CHIRON CORP
Form 10-K
March 03, 2004

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark one)

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

For the fiscal year ended December 31, 2003

OR

o **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	**94-2754624**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
4560 Horton Street, Emeryville, California	**94608**
(Address of principal executive offices)	(Zip code)

(510) 655-8730
(Registrant's telephone number, including area code)

Not Applicable
(Former name, former address and former fiscal year, if changed since last report)

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 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. o

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

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, 2003 as reported on the NASDAQ National Market, was approximately $3.5 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, 2003 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, 2004 was $4.4 billion. The number of shares outstanding of each of the registrant's classes of common stock as of January 31, 2004:

Title of Class	Number of shares
Common Stock, $0.01 par value	187,524,120

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 May 27, 2004 are incorporated by reference into Part II and 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, new product marketing, acquisitions, competition, in- and out-licensing activities and expected cost savings that involve risks and uncertainties and are subject to change. The forward-looking statements contained in this 10-K reflect our current beliefs and expectations on the date of this 10-K. Actual results, performance or outcomes may differ from current expectations. Our actual performance may differ from current expectations due to many factors, including the outcome of clinical trials, regulatory review and approvals, manufacturing capabilities, intellectual property protections and defenses, stock-price and interest-rate 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. There can be no assurance that our out-licensing activity will generate significant revenue, or that our in-licensing activities will fully protect us from claims of infringement by third parties. In addition, we may engage in business opportunities, the successful completion of which is subject to certain risks, including stockholder and regulatory approvals and the integration of operations. We have discussed the important factors, which 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." Consistent with SEC Regulation FD, we do not undertake an obligation to update the forward-looking information contained in this 10-K.

Company Summary

Chiron Corporation is a global pharmaceutical company that leverages a diverse business model to develop and commercialize high-value products that make a difference in people's lives. We apply our advanced understanding of the biology of cancer and infectious disease to

develop products from our platforms in proteins (therapeutic proteins and monoclonal antibodies), small molecules and vaccines. We commercialize our products through three business units: blood testing, vaccines and biopharmaceuticals.

Focus on Cancer and Infectious Disease

Chiron is focused on developing products for cancer and infectious diseases. We continue to build upon our cancer franchise, which has three dimensions: immune-based therapies, antibodies and novel small molecule anti-cancer agents. In the infectious disease area, we have a range of products spanning all three of our business units.

Blood Testing

Chiron Blood Testing develops and commercializes a range of blood safety products used by the blood banking and transfusion medicine industry. Our commercial products include:

Procleix® HIV-1/HCV Assay: A nucleic acid test (NAT) co-developed with Gen-Probe Incorporated for the simultaneous detection of HIV-1 and hepatitis C virus (HCV) in whole blood, organs and tissue;

RIBA® tests: Immunodiagnostic supplemental confirmatory tests for HIV and HCV developed by Chiron and marketed through our joint business contractual arrangement with Ortho-Clinical Diagnostics, Inc., a Johnson & Johnson company; and

A line of immunodiagnostics screening tests for infectious diseases, also marketed through our joint business contractual arrangement with Ortho.

Also available for sale outside the United States or under IND are the following products:

Procleix® Ultrio Assay: A nucleic acid test co-developed with Gen-Probe Incorporated for the simultaneous detection of HIV-1, HCV and hepatitis B virus (HBV) in whole blood, organs and tissue; and

Procleix® WNV Assay: A nucleic acid test co-developed with Gen-Probe Incorporated for the detection of West Nile virus (WNV) in whole blood, organs and tissue.

Vaccines

Chiron Vaccines, the fifth largest vaccines business in the world, currently offers more than 30 vaccines including flu, meningococcal, travel and pediatric vaccines. We provide a range of vaccines, including:

Fluvirin®, Agrippal® S1 and Begrivac , trivalent influenza vaccines;

Fluad®, an innovative adjuvanted influenza vaccine;

Menjugate®, a conjugated vaccine against meningococcal meningitis caused by the bacterium N. meningitidis serogroup C;

Encepur , a preservative-free vaccine against tick-borne encephalitis;

Rabipur®/RabAvert®, a cell culture vaccine against rabies;

Arilvax , a vaccine against yellow fever;

DTP, diphtheria, tetanus and pertussis (whooping couch) vaccine; and

Oral polio vaccine.

Biopharmaceuticals

Chiron Biopharmaceuticals discovers, develops, manufactures and markets a range of therapeutic products. Our products include:

TOBI® (tobramycin solution for inhalation) for pseudomonal lung infections in cystic fibrosis patients;

Proleukin® (aldesleukin) for cancer (metastatic melanoma and renal cell carcinoma); and

Betaseron® (interferon beta-1b) for multiple sclerosis.

Intellectual Property

Chiron has a large portfolio of intellectual property, with key positions in hepatitis C virus and HIV. Chiron has entered into numerous collaborations and licensing agreements with major companies, particularly in the areas of blood screening and diagnostics.

Corporate History, Headquarters and Website Information

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. Investors can obtain access to this annual report on Form 10-K, our quarterly reports on Form 10-Q, our current reports on Form 8-K

and all amendments to these reports, free of charge, on our website at *http://www.chiron.com* as soon as reasonably practicable after such filings are electronically filed with the SEC.

We also make available on our website our Corporate Governance Guidelines, the charters of the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee of our board of directors, and our Code of Conduct. The information contained on our website, or on other websites linked to our website, is not part of this report.

Product Descriptions

Blood Testing

Our blood testing business consists of two separate collaborations: an alliance with Gen-Probe Incorporated and a joint business contractual arrangement with Ortho-Clinical Diagnostics, Inc.

Our collaboration with Gen-Probe is focused on developing and commercializing nucleic acid testing (NAT) products using transcription-mediated amplification 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 the test and enables infection to be detected earlier than previously approved technologies. Under the terms of the collaboration agreement, Gen-Probe performs certain product development and assay and instrument manufacturing functions, while Chiron and Gen-Probe jointly participate in new assay and instrument research and development. Chiron sells the collaboration's products under the Procleix® brand name, and Gen-Probe receives a percentage of our sales revenues.

The Chiron/Gen-Probe collaboration's first product, the Procleix® HIV-1/HCV Assay and System received FDA approval in February 2002 and CE Mark in Europe in 2003. It is the first and only NAT test that allows for the simultaneous detection of HIV-1 and hepatitis C virus (HCV) and is performed on a semi-automated instrument system. The Procleix® HIV-1/HCV Assay and System is commercially available in the United States and throughout Europe, Australia and New Zealand and is under evaluation in South American and Asian countries.

On July 1, 2003, following a 9-month development cycle, Chiron introduced the Procleix® WNV Assay under an Investigational New Drug (IND) protocol. The test was developed in collaboration with Gen-Probe in response to an FDA request for a NAT test able to detect the West Nile virus by the start of the 2003 mosquito season. Between July 1 and December 31, 2003 over 800 confirmed West Nile virus contaminated units of donated blood were detected by the Procleix® WNV Assay, potentially preventing over two thousand transfusion transmissions of the virus. The primary market for this product is the U.S., though European and Asian medical authorities have expressed interest in conducting epidemiological studies in 2004. We expect to begin pivotal clinical trials of the Procleix® WNV Assay in the first half of 2004 as a first step towards seeking licensure of this assay in the United States.

The Procleix® Ultrio Assay is the collaboration's premium 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, and 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. In the U.S. and Western Europe infection rates are estimated at approximately 2% of the population. The Procleix® Ultrio Assay received CE Mark Registration in Europe in January 2004. Clinical trials in the U.S. began in the fourth quarter 2003 on the semi automated instrument system, to be followed on the fully automated TIGRIS instrument. Chiron expects to file a Biologics License Application (BLA) in 2004.

