleshwar, India. We mainly operate in India through a joint venture, Chiron Behring Vaccines Private Limited.

The principal markets for our manufactured vaccines and vaccines that we market under license are the United States, Germany, Italy, and the United Kingdom. We have two vaccines licensed in the United States: FLUVIRIN® influenza virus vaccine and RABAVERT® rabies vaccine. We also supply diphtheria and tetanus (DT) concentrate to GlaxoSmithKline for use in its DT-containing vaccines licensed by the FDA.

In addition, we market our vaccines in other European countries and in the Middle East, the Far East, Africa and South America, and to international health agencies such as UNICEF and the Pan American Health Organization.

In addition to revenues from the sale of the vaccines described above, we receive royalties from the sale of certain vaccines by Merck and Company, Inc. and GlaxoSmithKline, based upon technology developed by us. Merck's hepatitis B virus vaccine, based on Chiron technology, was the first genetically engineered vaccine licensed by the FDA for human use.

Sales of our influenza vaccine franchise products accounted for approximately 12%, 9%, and 19% of our consolidated total revenues in 2005, 2004 and 2003, respectively. In 2005, 2004, and 2003, sales of FLUVIRIN® vaccine accounted for 5%, 0%, and 12% of our consolidated total revenues. As a result of the MHRA's suspension of our license to manufacture FLUVIRIN® vaccine from October 5, 2004 through March 2, 2005, we had no sales of FLUVIRIN® vaccine in 2004 other than \$2.3 million in late 2003-2004 season sales. Sales of pediatric and other vaccines accounted for approximately 9%, 12% and 11% of our consolidated revenues in 2005, 2004 and 2003, respectively. No other single vaccine product or class of vaccine product accounted for 10% or more of our consolidated total revenues in any of the last three fiscal years.

On March 16, 2006, we announced a recall and withdrawal of MORUPAR®, our measles, mumps and rubella (MMR) vaccine. We previously supplied MORUPAR® vaccine to customers in a limited number of developing countries, largely via the United Nations Children's Fund (UNICEF) and the Pan American Health Organization (PAHO), and to Italy. Results of pharmacovigilance surveillance in Italy suggest that MORUPAR® vaccine may be associated with a higher reported rate of adverse events following immunization than other MMR vaccine products. We expect to work with the World Health Organization (WHO) to assist it in conducting a risk-benefit analysis to determine whether UNICEF or PAHO will require a limited quantity of the existing inventory of MORUPAR® vaccine for their ongoing public health programs. We have written-off in 2005 approximately \$6.0 million of MORUPAR® inventory as a result of the withdrawal and recorded approximately \$1.7 million of product returns reserves in 2005 in connection with expected returns of 2005 product sales from the recall.

Biopharmaceuticals

Our biopharmaceutical segment discovers, develops, manufactures and markets a range of therapeutic products primarily for cancer and infectious and pulmonary disease. The following describes our primary marketed products.

TOBI® tobramycin solution for inhalation, USP We manufacture and market TOBI® solution, a stable, premixed, proprietary formulation of the antibiotic tobramycin for delivery by inhalation using a nebulizer. TOBI® solution has been tested and approved for cystic fibrosis patients with *Pseudomonas aeruginosa* lung infections and is the first and only inhaled antibiotic solution to be approved by the FDA

for cystic fibrosis. Cystic fibrosis is caused by a genetic mutation that prevents cells from building a special protein required for normal movement of sodium chloride (salt) in and out of cells lining the lungs and other organs. This abnormal movement causes secretion of thick, sticky mucus in the airways. This mucus is not cleared from the airways and, as a result, bacteria begin to grow, causing infection. *Pseudomonas aeruginosa* is the most common bacterium causing lung infections in people with cystic fibrosis. In cystic fibrosis patients with pseudomonal lung infections, tobramycin is the most commonly used intravenous antibiotic. The advantage of inhalation is that it permits higher antibiotic concentrations in the lung and reduces side effects by limiting systemic exposure. Treatment with TOBI® solution decreases the bacterial load and improves overall lung function. We market the TOBI® solution in the United States, the European Union, Canada, Switzerland, Norway, Israel, Argentina and Brazil.

