

**CANGENE CORPORATION**  
**RENEWAL ANNUAL INFORMATION FORM**  
**2004**

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**GLOSSARY OF TECHNICAL TERMS**

The text following the technical terms reproduced in this glossary is explanatory only and does not in any way modify the meanings of such terms.

|                                             |                                                                                                                                                                                                                                               |
|---------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>antibody</b>                             | a specialized protein produced by blood cells that binds specifically to a foreign substance and inactivates it; autoimmune disorders occur when the body inappropriately produces antibodies against its own tissues                         |
| <b>Antigen</b>                              | see antibody                                                                                                                                                                                                                                  |
| <b>bioequivalence/<br/>bioavailability</b>  | comparison of a test drug with a reference (approved) drug                                                                                                                                                                                    |
| <b>biopharmaceuticals</b>                   | therapeutically-active substances derived from or related to gene sequences                                                                                                                                                                   |
| <b>Cangeneus™</b>                           | a proprietary gene expression system developed by Cangene that uses a type of bacteria, known as <i>Streptomyces</i> , as the production vehicle and is capable of expressing or producing selected proteins in commercially-relevant amounts |
| <b>CBRN</b>                                 | Chemical, biological, radiological or nuclear incidents                                                                                                                                                                                       |
| <b>CDC</b>                                  | Centers for Disease Control and Prevention; an agency of the U.S. Department of Health and Human Services                                                                                                                                     |
| <b>cGMP</b>                                 | Current Good Manufacturing Practices                                                                                                                                                                                                          |
| <b>DNA</b>                                  | deoxyribonucleic acid; the chemical in living cells that carries the heredity or genetic information of the organism                                                                                                                          |
| <b>expression system</b>                    | The cells into which a gene has been inserted to manufacture a desired protein                                                                                                                                                                |
| <b>FDA</b>                                  | United States Food and Drug Administration; the government agency that regulates the manufacture, use and sale of foods and drugs in the United States                                                                                        |
| <b>fermentation</b>                         | the biochemical process of converting raw materials into a desired product through the biological processes of an organism                                                                                                                    |
| <b>Follow-on protein product</b>            | a protein that is intended to be a similar version or copy of an already approved or licensed protein pharmaceutical product                                                                                                                  |
| <b>GAAP</b>                                 | Generally accepted accounting principles                                                                                                                                                                                                      |
| <b>gene</b>                                 | the hereditary unit; a segment of DNA coding for a specific protein                                                                                                                                                                           |
| <b>gene expression</b>                      | the production of proteins from encoded genetic information                                                                                                                                                                                   |
| <b>GM-CSF</b>                               | Granulocyte-Macrophage Colony-Stimulating Factor; a protein that normally stimulates the proliferation and maturation of certain infection-fighting white blood cells                                                                         |
| <b>HDN</b>                                  | hemolytic disease of the newborn; a serious immunological incompatibility between a pregnant woman and the fetus                                                                                                                              |
| <b>Hodgkin's and non-Hodgkin's lymphoma</b> | two types of lymphoma differentiated by certain cellular characteristics. Lymphoma is cancer of the lymphoid tissue.                                                                                                                          |

|                                          |                                                                                                                                                                                                                                                |
|------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>hyperimmune</b>                       | a highly purified preparation of specific antibodies made from specialty plasma                                                                                                                                                                |
| <b>immunoglobulin or immune globulin</b> | class of proteins that function as antibodies. Hyperimmunes are preparations of immune globulins.                                                                                                                                              |
| <b>indication</b>                        | symptom or circumstance that indicates the advisability or necessity of a particular medical treatment                                                                                                                                         |
| <b>ITP</b>                               | Immune thrombocytopenic purpura: an autoimmune disorder causing abnormal destruction of blood platelets, potentially leading to severe bleeding                                                                                                |
| <b>molecule</b>                          | a grouping of defined atoms joined in a particular way                                                                                                                                                                                         |
| <b>monoclonal antibody</b>               | antibodies made in the laboratory from a single source or clone of cells that recognize only one kind of antigen                                                                                                                               |
| <b>Mutual Recognition Procedure</b>      | A pan-European regulatory procedure to obtain marketing authorizations in European Union countries based on marketing authorization in member EU country                                                                                       |
| <b>nanofiltration</b>                    | a highly effective filtration process                                                                                                                                                                                                          |
| <b>NIAID</b>                             | U.S. National Institute of Allergy and Infectious Diseases                                                                                                                                                                                     |
| <b>Orphan Drug status</b>                | FDA designation for drugs approved to treat limited patient populations (<200,000 people); guarantees U.S. market exclusivity for seven years                                                                                                  |
| <b>passive immunity</b>                  | immediate but temporary immunity provided by a therapeutic dose of a concentrated antibody preparation—it fades with time and does not produce the memory effect that contracting an infectious disease or administration of a vaccine produce |
| <b>peptide</b>                           | a portion of a protein that may or may not have biological activity, and may share some or all activity with a larger protein counterpart                                                                                                      |
| <b>plasma</b>                            | the fluid (non-cellular) portion of blood                                                                                                                                                                                                      |
| <b>platelet</b>                          | small disk-shaped body in the blood—critical for normal blood clotting                                                                                                                                                                         |
| <b>polyclonal antibodies</b>             | a preparation that is obtained from the plasma of individuals who were either previously exposed to or were actively immunized against a specific antigen or antigens                                                                          |
| <b>protein</b>                           | a precise chain of amino acids, the sequence of which is specified through the genetic code, and which, when folded into its natural shape, will have a specific biological activity                                                           |
| <b>R&amp;D</b>                           | Research and development                                                                                                                                                                                                                       |
| <b>recombinant DNA (rDNA)</b>            | methodologies involving biochemical manipulation and rearrangement of genetic material (DNA). Recombinant proteins are made using recombinant DNA                                                                                              |