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. The joint business contractual arrangement 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 for further manufacture by Ortho-Clinical Diagnostics into testing assays and supplemental hepatitis and HIV tests. Ortho-Clinical Diagnostics manufactures and sells the assays and instrument systems. Chiron and Ortho-Clinical Diagnostics 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 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.

Chiron has engaged Gen-Probe and Ortho-Clinical Diagnostics in extensive business continuity planning to limit any disruption to our current source of these blood safety products in the event of a loss of manufacturing capability. Chiron maintains several months' supply of NAT reagents in inventory. Ortho maintains similar inventories of immunodiagnostics products.

Sales of nucleic acid testing products accounted for 11%, 10% and 4% of our consolidated total revenues in 2003, 2002 and 2001, respectively. Revenues related to our arrangement with Ortho, including the joint business contractual arrangement, accounted for approximately 8%, 10% and 9% of our consolidated total revenues in 2003, 2002 and 2001, respectively.

Vaccines

Following the acquisition of United Kingdom based PowderJect Pharmaceuticals in July 2003, Chiron commenced sales of Fluvirin®, a trivalent influenza vaccine. Fluvirin® is one of only two injectable flu vaccines approved for use in the U.S. by the regulatory authorities. Between 10% and 20% of the U.S. population contracts the flu each year. Vaccination not only decreases the risk of illness for the vaccine recipient, but also helps prevent the spread of the flu virus and limits its role in the potential development of life-threatening complications. In an average year in the U.S., flu kills an estimated thirty-six thousand people, primarily in the over-65 population, and results in one hundred and fourteen thousand people being hospitalized. In addition to its U.S. approval, Fluvirin® is registered for use in over 20 countries. The vast majority of Fluvirin® production is supplied to the U.S. market, with the United Kingdom accounting for most of the balance. Chiron's flu vaccine franchise is complemented by three other established brands, Agrippal® S1, Begrivac , and Fluad®, which are marketed outside of the

U.S., largely in Europe.

In 2000, Chiron commenced sales of Menjugate®, a conjugate vaccine against meningococcal disease caused by the bacterium N. meningitidis serogroup C. Invasive infection with the bacteria N. meningitidis can lead to meningitis and septicemia (blood poisoning). Meningococcal meningitis, which can be caused by multiple serogroups (A, B, C, W, Y and others), is associated with both high mortality and morbidity. In March 2000, the Medicines Control Agency approved Menjugate® for sale in the United Kingdom. The National Health Service in the United Kingdom accepted our tender to supply Menjugate® each year since then. We are also selling Menjugate® in Canada, Germany, Ireland, Spain, Hungary, France and Australia. We have received approval to market Menjugate® elsewhere in the European Union through the mutual recognition procedure.

Chiron also manufactures and markets Fluad®, an adjuvanted flu vaccine, which uses our proprietary MF-59, an adjuvant which improves the body's immune response to vaccination. Adjuvants are compounds that amplify the immune response generated by vaccine antigens. This adjuvanted vaccine accords longer lasting protection to older patients protecting them from influenza and its complications. Fluad® currently is marketed in Germany, Austria, Italy (under the trade names Fluad

and Influpozzi Adiuvato) and Spain (under the trade name Chiromas). We have gained approval to market Fluad® in 12 countries of the European Union through the European mutual recognition procedure.

In 2000, we entered into a co-promotion and co-marketing agreement with Aventis Pasteur MSD related to Menjugate® and Fluad®. Under the agreement, Aventis Pasteur MSD assists Chiron in marketing and sales efforts (co-promotion) related to Menjugate® in the United Kingdom and Ireland. Aventis Pasteur MSD distributes, co-markets and sells Menjugate® under its own label in the rest of Europe. Aventis Pasteur MSD similarly co-markets Fluad® in Europe.

In Italy, we manufacture and/or market vaccines for:

- meningococcal infection;
- haemophilus influenza type b;
- influenza;
- measles;
- mumps;
- rubella; and
- polio (oral vaccine).

Also in Italy, under license, we market vaccines for pneumococcal disease.

In Germany, we manufacture and/or market vaccines for:

- meningococcal infection;

diphtheria;

tetanus;

pertussis;

influenza;

rabies;

tick-borne encephalitis; and

cholera.

Also in Germany, under distribution agreements with other manufacturers, we market vaccines for:

hepatitis A virus;

measles;

mumps;

rubella;

typhoid fever;

pneumococcal disease;

polio (inactivated vaccine); and

hepatitis B (recombinant vaccine).

In the United Kingdom, we manufacture and/or market vaccines for:

influenza;

yellow fever; and

tetanus.

Also in the United Kingdom, under distribution agreements, we sell vaccines for rabies.

In India, we manufacture, through Chiron Behring Vaccines Limited, a vaccine against rabies.

We market most of our manufactured vaccines in other European countries and in the Middle East, the Far East, Africa and South America, and to international health agencies such as the World Health Organization. We market our flu and rabies vaccines in the U.S.

In addition to revenues from the sale of the vaccines described above, Chiron receives royalties from the sale of certain vaccines from Merck and Company, Inc. and SmithKline Beecham Biologics (now part of GlaxoSmithKline plc), based upon technology developed by Chiron. Merck's hepatitis B virus vaccine, based on Chiron technology, was the first genetically engineered vaccine licensed by the U.S. Food and Drug Administration for human use.

Sales of Fluvirin® accounted for approximately 12% of our consolidated total revenues in 2003, with sales of our flu vaccine franchise accounting for approximately 19% of our consolidated total revenues in 2003. Sales of pediatric and other vaccines accounted for approximately 11% of our consolidated revenues in 2003. 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.

Biopharmaceuticals

We manufacture interferon beta-1b which is marketed by Schering AG and its affiliates, including Berlex Laboratories, Inc. (collectively "Schering"), under the trade names Betaseron® (in the U.S and other non-European markets) and Betaferon® (in Europe). Boehringer Ingelheim also supplies Betaferon® 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® is thought to help slow down the immune system's attack on nerve tissue. While the ways in which Betaseron® actually affects multiple sclerosis are not clearly understood, it has been demonstrated clinically that Betaseron® 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® is approved for relapsing/remitting multiple sclerosis in over 70 countries, including the U.S. and the European Union, and for secondary progressive multiple sclerosis in approximately 60 countries, including the European Union, Canada, Australia and New Zealand. In the second quarter of 2002, we launched a room temperature formulation of Betaseron®, which is the only beta interferon currently marketed in the U.S. that can be stored at room temperature long term, up to two years. To further increase ease of use, a diluent syringe presentation for Betaseron® was introduced in the U.S. in January 2004 and in Japan in December 2003.

TOBI® is a stable, premixed, proprietary formulation of the antibiotic tobramycin for delivery by inhalation using a nebulizer. TOBI® has been tested and approved for cystic fibrosis patients with *Pseudomonas aeruginosa* lung infections. *Pseudomonas aeruginosa* is the most common bacterium causing lung infections in people with 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. The use of oral and intravenous antibiotics to treat pseudomonal and other bacterial infections is well established. 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. Appropriate treatment of these chronic lung infections is a major contributor to the extended life span of patients with cystic fibrosis and to improve quality of life. The TOBI® formulation is well tolerated by patients, thereby leading to increased patient compliance and more effective control of infection. Treatment with TOBI® decreases the bacterial load, reduces the associated inflammatory response, and improves overall lung function. TOBI® is the first and only inhaled antibiotic solution to be approved by the U.S. Food and Drug Administration. TOBI® is marketed in the U.S., the European Union, Canada, Switzerland, Norway, Israel, Argentina and Brazil.

Chiron manufactures and markets Proleukin®, a recombinant form of interleukin-2. Interleukin-2 is a protein produced naturally in the body in very small quantities. Interleukin-2 stimulates the immune system to increase the production and function of immune cells. While the precise anti-tumor mechanism of Proleukin® is unknown, research has demonstrated that Proleukin® 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® directly or through distributors in the U.S. 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 U.S. and Canada to treat metastatic melanoma (a form of skin cancer).