PROLEUKIN® (aldesleukin) for injection We manufacture and market PROLEUKIN® (aldesleukin), a recombinant form of interleukin-2. Interleukin-2 is a protein produced naturally in the body in very small quantities, which stimulates the immune system to increase the production and function of immune cells.

While the precise anti-tumor mechanism of PROLEUKIN® (aldesleukin) is unknown, research has demonstrated that PROLEUKIN® (aldesleukin) induces the proliferation of immune cells, including natural killer and cytotoxic T cells that can recognize and mobilize against tumor-specific antigens on the surface of malignant cells. We market PROLEUKIN® (aldesleukin) directly or through distributors in the United States and over 50 other countries in North America, Europe, Asia and South America to treat metastatic renal cell carcinoma (a type of kidney cancer), and in the United States and Canada to treat metastatic melanoma (a form of skin cancer). Studies have demonstrated that PROLEUKIN® (aldesleukin) offers the possibility of a complete and long-lasting remission in these diseases.

BETASERON® (interferon beta-1b) for SC injection We manufacture BETASERON® (BETAFERON® in Europe) interferon beta-1b which is marketed by Schering AG and its affiliates, including Berlex Laboratories, Inc. (collectively, Schering). Boehringer Ingelheim also supplies BETAFERON® interferon beta-1b to Schering for sale in Europe. Multiple sclerosis is an autoimmune disease in which the patient's immune system attacks and destroys an element of the patient's own central nervous system. The active ingredient in BETASERON® is a modified form of a beta interferon produced naturally by the human body. Interferons help to regulate the immune system, and BETASERON® interferon beta-1b is thought to help slow down the immune system's attack on nerve tissue. While the ways in which BETASERON® interferon beta-1b actually affects multiple sclerosis are not clearly understood, it has been demonstrated clinically that BETASERON® interferon beta-1b may decrease the nerve damage associated with multiple sclerosis. It has been shown to reduce the overall frequency of multiple sclerosis relapses, which are also called exacerbations or attacks, as well as the number of moderate and severe relapses. BETASERON® interferon beta-1b is approved for relapsing/remitting multiple sclerosis in over 70 countries, including the United States and the nations of the European Union, and for secondary progressive multiple sclerosis in approximately 60 countries, including the nations of the European Union, Canada, Australia and New Zealand. In 2002, we and Schering AG launched a room temperature formulation of BETASERON® interferon beta-1b, which is the only beta interferon currently marketed in the United States that can be stored at room temperature long term up to two years. To further increase ease of use, Chiron and Schering AG introduced a diluent syringe presentation for BETASERON® interferon beta-1b in the United States in January 2004 and in Japan in December 2003. On February 24, 2006 Schering AG notified Chiron of its intention to exercise its option under the companies' Regulatory Filing, Development and Supply Agreement to purchase or lease all assets used by Chiron in the manufacture for Schering of BETASERON® interferon beta-1b products and all contractual rights at their fair market or lease value. The purchase/lease option is subject to the closing of the

proposed acquisition of Chiron by Novartis AG. The agreement requires that the value be determined by an independent third party mutually agreed upon by both parties.

CUBICIN® (daptomycin) In January 2006, European Commission granted marketing approval to Chiron for CUBICIN®, a first-in-class IV antibiotic. The marketing approval was granted in the 25 member states of the European Union, Iceland, Liechtenstein and Norway. Under the approval, CUBICIN® is indicated for the treatment of complicated skin and soft-tissue infections (cSSTI) caused by Gram-positive bacteria. The CUBICIN® antibiotic is also approved by the FDA for the treatment of complicated skin and skin structure infections caused by Gram-positive bacteria, and is marketed in the United States by Cubist Pharmaceuticals, Inc. We acquired marketing rights to the antibiotic for certain countries outside of the United States from Cubist. CUBICIN® antibiotic is manufactured for us by Cubist Pharmaceuticals, Inc.