Sales of Betaseron®, which include product sales to Berlex Laboratories and Schering and royalties earned on Schering's European sales of Betaferon®, accounted for approximately 11% (7% product sales and 4% royalties), 13% (9% product sales and 4% royalties) and 12% (9% product sales and 3% royalties) of our consolidated total revenues in 2003, 2002 and 2001, respectively. Sales of TOBI® accounted for approximately 10%, 12% and 11% of our consolidated total revenues in 2003, 2002 and 2001, 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

As a global pharmaceutical company, our focus on treatment of cancer and infectious disease in the Vaccines and Biopharmaceutical business units starts with the discovery process, using our three product platforms proteins (therapeutic proteins and antibodies), small molecules and vaccines and if successful, continues into the clinic and on to commercialization. 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 business units.

Products or product candidates that are inappropriate for our commercial organization are out-licensed to other companies. This portfolio of intellectual property is, and will continue to be, an important part of our business model.

Blood Testing

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

Chiron and Gen-Probe Incorporated are working toward expanding the nucleic acid test menu on the Procleix® System. The current menu consists of a combination test for HIV-1 and hepatitis C virus and is being expanded to include other transfusion transmitted viruses, such as hepatitis B virus, hepatitis A virus, Parvo virus B19 and the West Nile virus.

Chiron is also developing enhancements to the current Procleix® Instrumentation System to provide a higher level of automation. The Procleix® Optiva System, which consists of multiple components is expected to automate several of the manual tasks performed on the current platform. In addition, clinical trials of the fully automated TIGRIS instrument, which is under development by Gen-Probe, are expected to begin in the first quarter of 2004. The Procleix® Ultrio Assay was designed to be run on both the current Procleix® Instrumentation System as well as TIGRIS. Future assays described above are also being designed to run on the TIGRIS instrument.

Two agreements entered into at the end of 2003 have the potential to move the business unit into the expanded realm of Blood Safety:

- The licensure of proprietary nucleic acid technology from Infectio Diagnostic Inc. (IDI) for which Chiron obtained the rights to all current and future products for the detection of bacteria in platelets and blood products for transfusion. Over the course of the next two years IDI will transfer all research and development and manufacturing to Chiron. This technology enables the rapid detection of bacteria in platelets, which is critical given the five-day shelf life of platelet concentrates; and

- The formation of a collaboration with ZymeQuest to develop and commercialize ZymeQuest's enzyme conversion system which converts groups A, B and AB red blood cells to enzyme-converted universal blood group O. Chiron made an equity investment in ZymeQuest and obtained worldwide marketing and commercial rights to the technology. We anticipate the technology to fill a critical need for blood and transfusion centers as up to 10% of the global blood supply is discarded each year due to non-matches between blood on the shelf and patients.

Vaccines

We are building on our successful flu vaccine franchise by developing next generation cell-culture production technology. This approach has the potential to increase the flexibility of our production process, while adding incremental capacity. We have currently undertaken a number of clinical studies, in which the vaccine demonstrated satisfactory safety and immunogenicity. We plan to initiate phase III testing in 2004.

We are building on the success of Menjugate®, Chiron's conjugate vaccine against Meningococcus C infection, through the development of other vaccines against additional Meningococcal strains responsible for human disease. These include a second-generation vaccine candidate utilizing Chiron's novel genomic approach against Meningococcus B for which no broadly efficacious vaccine is currently available, which will enter phase I testing in 2004, and a tetravalent conjugate ACWY vaccine, which is currently in phase II. Through collaborations, Chiron also is obtaining human safety and immunogenicity information on hepatitis C virus vaccines candidates, and Chiron's vaccine against HIV, which began Phase I testing in 2003.

We are also developing novel adjuvants, compounds that amplify the immune response generated by vaccine antigens. One of our adjuvants, MF-59, is a component of Fluad®, our novel flu vaccine. In addition, we are conducting preclinical investigations of alternative delivery approaches for vaccines that may be used in lieu of injection, such as via intranasal or oral administration.

Biopharmaceuticals

Research

We create proteins (therapeutic proteins and monoclonal antibodies) and small molecules as therapeutic agents for the treatment of cancer and infectious diseases. The drug discovery process is

somewhat different for these therapeutic modalities but starts with the identification and validation of targets using a variety of technologies.

With small molecules, the initial drug starting points are identified by high throughput screening, and structure based drug design, if the structure of the target has been solved. Optimization of potency, selectivity and drug properties are followed by in vivo testing and further improvements.

Proteins produced naturally by the human body play a variety of roles, including controlling disease. Administered as therapeutic agents, some proteins or specific antibodies can enhance the patient's natural ability to fight disease. As in the small molecule development process therapeutic proteins and antibodies can be engineered to improve their activity and drug properties, and genetically engineered cells can produce large quantities of the proteins at reasonable cost.

Development

Our Biopharmaceuticals business unit focus is in oncology and infectious disease. We conduct clinical trials by contracting some services with Clinical Research Organizations. Chiron is subject to the general risks of drug development, and as such, we expect both pipeline advancement and attrition in any given year.

Development Infectious Disease

Chiron continues to build its portfolio of products to treat and prevent infectious disease.

Tifacogin Tifacogin (recombinant Tissue Factor Pathway Inhibitor), a coagulation inhibitor, was developed in collaboration with Pfizer, Inc. (formerly Pharmacia & Upjohn, Inc.). In October 2003 Chiron acquired all of Pfizer, Inc.'s interest in tifacogin, in return for which Pfizer will receive royalties on sales of tifacogin. We are initiating plans for a Phase III trial for tifacogin in patients with severe community-acquired pneumonia.

Daptomycin We acquired rights in the antibiotic daptomycin for certain countries outside of the U.S. from Cubist Pharmaceuticals, Inc. Daptomycin has been approved by the FDA for the treatment of complicated skin and skin structure infections caused by Gram-positive bacteria. We are determining the regulatory path forward for daptomycin in the European union.

Cyclosporine for Inhalation We acquired worldwide development and commercial rights from Novartis for aerosolized cyclosporine (ACsA), a therapy under evaluation for treatment of acute rejections in lung transplant recipients. We plan to file an NDA in 2004.

TOBI® (tobramycin) for Inhalation We are working to develop and register a product combining TOBI® and a new inhalation device. In December 2001, we entered into a collaboration with Nektar Therapeutics, Inc. (formerly Inhale Therapeutic Systems, Inc.) to develop a dry powder formulation of TOBI® for use with such new device. Our goal is to improve convenience through the development of a portable device which will reduce the time to deliver TOBI® to the cystic fibrosis patient's lungs. We initiated Phase I clinical trials in 2003 to test the new device and the dry powder formulation of TOBI. We anticipate Phase I results for this study in the first half of 2004 and, based on an understanding with the FDA, may move directly to Phase III testing.

SILCAAT Proleukin® (aldesleukin), a recombinant protein already approved for marketing as a treatment for certain forms of kidney and skin cancer, is being clinically evaluated for treatment of patients with HIV infection through an agreement between Chiron, the National Institutes Allergy and Infectious Disease (NIAID) and University of Minnesota.

Development Oncology

Chiron's oncology franchise has three dimensions: immune-based therapies, monoclonal antibodies and novel cancer agents.

Proleukin® (aldesleukin) for injection plus rituximab We are expanding enrollment in the Phase II study of Proleukin (aldesleukin) for injection plus rituximab in patients with low-grade non-Hodgkin's lymphoma who have failed rituximab therapy. In addition, a new controlled study will be initiated to study Proleukin plus rituximab in rituximab-naïve patients to determine the combination's potential as an early treatment option in non-Hodgkin's lymphoma.

Tezacitabine We are conducting a Phase II clinical trial for tezacitabine, one of several novel cancer therapies we are developing, to study the compound's safety and efficacy as a second-line therapy in gastroesophogeal cancer.

GFKI We have initiated Phase I clinical trials for a growth factor kinase inhibitor, GFKI, Chiron's first small-molecule oncology compound.

Anti-CD40 We are planning to file an investigational new drug application (IND) for a monoclonal antibody oncology compound, anti-CD40, in 2004.

Cardioxane dexrazoxane We are analyzing results of a clinical trial and considering a submitting license amendment in the E.U.

Development Discontinued Projects

During the year the following projects were discontinued:

PA-2794 In addition to our collaboration with Nektar regarding TOBI®, we entered into a collaboration with Nektar in June 2002 to develop a dry powder formulation of PA-2794, a proprietary anti-infective for treatment of lung infections. Development of PA-2794 was discontinued in 2003.

Angiozyme In 2003, we discontinued our research and development of Angiozyme, a synthetic ribozyme designed as an angiogenesis inhibitor for cancer and developed jointly in a collaboration led by Sirna Pharmaceuticals, Inc. (formerly Ribozyme Pharmaceuticals).

Research and Development Expenses and Related Revenues

Research and development expenses for the years ended December 31, 2003, 2002 and 2001 for Chiron-sponsored research, including payments to collaboration partners, was $409.8 million, $325.8 million and $344.4 million, respectively. Under contracts where we recognize revenue based upon research and development work performed, the revenues amounted to $16.8 million, $19.5 million and $30.2 million in 2003, 2002 and 2001, 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.

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 marketing rights are assigned to the collaborator, we often retain the right to manufacture and supply key raw materials; and

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. Agreements under which we currently derive royalty revenues for technologies licensed to third parties include:

- an agreement with Bayer Corporation relating to, among other things, use of Chiron's hepatitis C virus and HIV technologies for nucleic acid amplification in *in vitro* diagnostics;
- agreements relating to hepatitis B virus vaccines;
- an agreement with GlaxoSmithKline plc relating to recombinant vaccine manufacturing technology;
- agreements with Novo Nordisk AS relating to technology used in the manufacture of recombinant human insulin and glucagon;
- a license to Abbott Laboratories, Inc. under our hepatitis C virus related patents for use in nucleic acid amplification in clinical diagnostics, excluding blood screening;
- licenses to F. Hoffmann-LaRoche Limited 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; and
- a license to Baxter under our hepatitis C virus and HIV related patents for use in plasma fractionation.

Sales and Marketing

We maintain several specialized marketing and sales forces that concentrate on individual classes of customers and markets.

Our blood testing global marketing, U.S. sales and global distribution organization for nucleic acid testing products is based in Emeryville, California and has representatives around the world. Our two primary regional offices are located in Paris, France and Hong Kong, China. We sell products to the public sector through tenders and to private sector blood banks and hospitals directly and through distributors.

Our vaccine international marketing organization and our marketing and sales organization for the German market are based in Marburg, Germany. Our marketing and sales organization for the Italian market is headquartered in Siena, Italy. Our sales and marketing organization for the United Kingdom market is based in Oxford, United Kingdom and we plan to further enhance our marketing organization in the U.S., which will be based in Philadelphia. Currently we market our influenza vaccine in the U.S. through a network of specialist distributors. Generally, we focus our direct sales efforts on pediatricians and general practitioners. We also sell products to the public sector through tenders (a bid solicitation process) and to private sector pharmacies directly and through wholesalers and distributors.

Our biopharmaceutical marketing and sales organization for the U.S. is headquartered in Emeryville, California, and its European operation is headquartered in London, England. We focus our sales efforts on specialist physicians, principally oncologists and pulmonologists, who are based in hospitals and large clinics. Generally, we sell products to wholesalers, distributors, clinics and hospital pharmacies.

Patents

Patents are very important to our business. We have a policy of seeking patents on inventions arising from our research and development activities. The time and expense required to develop and obtain regulatory approval to market human healthcare products is significant. Without the protection of patents or trade secrets, competitors may be able to use our inventions to manufacture and market competitive products without being required to undertake the lengthy and expensive development efforts made by us. We also receive significant revenue through the licensing of these patents to third parties. We have a substantial number of granted patents and pending patent applications in the U.S. and other important markets. Additionally, we have licensed a number of patents and patent applications from third parties. Additional information is provided below on the certain patents held or licensed by Chiron that relate to our key products. The existence of such patents does not mean they are valid or can be enforced against competitive products. We seek term extensions for some patents, which are available in certain countries based on delays in the grant of regulatory approvals for the sale of products covered by these patents. For these reasons the expiration dates provided below are not definitive.

Trade secrets and confidential information are also important to our commercial success. Although we seek to protect trade secrets and confidential information, others may obtain access to such information or develop the same or similar information independently. Also, third parties may obtain patent protection that precludes us from using our trade secrets or confidential information.

Blood Testing

The Procleix® HIV-1/HCV Assay is covered by numerous patents held by Chiron in the U.S. and worldwide. These patents contain claims directed to methods of hybridization, methods for determining the presence of the hepatitis C virus in a sample and to probes/primers utilized in such a process. The hepatitis C virus patent family expire in the U.S. in 2015 and 2016 and expire in Europe in 2010. The earliest family of European HIV related patents expires in 2005. The Procleix® System product line is also covered by several patents held by Gen-Probe Incorporated and licensed to Chiron.

The hepatitis C virus immunoassay diagnostic products sold by our joint business contractual arrangement with Ortho-Clinical Diagnostics, Inc. are covered by numerous patents in the U.S. and worldwide. These patents contain claims directed to hepatitis C virus immunoassay methods, kits and hepatitis C virus polypeptides. In the U.S., patents expire between 2011 and 2017. The earliest European family of patents expire in 2010.

The HIV immunoassay diagnostic products sold by our joint business contractual arrangement with Ortho-Clinical Diagnostics, Inc. are covered by numerous patents in the U.S. and worldwide. The earliest patents expire in 2019 in the U.S. and 2005 in Europe.

Chiron owns additional HCV and HIV patent families and pending applications.

Vaccines

Fluad®, our adjuvanted flu vaccine, contains the proprietary adjuvant MF-59. The U.S. and German patents containing claims related to MF-59 expire in 2018 and 2010, respectively.

Biopharmaceuticals

One of the earliest patent families that relate to Betaseron® interferon beta-1b and Betaferon® in the U.S. and Europe relate to serine-17 interferon-beta protein used in manufacturing the product. The U.S. patent in this family expires in 2007. The European patent in this family expires in 2008.

The patent family related to our first generation TOBI® tobramycin product includes claims related to product formulation and methods of treating *pseudomonas aeruginosa* infections. The U.S. and European patents expire in 2014 and 2015, respectively.

Chiron owns or is the exclusive licensee of various patent families related to IL2, Proleukin® (aldesleukin), the serine-125 Interleukin-2 mutein product, and uses thereof. The patents related to the Proleukin® product will expire in the U.S. in 2006-2012 and in Europe in 2004-2005.

Chiron owns additional pending patent applications directed to the use of IL2 in combination therapy in oncology or infectious disease.

Chiron owns patent applications related to the use of TFPI or TFPI analogs in severe pneumonia. Any eventual patent in this family will expire in 2022.

Trademarks

Registered trademarks of Chiron and our subsidiaries:

Proleukin®

TOBI®

Procleix®

Fluvirin®

Menjugate®

Fluad®

Agrippal®

Rabavert®

RIBA®

Rabipur®

Trademarks of Chiron and our subsidiaries:

Begrivac

Encepur

Polioral

Triacelluvax

Ultrio

Optiva

Cardioxane

Arilvax

This report also includes trademarks, service marks and trade names of other companies.

Seasonality

Sales of certain of our products, particularly flu vaccines, are seasonal, with higher sales in the third and fourth quarters of the year. Encepur , our vaccine against tick-borne encephalitis, is also seasonal with higher sales in the first half of the year.