CARDIOXANE dextrazoxane (ICRF-187) Dextrazoxane is the only cardioprotectant indicated to prevent cardiac damage induced by anthracyclines, a group of chemotherapy medications used to treat a variety of cancers. CARDIOXANE dextrazoxane is currently approved in 31 countries in over four continents.

Our biopharmaceutical products are manufactured primarily in our Emeryville, California and Vacaville, California facilities. Sales of TOBI® formulation accounted for approximately 12%, 12% and 10% of our consolidated total revenues in 2005, 2004 and 2003, respectively. Revenues from BETASERON® interferon beta-1b, which include product sales to Schering and royalties earned on Schering's European sales of BETAFERON® interferon beta-1b, accounted for approximately 11% (7% product sales and 3% royalties), 11% (8% product sales and 3% royalties) and 11% (7% product sales and 4% royalties) of our consolidated total revenues in 2005, 2004 and 2003, respectively. No other biopharmaceutical product accounted for 10% or more of our consolidated total revenues in any of the last three fiscal years.

Research and Development

Our research and development focuses on the prevention and treatment of cancer and infectious and pulmonary diseases. In addition to our research and development activities, technologies that are developed in collaborations with third parties, as well as technologies licensed from outside parties, also are sources of potential products for our segments. Products or product candidates that are inappropriate for our commercial organization are often out-licensed to other companies.

Blood Testing

Chiron pursues research and development of assays for transfusion-transmitted diseases, such as variant Creutzfeldt-Jakob disease (vCJD). In August 2004, we supplemented our existing vCJD research and development program by acquiring Prion Solutions, Inc., a privately held company focused on research into vCJD and other prion-related diseases.

We also participate in the development of a range of hepatitis and retrovirus immunoassays for use in screening of donated blood, plasma, organs and tissue and in-vitro clinical diagnostics through our joint business contractual arrangement with Ortho-Clinical Diagnostics.

We moved beyond Blood Testing and into the broader realm of blood safety when we entered into a collaboration with ZymeQuest in 2003 to develop and commercialize ZymeQuest's enzyme conversion system. This system is designed to convert groups A, B and AB red blood cells to enzyme-converted universal blood group O (ECO). This technology could fill a critical need for blood and transfusion centers since between 5% and 10% of the global donated blood supply is discarded each year due to non-matches between donated blood and patients' blood type requirements. We made an equity investment in

ZymeQuest and obtained worldwide marketing and commercial rights to the technology. In 2005 we initiated the pre-pivotal clinical trial for the conversion of type A red blood cells to ECO, or A-ECO.

Vaccines

Our vaccines segment research and development is focused on developing next generation influenza manufacturing capability, developing new vaccines for pandemic preparedness and broadening our meningococcal franchise. Next generation cell culture production technology may offer significant advantages over traditional methods of influenza vaccine manufacturing by eliminating the dependence on chicken eggs for production. The removal of egg supply lead times may enable a more flexible start-up of vaccine production in the event of an annual vaccine supply shortfall or an avian influenza pandemic. In Europe, we completed an initial Phase 3 study of our influenza cell culture vaccine in the 2004-2005 influenza season, in which the vaccine demonstrated satisfactory safety and immunogenicity, and we are conducting the remainder of the Phase 3 program during the 2005-2006 influenza season. In the United States we are conducting Phase 1 / Phase 2 studies during the 2005-2006 influenza season.

World health agencies are concerned about recent outbreaks of highly pathogenic avian influenza in poultry and a limited number of humans and are concerned that the present situation could give rise to another influenza pandemic. In 2004, we were awarded contracts by the National Institutes of Health (NIH) for production of H5N1 and H9N2 candidate vaccines, to be used by the National Institute of Allergy and Infectious Diseases (NIAID) in clinical studies of safety and immunogenicity. The H9N2 candidate vaccine study was completed, using H9N2 antigens with and without Chiron's adjuvant MF59, and preliminary data indicated that the vaccine formulations containing the adjuvant MF59 proved highly immunogenic, inducing antibody levels believed to confer protection against the influenza strain while the unadjuvanted vaccine induced significantly lower antibody titers. The NIAID study using our H5N1 candidate vaccine is ongoing. We have entered into supply contracts with several governments, including the U.S. and the UK governments, for influenza vaccines for stockpiles based on the H5N1 avian influenza strain. The commercial potential for stockpiling is unclear due to among other things, the fact that larger demands would require greater capacity, the fact that production for stockpiling can only occur between normal seasonal campaigns, and government pressure on pricing. There are also technical obstacles that need to be addressed in order to produce a commercial pandemic vaccine.

In our meningococcal franchise, we are expanding our product line beyond MENJUGATE® vaccine, our conjugate vaccine against *Meningococcus C* infection, through the development of other vaccines against additional Meningococcal strains responsible for human disease. Meningococcal disease is associated with infections affecting the membranes around the brain and spinal cord or the bloodstream, and can result in brain damage, blindness, deafness, limb amputations and death. Infection may be fatal even if diagnosed early, making prevention essential. Young children and persons in close living quarters such as college dorms or military facilities are at highest risk for meningococcal disease.

Serotype B, along with serotypes A, C, W and Y cause approximately 95% of the meningococcal infections worldwide. Multivalent vaccines are effective against more than one serotype. We are developing a tetravalent conjugated vaccine against serotypes A, C, W and Y and we are completing Phase 2 studies of this ACWY vaccine in a variety of age groups, including ages under two.

In 2004, we began distributing a meningococcal B vaccine in New Zealand, MENZB , to protect against the specific meningococcal B strain responsible for a 13-year epidemic in that country. While our current meningococcal B product, MENZB is efficacious against only a single strain of meningococcal B, we are also developing a second-generation vaccine candidate utilizing our novel genomic approach against *Meningococcus B*, a disease for which no broadly efficacious vaccine is currently available. Our meningococcal B vaccine was in a Phase 1 clinical trial in 2005.

Through collaborations, we are obtaining human safety and immunogenicity information on hepatitis C virus vaccine candidates, and our vaccine against HIV, which is in Phase 1 testing in collaboration with NIH. We are also developing novel adjuvants, compounds that amplify the immune response generated by vaccine antigens.

Biopharmaceuticals

Research and development in the biopharmaceutical segment focuses on protein and small molecule therapies for cancer and infectious and pulmonary disease.

Infectious and Pulmonary Disease

Tifacogin (recombinant Tissue Factor Pathway Inhibitor) *Tifacogin* a coagulation inhibitor, was developed in collaboration with Pfizer, Inc. In October 2003 we acquired all of Pfizer, Inc.'s interest in *tifacogin*, in return for which Pfizer will receive royalties on sales of *tifacogin*. In 2004 we initiated CAPTIVATE, a Phase 3 trial for *tifacogin* in patients with severe community-acquired pneumonia (CAP). CAP is a serious infection of the lungs caused by various, well-defined pathogens. Severe CAP affects approximately 300,000 patients in the United States annually requiring ICU admission, of whom approximately 30 percent die. In December 2005 an independent Data Monitoring Committee completed an interim analysis of clinical data from the study and recommended the continuation of the study.

Tobramycin inhalation powder (TIP) In December 2001, we entered into a collaboration with Nektar Therapeutics Inc. (Nektar) to develop and register an inhalable dry-powder formulation of the antibiotic tobramycin as an extension of our TOBI® formulation franchise. TIP is used with Nektar's new hand-held, fully portable device. We are currently conducting Phase 3 clinical trials of the product.

Oncology

Using a translational-medicine approach to drug development, Chiron's research department continues to feed a growing oncology pipeline, which includes CHIR-258, CHIR-12.12 and CHIR-265.