Major Revenue Sources

We have an agreement with Berlex Laboratories, Inc. and its parent company, Schering AG of Germany for Betaseron® interferon beta-1b. Revenues recognized under this agreement, together with certain other arrangements with Berlex Laboratories and Schering, contributed 11% of our consolidated total revenues in 2003, 13% of our consolidated total revenues in 2002 and 12% of our consolidated total revenues in 2001.

Competition

We operate in a highly competitive environment, and we expect competition to increase. Competitors include large pharmaceutical, chemical and blood testing companies, and biotechnology companies. Some of these competitors, particularly large pharmaceutical and blood testing companies, have greater resources than us. Chiron 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 advertising, 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

We are the sole manufacturer of hepatitis C virus antigens for use in immunodiagnostic assays of the Ortho-Clinical Diagnostics, Inc. joint business contractual arrangement. 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 with the introduction of the 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, have substantial positions in the market segment.

The Procleix® system 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-LaRoche, 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 develop 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.

Currently we are in multi-year contracts though the tender process with the public sector blood services of many countries with the most significant ex-U.S., in terms of size, being the United Kingdom, Belgium, France and Australia.

In addition, in 2002 we signed a multi-year agreement with the American Red Cross, which represents approximately 50% of the 14 million units of blood collected in the U.S. each year.

Vaccines

Four large companies hold the majority share of the worldwide vaccine market: Merck and Company, Inc., GlaxoSmithKline plc, Wyeth and Aventis Pasteur. Chiron is the world's fifth largest vaccines company. Aventis Pasteur has a strategic alliance with Merck in Europe. All of these companies have substantial research and development programs. Additionally, there are a number of biotechnology companies involved in research programs, primarily involving a limited range of vaccines.

The competitive factors in vaccines are proven ability to supply product (particularly for flu sales in the U.S.), price, the introduction of new products, including vaccines against diseases for which no vaccine was previously available, and new combination vaccines that combine existing vaccines for several diseases into 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.

We believe flu vaccines remain competitive in all markets. Competition varies by market according to product license approvals. All flu vaccines producers, including Chiron, face an annual change in flu strains, which can act as a barrier for new competitors.

Menjugate®, our meningococcal C vaccine, faces competition from vaccines produced by two other companies, both of which participated in tenders. These companies are also competing for future meningococcal vaccine business in the worldwide market.

Biopharmaceuticals

Betaseron® interferon beta-1b, as a treatment for multiple sclerosis, competes with Avonex®, a recombinant beta interferon sold by Biogen, Inc., Rebif®, a recombinant beta interferon from Serono, S.A., marketed and sold in the U.S. by Pfizer Inc., and with Copaxone® from Teva Pharmaceutical Industries, Ltd. Novantrone® is marketed and sold by Serono for the treatment of secondary progressive multiple sclerosis. Other companies have treatments for multiple sclerosis in clinical development.

TOBI® tobramycin is the first and only inhaled antibiotic solution to be approved by the U.S. Food and Drug Administration. Pursuant to the U.S. Food and Drug Administration's orphan drug regulations, TOBI has limited exclusivity in the U.S. through December 2004. However, the use of oral and intravenous antibiotics to treat pseudomonal and other bacterial infections is well established. 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 generic tobramycin, oral replacement enzymes to maintain nutrition and mucolytics to clear pulmonary secretions.

Proleukin® (aldesleukin) is the only product approved by the U.S. Food and Drug Administration to treat metastatic renal cell carcinoma and one of two approved treatments for metastatic melanoma.

However, there are numerous products that are used to treat both cancers on an off-label basis, including alpha interferons sold by F. Hoffmann-LaRoche Limited and Schering-Plough Corporation. Other competitors include Eli Lilly and Company, Bristol-Myers Squibb

Company and Celgene Corporation.

Government Regulation

Regulation by governmental authorities in the U.S. and other important markets is a significant factor in the manufacture and sale of Chiron's products and in our research and development activities.

Blood Testing

In the U.S., blood testing products, whether based upon immunodiagnostic or nucleic acid testing technologies, may only be used pursuant to the terms of approval of specific license applications in which the product's safety and effectiveness must be demonstrated based upon well controlled studies. Upon approval of the license application, the product may be marketed for the specific uses, which were identified in the approval. Facilities, processes and operations used for the manufacture, testing, storage and distribution of Chiron's blood testing products in the U.S. are subject to U.S. Food and Drug Administration approval and periodic inspection.

In Europe, our blood testing products are regulated through the In Vitro Diagnostic Medical Devices Directive. During the transition period that ended in December 2003, manufacturers and distributors of *in vitro* diagnostic devices could sell these products under the current local country regulations or under the provisions of the Directive. The Procleix® HIV-1/HCV Assay and Procleix® Ultrio Assay are in compliance with the IVD Directive that went into effect December 6, 2003.

For all our products, the time and expense needed to complete the required clinical studies, prepare and submit the required applications and supporting documentation and respond to inquiries generated by regulatory review can far exceed the time and expense of the research initially required to create the product. These factors largely determine the speed with which a successful research program is translated into a marketed product.

Biopharmaceuticals and Vaccines

In the U.S., Chiron's therapeutic and vaccine products (both commercial and investigational) are primarily regulated under federal law and are subject to rigorous U.S. Food and Drug Administration approval procedures. No product can be marketed in the U.S. until an appropriate application is approved by the U.S. Food and Drug Administration. The U.S. Food and Drug Administration applies the approval procedures on a product-by-product basis and typically requires, among other things, an extensive three-phase human clinical testing program. In Phase I, studies are conducted with a relatively small number of subjects to assess the safety of the product. In Phase II, the product is evaluated in a larger group of subjects to begin to assess efficacy and appropriate dosing. Phase III studies are conducted in the target population with a number of subjects that is large enough to provide sufficient data to establish statistically the safety and efficacy of the product. The U.S. Food and Drug Administration approves products to treat specified medical conditions or disorders. Further studies would be required to market the product for other uses. The U.S. Food and Drug Administration must inspect and approve all facilities used to manufacture, fill, test and distribute biologic products. If any change in manufacturing facilities or processes occurs after U.S. Food and Drug Administration approval, additional regulatory review and possibly additional clinical studies may be required.

Licensing procedures in Europe are comparable to those in the U.S. In 1995, the European Union established a centralized procedure for licensing of products derived from the use of high technology/biotechnology processes. This procedure leads to the grant of a single license for the entire European

Union. Effective January 1, 1998, the European Union has also adopted a decentralized procedure under which a license granted in one member state is mutually recognized by the other member states, leading to a grant of licenses in member states recognizing the original license. This procedure is replacing independent national licensing of products in the European Union. In addition, products must receive specific country pricing approvals before they can be marketed in that country.

Compliance with Environmental Laws

We do not expect expenses for compliance with environmental laws to have a material impact upon our capital expenditures, earnings or competitive position.

Employees

As of December 31, 2003, Chiron and its subsidiaries had 5,332 employees.

Relationship With Novartis AG

In January 1995, we established an alliance with Novartis, a life sciences company headquartered in Basel, Switzerland. As of January 31, 2004, Novartis owned 42% of our outstanding common stock.

We have entered into a series of agreements with Novartis as discussed in Note 9, "Related Party Transactions," of Notes to Consolidated Financial Statements, which provide, among other things and subject to certain conditions and exceptions:

Novartis will not increase its ownership interest in Chiron above 55% unless it acquires all of Chiron's outstanding capital stock in a "buy-out" transaction. Novartis may exceed this amount and increase its ownership interest up to 79.9% in a transaction approved by a majority of the independent members of Chiron's Board of Directors.

Novartis has the right to nominate three members to Chiron's twelve member Board of Directors. The number of directors that Novartis may nominate declines if Novartis' ownership interest in Chiron is less than 30%.