CHIR-258 (growth factor kinase inhibitor) *CHIR-258* is a novel, orally available, highly selective, multi-targeted receptor tyrosine kinase inhibitor, which acts on both tumor cell growth and angiogenesis. As of January 2006, disease-specific Phase 1 studies of *CHIR-258* are ongoing in acute myelogenous leukemia (AML), multiple myeloma and melanoma.

CHIR-12.12 *CHIR-12.12* is a novel, highly potent, fully human antagonist monoclonal antibody that targets the CD40 antigen. In 2005, we initiated two Phase 1 studies of *CHIR-12.12* - one in patients with chronic lymphocytic leukemia and a second in patients with multiple myeloma, both types of cancer that are associated with expression of the CD40 antigen on the cancer cell surface. This is the first project being developed under our collaboration agreement with XOMA Ltd. for the commercialization of therapeutic antibodies for cancer.

CHIR-265 In December 2005 we filed an IND for *CHIR-265*, a novel, orally available, highly selective Raf kinase inhibitor.

Research and Development Expenses and Related Revenues

Research and development expenses for the years ended December 31, 2005, 2004 and 2003 for Chiron-sponsored research, including payments to collaboration partners, were \$433.9 million, \$431.1 million and \$409.8 million, respectively. Under contracts where we recognize revenue based upon research and development work performed, the revenues amounted to \$16.3 million, \$20.9 million and \$16.8 million in 2005, 2004 and 2003, respectively. We recorded these revenues in Collaborative agreement revenues and Other revenues in the Consolidated Statements of Operations. Generally,

these revenues include fees for research services as they are performed or completed and milestone payments upon attainment of specified benchmarks.

Business Relationships

We have important business relationships with various companies, including the following.

Gen-Probe Incorporated

We have a collaboration with Gen-Probe relating to the development and commercialization of NAT products under the PROCLEIX® brand name to screen donated blood, plasma, organs and tissue for viral infection. PROCLEIX® assays and systems incorporate NAT technology to detect viral RNA and DNA in donated blood and plasma during the very early stages of infection, when those infectious agents are present but cannot be detected by immunodiagnostic tests. Gen-Probe manufactures the NAT assays and certain instruments, and Chiron sells both assays and instruments under the PROCLEIX® brand name. Effective January 1, 2004, under an amendment to the worldwide blood screening collaboration agreement with Gen-Probe, permanent, fixed revenue sharing percentages were adopted for each party. Gen-Probe's share was set at 45.75% of net revenues for assays that include a test for the hepatitis C virus. For commercial assays, that do not test for hepatitis C virus, such as the West Nile Virus assay, each party receives 50% of the net revenues after deduction of specified expenses.

Ortho-Clinical Diagnostics, Inc.

We have a joint business contractual arrangement with Ortho-Clinical Diagnostics relating to the development and commercialization of immunodiagnostic tests using recombinant DNA and antibody technologies to detect retroviruses and hepatitis viruses in blood. Under the terms of the arrangement, Ortho-Clinical Diagnostics manufactures and sells the assays and instrument systems, and Chiron supplies raw materials for the assays. Chiron and Ortho-Clinical Diagnostics share equally in the pretax operating earnings generated by the joint business contractual arrangement. Our joint business arrangement with Ortho-Clinical Diagnostics is operated under a contractual arrangement and is not a separate and distinct legal entity. The joint business contractual arrangement holds the immunodiagnostic rights to our hepatitis and retrovirus patents and receives royalties from the sale of hepatitis C virus and HIV tests sold by Abbott Laboratories, Inc. and from sales of hepatitis C virus tests by Bio-Rad Laboratories, Inc. and certain other licensees.

Cubist Pharmaceuticals

In October 2003, we entered into a license agreement for the development and commercialization of Cubist's antibiotic, CUBICIN® daptomycin, in Western and Eastern Europe, Australia, New Zealand, India and certain Central American, South American and Middle Eastern countries. Under the agreement, we are obligated to pay upfront payments, regulatory and sales milestones, and a tiered royalty on CUBICIN® daptomycin sales in the territories.

Schering AG and Berlex Laboratories, Inc.

Chiron and Berlex, Inc., a subsidiary of Schering AG of Germany, jointly developed BETASERON® (BETA FERON® in Europe) interferon beta-1b. Under the terms of the Regulatory Filing, Development and Supply Agreement with Schering AG, BETASERON® product is manufactured by us and sold in the United States and Canada by Berlex. BETA FERON® interferon beta-1b is manufactured by us and Boehringer Ingelheim and is sold by Schering AG in Europe. BETA FERON® and BETASERON® revenues recognized under this agreement contributed 11% of our consolidated total revenues in each of 2005, 2004 and 2003. Under the agreement, for product manufactured by us and marketed by Schering AG

and its affiliates, including Berlex, we receive revenue, which is recorded as product sales. For product manufactured by Boehringer Ingelheim and marketed by Schering in Europe under the trade name BETAFERON®, we receive royalties net of Schering's supply costs. The Regulatory Filing, Development and Supply Agreement expires in October 2008 unless renewed. On February 24, 2006 Schering AG notified Chiron of its intention to exercise its option under the Regulatory Filing, Development and Supply Agreement to purchase or lease all assets used by Chiron in the manufacture for Schering of BETASERON® interferon beta-1b products and all contractual rights at their fair market or lease value. The purchase/lease option is subject to the closing of the proposed acquisition of Chiron by Novartis AG. The agreement requires that the value be determined by an independent third party mutually agreed upon by both parties.

Nektar Therapeutics, Inc.

In December 2001, we entered into a collaboration with Nektar (then operating as Inhale Therapeutic Systems) to develop and register an inhalable dry-powder formulation of the antibiotic tobramycin as an extension of our TOBI® formulations franchise. Under the terms of the collaboration, Nektar is responsible for development of the dry powder formulation and inhalation device, as well as supplying drug product for clinical trials and the market. Chiron is responsible for all other aspects of drug development including clinical trial conduct, regulatory submissions, preparation for product launch and sales and marketing of the final drug product. Under the agreement, we are obligated to pay upfront payments and development milestones, and we will pay royalties when the product is commercialized.

XOMA Ltd.

We have a worldwide, exclusive, multi-product, collaborative agreement with XOMA for the development and commercialization of antibody products for the treatment of cancer. Under the terms of the agreement, we and XOMA agreed to jointly research, develop, and commercialize multiple antibody product candidates. Under the agreement, we also share development and commercialization expenses, including preclinical and clinical development, manufacturing and worldwide marketing costs, as well as revenues, generally on a 70-30 basis, with Chiron's share being 70% and XOMA's share being 30%. We made an initial payment of \$10.0 million, and have made a loan facility of up to \$50.0 million available to XOMA, starting on January 1, 2005 to fund 75% of XOMA's share of development expenses. Under this arrangement, we made \$12.1 million in loan advances to XOMA as of December 31, 2005.

Commercialization

Technologies arising out of our research and development efforts are commercialized in various ways:

- We market and distribute certain products, either directly or through distributors. See Sales and Marketing below.
- We develop other products in collaboration with third parties. Under collaboration agreements, marketing rights may be assigned to us or to the collaborator or shared by both parties. In the event rights are assigned to us, we generally pay royalties to or enter into revenue split agreements with our collaborator. In the event marketing rights are assigned to the collaborator, we often retain the right to manufacture and supply key raw materials.
- We license other technologies to third parties, with the licensee assuming responsibility for further development. We generally receive royalties on sales of the resulting product. Selected agreements under which we currently derive royalty revenues for technologies licensed to third parties include:
 - Licenses to F. Hoffmann-La Roche Ltd. and Roche Molecular Systems, Inc. under our hepatitis C virus and HIV related patents for use in nucleic acid amplification in *in vitro* diagnostics and in blood screening.