Novartis provided certain funding to Chiron for research on certain adult and pediatric vaccines, Insulin-like Growth Factor-I, Factor VIII and Herpes Simplex Virus-thymidine kinase. Funding under this agreement ended December 31, 2001. In exchange for providing this funding, Novartis has certain co-promotion rights for certain vaccines and an interest in certain royalties on sales of certain products resulting from the funded research.

Novartis will guarantee certain indebtedness on behalf of Chiron through January 1, 2008.

Chiron may require Novartis to purchase shares of Chiron's common stock directly from Chiron at fair market value, up to a maximum subscription amount (initially $500.0 million, subject to adjustment based on other purchases made by Novartis under related agreements or otherwise).

Novartis has an option to purchase newly issued shares of Chiron's common stock directly from Chiron at fair market value, subject to the standstill restrictions described above.

Chiron and Novartis will cooperate in research, development, manufacturing and marketing of biotechnology products on an arm's-length basis while remaining independent to pursue their respective corporate strategies and opportunities.

ITEM 2. PROPERTIES

Emeryville Campus

Our principal executive offices are located in Emeryville, California. As of December 31, 2003, our campus consisted of 25 buildings, of which 15 are leased and 10 are owned. Our Emeryville facilities include research and development, manufacturing and administrative facilities and a parking structure for our biopharmaceutical, vaccine and blood testing businesses.

Other Facilities

In 2003, Chiron's Board of Directors approved $50.7 million in expenditures for a 25-year lease for buildings and $42.2 million for capital improvements, both of which are part of a $97.0 million project for a new flu vaccines manufacturing facility in Liverpool, England. The new manufacturing facility will replace existing flu vaccines manufacturing facilities in Liverpool, England.

We also own and lease manufacturing facilities in Vacaville, California used principally for our biopharmaceutical business. The owned facility has available capacity due to lower than expected demand for certain of our products and improved production yields from other facilities. As a result, we have entered into contract manufacturing agreements to utilize this available capacity (see the Biopharmaceuticals section in Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" below).

We have the following facilities for our vaccines operations:

Owned

- Manufacturing, administrative and research and development facilities in Rosia, Italy;
- Manufacturing, administrative and research and development facilities in Siena, Italy;
- Manufacturing facilities in Liverpool, England; and
- Manufacturing facilities in Ankleshwar, India

Leased

- Manufacturing facilities in Liverpool, England;
- Administrative and research and development facilities in Oxford, England;
- Administrative and research and development facilities in Madison, Wisconsin;
- Manufacturing and administrative facilities in Solna and Matfors, Sweden;
- Manufacturing, research and development facilities in Marburg, Germany;
- Administrative and sales offices in Mumbai, India;
- Sales office in Thailand;
- Sales office in China;
- Sales office in Brno-Slatina, Czech Republic; and
- Administrative and warehouse facilities in Amsterdam, The Netherlands.

We have the following facilities for our biopharmaceutical operations:

- research and development and administrative facilities in Seattle, Washington (leased);

manufacturing and distribution facilities in Annandale, New Jersey (leased);

several sales offices in Europe and Canada (leased); and

a sales and marketing and administrative facility in Cranford, England (owned).

We owned research and development, manufacturing and administrative facilities in Claremont, California. We used the facilities principally for our former ophthalmic products business, which we sold to Bausch & Lomb Incorporated in December 1997. Bausch & Lomb occupied a significant

portion of the facilities under a three-year lease, which expired in December 2000. We sold the last warehouse on the Claremont campus in April 2001.

We lease a number of other facilities in North America and Europe primarily for sales and service offices.

We believe that our current facilities are in good operating condition and are adequate for our current needs; however, we are expanding to meet future requirements. We continually evaluate future requirements for our facilities.

ITEM 3. LEGAL PROCEEDINGS

Average Wholesale Price Litigation

The Office of the Inspector General of the United States Department of Health and Human Services is investigating pharmaceutical industry practices concerning reporting of average wholesale prices for products covered by Medicare and Medicaid. Chiron and a number of other companies have received document subpoenas in connection with that investigation. Chiron has produced documents responsive to two subpoenas, which relate specifically to pricing of certain generic oncology drugs sold by Cetus-Ben Venue Therapeutics, a joint venture between Chiron and Ben Venue Laboratories. Chiron sold its interest in that joint venture in 1996. It appears that the Office of the Inspector General's investigation is connected to a pending, but as yet unserved, qui tam (whistle blower) lawsuit, in which Chiron and other companies are named defendants.

Certain State Attorneys General also are investigating reporting of average wholesale prices related to State Medicaid programs. In September 2000, the Office of the Attorney General of the State of California Department of Justice propounded a document subpoena to Chiron focused on pricing of certain generic oncology drugs sold by Cetus-Ben Venue under the Medi-Cal program. In December 2003, the Attorneys General for the States of Florida and Kentucky informed Chiron that they were investigating Chiron's calculation and reporting of the average manufacturer price and best price to the Center for Medicare and Medicaid Services and the Health Care Financing Administration.

It is anticipated that additional lawsuits involving the average wholesale price issues for these and other products sold by Chiron through Medicaid and/or Medicare may arise. If any such action resulted in a final judgment against Chiron, Chiron could face substantial damages exposure. It is not currently possible to estimate the probability of loss or to estimate the amount of liability related to these matters.

In February 2002, the State of Montana through its Attorney General filed a complaint in the First Judicial District Court in Lewis and Clark County against numerous biotechnology and pharmaceutical companies, including Chiron, in connection with setting average wholesale prices for various products, including DepoCyt®, that are reimbursed by Medicare and Medicaid. In March 2002, a similar suit was filed by the State of Nevada's Attorney General in the Second Judicial District Court in Washoe County against Chiron. Between July and September 2002, three similar class action lawsuits were also filed in two California Superior Courts against Chiron (the "California Actions"). In each suit, Plaintiffs alleged that Defendants violated respective state and common laws, and sought both compensatory and punitive damages. In October 2002 and February 2003, the Montana, Nevada and California actions were coordinated and consolidated with the In re Pharmaceutical Industry Average Wholesale Price Litigation pre-trial proceedings. In August 2003, the States of Montana and Nevada both filed amended complaints that did not name Chiron as a defendant. As of February 2004, all claims in the California Actions were dismissed with prejudice respect to Chiron. Therefore, Chiron is no longer a party to any of these actions.

In January 2003, the County of Suffolk filed a complaint in the United States District Court for the Eastern District of New York against 29 biotechnology and pharmaceutical companies, including

Chiron, in connection with setting average wholesale prices for various products, including TOBI®, which are reimbursed by Medicaid. Plaintiff alleged that defendants violated federal racketeering laws, federal and state laws on Medicaid fraud, and state laws on unfair trade practice, breach of contract, fraud and unjust enrichment by devising and implementing a fraudulent pricing scheme against Medicaid beneficiaries, and sought declaratory relief, as well as compensatory and punitive damages.

It is not known when nor on what basis these matters will be resolved.

F. Hoffmann-La Roche Ltd. and Roche Molecular Systems, Inc. HIV

On March 11, 2003, the U.S. Patent and Trademark Office issued Chiron's U.S. Patent No. 6,531,276 (addressed to Methods For Detecting Human Immunodeficiency Virus Nucleic Acid) (the "'276 Patent"). Chiron asserts that under its October 10, 2000 HIV Probe License Agreement and the January 1, 2001 HIV Blood Screening Agreement (the "License Agreements") with F. Hoffman-La Roche Ltd. and Roche Molecular Systems (collectively, "Roche"), that Roche is obligated to pay certain licensing fees and ongoing royalties for the sale of certain Roche HIV nucleic acid tests which infringe the '276 Patent. Roche disputes these obligations on a variety of grounds including non-infringement and invalidity. Roche further contests the rate at which royalties must be paid if in fact its products are covered by the License Agreements. In November 2003, Chiron initiated an arbitration against Roche pursuant to the rules of the CPR Institute for Dispute Resolution. The arbitration is currently scheduled to begin in June, 2004.