- An agreement with Schering AG relating to BETASERON® (BETAIFERON® in Europe) interferon beta-1b as described above.
- An agreement with Bayer Corporation relating to, among other things, use of our hepatitis C virus and HIV technologies for nucleic acid amplification in *in vitro* diagnostics.
- A license agreement with Laboratory Corporation of America Holdings (LabCorp) and its affiliates, for our HCV intellectual property for nucleic acid testing (NAT).
- A non-exclusive license agreement with the Blood Transfusion Centers of the German Red Cross (Blutspendediensten des Deutsche Rotes Kreuz, or DRK), for the use of our HCV technology for use in molecular probe homebrew blood screening.

Sales and Marketing

Blood Testing

Global marketing and distribution and our U.S. sales organization for nucleic acid testing products are based in Emeryville, California. Blood Testing has representatives around the world. International sales are conducted out of regional offices, including our primary offices located in Paris, France and Hong Kong, China. We sell products to the public sector through tenders (a bid solicitation process) and to private sector blood banks directly and through distributors.

In 2002, we signed a multi-year agreement with the American Red Cross, which collects approximately 50% of the 14 to 15 million units of blood collected in the United States each year. Under that agreement, the American Red Cross purchases from Chiron certain products, instrumentation and services that enable the American Red Cross to perform amplified nucleic acid screening on the blood it collects. Currently we are a party to multi-year contracts awarded through the tender process with the public sector blood services of many countries outside the United States, with the most significant in terms of donations being Australia, Italy, South Africa and the United Kingdom.

Vaccines

Our vaccines marketing and sales organization is based in Marburg, Germany for the German market, in Siena, Italy for the Italian market, and in Oxford, United Kingdom for the United Kingdom market. In 2004, we established a U.S. Vaccines headquarters in Philadelphia, Pennsylvania. In general, we market our influenza and rabies vaccines in the United States through a network of wholesalers and distributors. In the United States our direct sales efforts are focused on public health, distributor channels, and non-traditional channels, e.g., employers, chain drug headquarters and service providers. Internationally, our direct sales efforts are focused on pediatricians and general practitioners. We also sell products to the public sector through tenders and to private sector pharmacies directly and through wholesalers and distributors.

BioPharmaceuticals

Our biopharmaceutical marketing and sales organization for the United States is headquartered in Emeryville, California, and European operations are headquartered in Uxbridge, United Kingdom. We focus our sales efforts on specialist physicians, principally oncologists, urologists and pulmonologists, who are based in hospitals and large clinics. Generally, we sell products to wholesalers, distributors, clinics and hospital pharmacies.

Competition

We operate in a highly competitive environment, and we expect competition to increase. Competitors include large pharmaceutical and blood testing companies, and biotechnology companies. Some of these competitors, particularly large pharmaceutical and blood testing companies, have greater resources than we have. We and our competitors apply rapidly evolving technologies and new developments that frequently result in price competition and product obsolescence. Substantial consolidation is underway in the global healthcare industry and is expected to produce greater efficiencies and even more intense competition. To compete effectively, we invest heavily in research and development, maintain specialized sales forces that concentrate on individual classes of customers and spend significant amounts on marketing, promotion and selling.

Important biotechnology research is performed in universities and nonprofit research organizations. These entities are becoming more active in seeking patent protection and licensing revenues for their discoveries. The competition among large pharmaceutical companies and smaller biotechnology companies to acquire technologies from these entities also is intensifying. We actively collaborate with such entities in research, and have and will continue to license their technologies for further development. However, these institutions also compete with us to recruit scientific personnel and to establish proprietary positions in technology.

Blood Testing

The PROCLEIX® product line is based on proprietary Transcription Mediated Amplification (TMA) technology developed by Gen-Probe. The primary competition is with polymerase chain reaction (PCR) based products. PCR-based products are supplied to the market by F. Hoffmann-La Roche, a Chiron licensee, or developed in-house by blood banks (referred to as homebrew). The commercial market for nucleic acid testing products in the blood banking and plasma industries has developed rapidly as regulatory agencies in developed countries began in 1999 to introduce policies and mandates that require this new technology to be implemented as an additional measure to improve blood safety. In developing countries there has been a move to implement nucleic acid based tests in the private health care sector and we anticipate this expanding to the public arena over the next several years. Competition in this sector is the same as in the developed countries.