It is not known when nor on what basis this matter will be resolved.

F. Hoffmann-La Roche A.G. and Roche Diagnostics GmbH HCV

In September 1999, F. Hoffman-LaRoche AG ("Roche") filed an appeal with the Court of Appeals in Dusseldorf, Germany, regarding a Regional Court's decision to enjoin Roche from the import, use, possession and sale of certain hepatitis C virus immunoassay products in Germany based on Chiron's EP 0 318 216 (the "'216 patent"). After withdrawing certain claims from the '216 patent, Chiron rescinded that injunction and substituted EP 0 450 931 (the "'931 patent") and Chiron's German Patent Nos. DD 298 527, DD 298 524 and DD 287 104 (collectively, the "German Patents") in the appellate proceeding. In October 2003, the Court of Appeals ruled that Roche's HCV immunoassay kits containing a certain antigen infringe all three German Patents. Accordingly, the Court of Appeals granted Chiron the right to enjoin Roche from the import, use, possession and sale of such kits in Germany. Chiron has enforced the injunction. Roche is attempting to appeal this decision to the German Federal Supreme Court.

In July 2000, Chiron filed suit against Roche Diagnostics GmbH ("Roche Diagnostics") in the German Federal Court ("Landgericht") in Dusseldorf, Germany, asserting that Roche Diagnostics' manufacture and sale of hepatitis C immunoassay products infringe Chiron's German Patent No. DD 298 524 (the "'524 patent"). In July 2003, the Landgericht decided that Roche Diagnostics' HCV immunoassay kits containing a certain antigen infringe Chiron's '524 patent. Accordingly, the Landgericht granted Chiron the right to enjoin Roche Diagnostics from the import, use, possession and sale of such kits in Germany. In August 2003, Chiron enforced the injunction against Roche Diagnostics. In November 2003, Roche Diagnostics filed an appeal with the Court of Appeals.

In December 2000, Roche Diagnostics initiated nullity proceedings before the German Federal Patent Court ("Bundespatentgericht") regarding Chiron's '931 patent and the German Patents. In August 2002, the Bundespatentgericht upheld the validity of the German Patents, but nullified the German portion of the '931 patent. In November 2002, both Chiron and Roche Diagnostics filed appeals before the Federal Supreme Court regarding the Bundespatentgericht's nullity decisions. Certain infringement actions related to the '931, '104 and '527 nullity proceedings are currently stayed pending the outcome of these appeals.

It is not known when nor on what basis these matters will be resolved.

German Red Cross Donation Service and Working Society of Physicians

In October 2001, the German Red Cross Donation Service and Working Society of Physicians brought a complaint against Chiron and Hoffman-La Roche before the Commission of the European Communities (the "Commission"). These matters generally alleged that Chiron and Roche have engaged in certain anticompetitive actions that violate Articles 81 and 82 of the Treaty Establishing the European Community (the "EC Treaty") in connection with HIV and hepatitis C virus nucleic acid tests in blood screening. The complainants sought a determination that Roche pricing for its blood screening kits based upon the number of donations tested is unreasonable and should be prohibited through interim measures to be ordered by the Commission prior to final resolution of the action. Blood banks from The Netherlands, United Kingdom, Finland and Luxembourg filed similar complaints against Chiron and Roche in about February of 2002. Chiron contested all of these complaints.

In July 2003, the European Commission accepted a joint settlement proposal made by Chiron and Roche. As part of the settlement, Chiron and Roche agreed to modify certain terms of their agreements under which Roche has licensed Chiron's hepatitis C virus and HIV-1 intellectual property for use in nucleic acid testing products in Europe. In resolving their inquiry, the European Commission concluded that the modified agreements satisfy the criteria for an individual exemption under Article 81(3) of the Treaty.

Laboratory Corporation of America Holdings

In April 2003, Chiron filed a complaint in the United States District Court for the Northern District of California against Laboratory Corporation of America Holdings ("LabCorp Holdings"), Laboratory Corporation of America ("LabCorp") and National Genetics Institute ("NGI") (collectively, the "Defendants"), seeking damages and an injunction against Defendants' manufacture, use and sale of the UltraQual HCV RT-PCR assay and HCV SUPERQUANT assay for infringing Chiron's U.S. Patent No. 6,074,816 (the "'816 patent"). The Defendants filed a complaint in the United States District Court for the District of Delaware against Chiron seeking a declaratory judgment that Defendants infringe neither the '816 patent, nor U.S. Patent Nos. 5,712,088, 5,863,719, 6,074,816, and 5,714,596 (collectively, the "Chiron Hepatitis C virus-related patents"), and that the Chiron Hepatitis C virus-related patents are invalid. In August 2003, the Delaware Court granted Defendants' motion to enjoin Chiron from proceeding with the California action and compel Chiron to dismiss that action. Chiron has appealed this judgment to the United States Court of Appeals for the Federal Circuit, and a hearing is scheduled for March 2004. The Delaware Court has scheduled a trial for May 2005.

In August 2003, Chiron filed a complaint in the United States District Court for the Northern District of California against Laboratory Corporation of America Holdings, Laboratory Corporation of America and National Genetics Institute (collectively, the "Defendants"), seeking damages and an injunction against Defendants manufacture, use and sale of certain HIV assays for infringing Chiron's U.S. Patent No. 6,531,276 (the "'276 patent"). In February 2004, Chiron voluntarily dismissed this case without prejudice and refiled the complaint before the United States District Court for the Central District of California.

It is not known when nor on what basis these matters will be resolved.

Institut Pasteur

In April 2003, Institut Pasteur filed a complaint in the United States District Court for the District of Columbia against Chiron seeking reversal of certain judgments entered by the Board of Patent Appeals and Interferences (the "Board") of the United States Patent and Trademark Office in Patent Interference No. 103,659 (the "'659 Interference"). The '659 Interference involved claims in Chiron's

U.S. Patent No. 5,156,949 (the "'949 patent") and in certain U.S. patent applications assigned to Institut Pasteur (the "Chang applications"), relating to HIV immunodiagnostic methods. In the '659 Interference, the Board decided that the inventors of Chiron's '949 patent were the first to invent the technology at issue. Institut Pasteur asks the Court to reverse the Board's decision.

It is not known when nor on what basis this matter will be resolved.

Active Biotech AB

In June 2003, PowderJect Pharmaceuticals Plc ("PowderJect") filed a Request for Arbitration before the Arbitral Tribunal of the Arbitration Institute of the Stockholm Chamber of Commerce in Sweden against Active Biotech AB ("Active Biotech"). PowderJect claims that Active Biotech breached certain warranties and representations made in the July 2, 2001 Agreement by which PowderJect acquired SBL Vaccin AB ("SBL") from Active Biotech (the "Agreement"). PowderJect seeks compensatory damages and legal fees. The arbitration hearing is currently scheduled to begin in April 2004.

It is not known when nor on what basis this matter will be resolved.

Sorin Biomedica/Snia

In June 1994, Sorin Biomedica S.p.A. ("Sorin") filed a lawsuit with the Court of Milan, Italy against Chiron and Ortho Diagnostic Systems S.p.A. seeking a declaration of nullity and non-infringement of the Italian counterpart to Chiron's European Patent 0 318 216 (the "'216 patent") claiming hepatitis C virus immunodiagnostic technology. Chiron denied Sorin's allegations and filed a counterclaim seeking a declaration of infringement. In February 1997, the Court enjoined Sorin from manufacturing or selling hepatitis C virus immunoassay kits in Italy. The Court ruled in October 1999 that certain '216 patent claims were valid and that Sorin's hepatitis C virus immunoassay infringed the '216 patent. In June 2000, the European Patent Office Technical Board Of Appeals upheld the validity of the '216 patent in an amended form which deleted claims that Chiron alleged to have been infringed by Sorin. In December 2000, Snia S.p.A., Sorin's parent company, ("Snia") filed an appeal in the Court of Milan asking the Court to declare the Italian portion of the '216 patent null and void and to award Snia damages. In March 2001, Chiron denied Snia's allegations and asked the Court to dismiss the case. In May 2002, the Court of Appeal of Milan declared that Snia's claims were inadmissible and dismissed Snia's appeal. In July 2003, Snia filed an appeal before the Supreme Court. Chiron in October 2003 filed its counter appeal.

In January 2002, Chiron filed a complaint against Snia in the Court of Milan asserting that Snia's manufacture and sale of certain hepatitis C virus immunodiagnostics in Italy infringe the '931 patent. Chiron seeks a declaration of infringement based on the '931 patent, as well as damages. Trial is currently scheduled for December 1, 2004.

It is not known when nor on what basis these matters will be resolved.

Sysmex Corporation

In March 2001, Chiron filed a complaint and petition for preliminary injunction with the Osaka District Court in Japan against Sysmex Corporation ("Sysmex") seeking damages and an injunction against Sysmex's manufacture and sale of the Ranream HCV II Ex kit for infringing Chiron's Japanese Patent No. 2733138 (the "'138 patent") claiming hepatitis C virus immunodiagnostic technology. Sysmex denied the infringement allegations and filed two invalidation appeals with the Japanese Patent Office Board of Appeals against the '138 patent. In February 2003, the Japanese Patent Office Board of Appeals, ruling on one of the invalidation appeals, found that the '138 patent was invalid. In May 2003, Chiron filed an appeal of the invalidation judgment before the Tokyo High Court. Furthermore, the second invalidation appeal has been stayed pending Chiron's appeal to the Tokyo High Court.

It is not known when nor on what basis these matters will be resolved.

Federal Express

On September 3, 1999, Federal Express Corporation filed suit in the Supreme Court of the State of New York, County of Orange against Perseptive Biosystems, Inc., Perkin-Elmer Corporation, PE Biosystems Group and PE Corporation (together, the "PE Defendants") and Chiron. The Federal Express Corporation complaint alleges that defendants are liable for damages caused by a fire that destroyed a Federal Express Corporation aircraft and the majority of its cargo in September 1996. Chiron owned and was shipping on the aircraft a machine that is alleged to have been involved in the fire. The machine was manufactured, serviced and packed for shipment by the PE Defendants.

It is not known when nor on what basis this litigation will be concluded.

Bayer Corporation

In January 2002, Bayer Corporation filed a complaint in the United States District Court for the District of Delaware against Chiron relating to the Stock Purchase Agreement dated September 17, 1998 between Chiron, Bayer Corporation and Chiron Diagnostics Corporation. Bayer Corporation alleges that Chiron violated certain representations and warranties made in the Stock Purchase Agreement and additionally seeks damages for alleged misrepresentation and fraud made in connection with the sale of Chiron Diagnostics Corporation. Based on these allegations, Bayer Corporation sought both compensatory and punitive damages. In April 2003, the parties settled the dispute and dismissed the case with prejudice except for Bayer's claim to indemnity for certain tax payments and for certain unasserted third party claims.

Roxane Laboratories, Inc.

In June 2003, Chiron and Children's Hospital and Regional Medical Center (collectively, "Plaintiffs"), filed a complaint in the United States District Court for the District of Delaware against Roxane Laboratories, Inc. ("Roxane") seeking damages and an injunction against Roxane's manufacture, use and sale or importation of an alleged generic version of Chiron's tobramycin solution for inhalation (TOBI®) described in Roxane's Abbreviated New Drug Application No. 65-105, for infringing Chiron's U.S. Patent No. 5,508,269 (the "'269 patent"). In October 2003, pursuant to a settlement agreement, the lawsuit was dismissed. Under the settlement terms, Roxane, which had previously withdrawn its U.S. Food and Drug Administration application for approval of a generic equivalent of TOBI®, agreed it would not seek U.S. approval to market the product until the '269 patent expires in 2014. Chiron and Children's Hospital agreed to dismiss their infringement relief claims against Roxane, and Roxane dropped its challenge to the '269 patent. No party received monetary compensation as part of the settlement. This matter is now concluded.

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

No matters were brought to a vote of Chiron's stockholders in the quarter ended December 31, 2003.

EXECUTIVE OFFICERS OF THE REGISTRANT

The executive officers of Chiron, who serve at the discretion of the Board of Directors, are as follows, in alphabetical order:

Name	Age	Title
Jack Goldstein	56	Vice President; President, Chiron Blood Testing
William G. Green	59	Senior Vice President, General Counsel and Secretary
John A. Lambert	51	Vice President; President, Chiron Vaccines
Seán P. Lance	56	Chairman of the Board
Leone D. Patterson	41	Vice President, Controller
Howard H. Pien	46	President and Chief Executive Officer
Rino Rappuoli	52	Vice President, Chief Scientific Officer
Linda W. Short	58	Vice President, Corporate Resources
David V. Smith	44	Vice President and Chief Financial Officer
Bryan L Walser	38	Vice President, Corporate Strategy
Craig A. Wheeler	43	Vice President; President, Chiron BioPharmaceuticals

Dr. Goldstein joined Chiron in September 2002 as Vice President and President, Chiron Blood Testing Division. From 2000 to 2002, Dr. Goldstein was General Partner at Windamere Venture Partners, L.L.C., a venture fund making investments in early stage biotechnology, pharmaceutical, medical device and diagnostic companies. From 1997 to 2001, Dr. Goldstein was President and CEO of Applied Imaging Corporation, a leading supplier of instrument systems for prenatal and cancer genetics. From 1999 until 2002, Dr. Goldstein also served as Chairman of the Board of Applied Imaging and continues to serve as a Director. From 1986 to 1997, Dr. Goldstein worked for Johnson & Johnson in various executive management positions, including President of Ortho Diagnostic Systems and Executive Vice President of Professional Diagnostics at Johnson & Johnson World Headquarters. Dr. Goldstein holds a B.A. degree in Biology from Rider University, an M.S. in Immunology and a Ph.D. in Microbiology from St. John's University.

Mr. Green joined Chiron as Vice President and General Counsel in October 1990, having served as Secretary or Assistant Secretary since Chiron's inception in 1981. Since March 2004, Mr. Green has served on a part-time basis as General Counsel, Secretary and member of the Management Committee of the Gordon & Betty Moore Foundation, a private, philanthropic foundation, in which Chiron directors, Lewis W. Coleman and Edward E. Penhoet also are employed respectively as the Chief Executive Officer and a Chief Program Officer. In February 1992, he became Senior Vice President, General Counsel and Secretary. In addition, from February through August 2002, Mr. Green served as President of Chiron's Blood Testing division. From 1981 to 1990, he was a partner in the San Francisco law firm of Brobeck, Phleger & Harrison.

Mr. Lambert joined Chiron as Vice President; President of Chiron Vaccines, in March 2001. Based in Europe, Mr. Lambert is responsible for the commercial operations of Chiron's global vaccines business. Prior to joining Chiron, Mr. Lambert headed John Lambert Associates, a company that provided consulting and coaching at the chief executive level to organizations both in the United Kingdom and internationally. From 1998 to 2000, Mr. Lambert was the President of Aventis Pasteur MSD, where he headed the vaccines venture formed between Pasteur Mérieux Connaught (now Aventis Pasteur) and Merck & Company, Inc. following four years as that company's Vice President of Operations. From 1998 to 1994, Mr. Lambert held various positions with the Pasteur Mérieux Connaught Group, in increasing levels of responsibility,

including Managing Director of Mérieux UK Ltd. Mr. Lambert also is the Vice-President of the European Vaccines Manufacturers. Mr. Lambert is a non-executive director of a U.K. Stock Exchange listed company, S.R. Pharma PLC in London,