We are the sole manufacturer of hepatitis C virus antigens for use in immunodiagnostic assays sold by the joint business contractual arrangement with Ortho-Clinical Diagnostics. We also manufacture hepatitis C virus antigens for Abbott Laboratories, Inc.'s immunodiagnostic assays. In the immunodiagnostic blood testing market, the Ortho-Clinical Diagnostics joint business contractual arrangement competes with Abbott Laboratories. The joint business contractual arrangement has experienced increased competitive pressures from Abbott Laboratories' ABBOTT PRISM® instrument system. The joint business contractual arrangement also develops and sells immunodiagnostic instruments and assays to detect hepatitis, retrovirus and other agents in clinical diagnostic applications. Many other companies, including F. Hoffmann-LaRoche Limited and Bayer Corporation, are significant competitors with respect to these products.

Vaccines

Four large companies hold the majority share of the worldwide vaccines business: Merck, GlaxoSmithKline, Wyeth and Sanofi-Aventis. We are the world's fifth largest vaccines company. Sanofi-Aventis has a strategic alliance with Merck in Europe. All of these companies have substantial research and development programs. Additionally, there is a number of biotechnology companies involved in research programs, primarily involving a limited range of vaccines. We are aware of a variety of companies that are developing influenza vaccine cell culture manufacturing technology.

The competitive factors in vaccines are proven ability to supply product, price, the introduction of new products including vaccines against diseases for which no vaccine was previously available and new combination vaccines which can prevent several diseases in a single product. Public health authorities, medical practitioners and patients frequently favor combination vaccines, particularly in pediatric vaccines, because they eliminate the need for multiple injections and may increase overall compliance with recommended vaccination schedules. As new combination vaccines are introduced, older combinations and single products often become obsolete. We may be limited in our ability to develop and market certain combination vaccines if one of the vaccines, which would otherwise be included in the combination, is covered by valid and enforceable patents or other proprietary rights held by third parties.

Prior to the suspension of our Liverpool manufacturing license from October 5, 2004 through March 2, 2005, we were one of two primary suppliers of influenza vaccine to the United States. Although the license suspension has been lifted, our inability to supply FLUVIRIN® vaccine during the 2004-2005 influenza season has led a competitor to introduce an influenza vaccine product in the United States during the 2005-2006 season and we expect competition to continue to increase. Our influenza vaccines approved in Europe also remain competitive there. Competition varies by region according to product license approvals. All influenza vaccines producers, including us, face an annual change in influenza strains, which can act as a barrier for new competitors.

MENJUGATE®, our meningococcal C vaccine, faces competition from vaccines produced by two other companies, Baxter International, Inc. and Sanofi-Aventis. These companies are also competing for future meningococcal vaccine business worldwide.

Biopharmaceuticals

TOBI® tobramycin solution for inhalation is the first and only inhaled antibiotic solution to be approved by the FDA for the treatment of infection associated with cystic fibrosis. The use of oral and intravenous antibiotics to treat pseudomonal and other bacterial infections is well established and in cystic fibrosis patients with pseudomonal lung infections, tobramycin is the most commonly used intravenous antibiotic. The advantage of inhalation is that it permits higher antibiotic concentrations in the lung and reduces side effects by limiting systemic exposure. Competitive medical therapies include generic antibiotics, anti-inflammatory drugs, pharmacist compounded tobramycin solutions, oral replacement enzymes to maintain nutrition and mucolytics to clear pulmonary secretions. In 2005, Chiesi, a competitor, obtained MRP positive opinion and local approval in Italy for their cystic fibrosis product.

PROLEUKIN® (aldesleukin) for injection is one of two products approved by the FDA to treat metastatic renal cell carcinoma and also one of two approved treatments for metastatic melanoma. In addition to longstanding competition for products, such as alpha interferons sold by Schering-Plough C