|                               |                                                                                                                                                                                                                                                                      |
|-------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Rh isoimmunization</b>     | antibodies formed in the bloodstream of a woman with a negative blood type against Rh <sup>+</sup> fetal blood                                                                                                                                                       |
| <b>SARS</b>                   | severe acute respiratory syndrome                                                                                                                                                                                                                                    |
| <b>solvent-detergent (SD)</b> | a process designed to inactivate certain viruses                                                                                                                                                                                                                     |
| <b>stem cell</b>              | undifferentiated cell that has the capacity to specialize into a specific type cell based on the type of chemical stimulus it receives. Transplantation can be used to repopulate a patient's blood with blood cells following chemotherapy or radiation treatments. |
| <b>VIG</b>                    | Vaccinia immune globulin                                                                                                                                                                                                                                             |

### **TRADEMARKS**

“Cangene”, “Cangenus”, “Leucotropin”, “VariZIG”, “WinRho”, “WinRho SDF” are trademarks belonging to Cangene Corporation. The term “WinRho” may be used in this document to refer to any of the WinRho family of products.

All other product names referred to in this document are the property of their respective owners.

### **CURRENCY**

Unless specified otherwise, dollar amounts are in Canadian dollars.

### **CORPORATE STRUCTURE**

#### **Name, Address and Incorporation**

Cangene Corporation (“Cangene” or the “Company” or the “Corporation”) was incorporated by Certificate and Articles of Incorporation under the *Business Corporations Act* (Ontario) on February 22, 1984. On December 5, 1984, the Articles of Cangene were amended to change the municipality in which Cangene’s registered office is located, and on July 30, 1991, the Articles of Cangene were further amended to create a class of preferred shares issuable in series. On September 27, 1991, the Articles of Cangene were amended to subdivide the common shares on a four-for-one basis.

Cangene’s registered office is located at 3403 American Drive, Mississauga, Ontario, L4V 1T4.

Cangene’s head office is located at 104 Chancellor Matheson Road, Winnipeg, Manitoba, R3T 5Y3.

## **Intercorporate Relationships**

Cangene Corporation owns 100% of the voting securities of Cangene U.S. Incorporated, which is incorporated in the State of Delaware in the United States. Cangene U.S. Incorporated owns 100% of the voting securities of Chesapeake Biological Laboratories, Inc. (“Chesapeake” or “CBL”), which is incorporated in the state of Maryland in the United States.

## **GENERAL DEVELOPMENT OF THE BUSINESS**

### **Three-Year History**

Cangene develops, manufactures and markets two types of products: specialty plasma products (hyperimmunes) and recombinant therapeutic proteins. In addition, the Company provides contract R&D and manufacturing services to the biopharmaceutical industry. For the hyperimmunes, the Company uses an innovative approach to manufacturing traditional plasma products giving it a high yield and product purity that separates it from traditional competitors. It has two approved hyperimmune products, three more that have been submitted for regulatory review in the U.S. and/or Canada, and others in various stages of development. The Company is pursuing a follow-on strategy for certain recombinant protein products it is developing; one of these has been submitted for regulatory review in Canada and it expects to file for the second in the coming months. Using its own efficient manufacturing processes, it plans to use a generic-style strategy to capitalize on the success of known commercial products.

An important factor in Cangene’s hyperimmune operation is its ability to obtain sufficient quantities of the type of plasma needed for manufacture of its hyperimmune products. Cangene collects a small portion of its plasma at two medium sized, wholly-owned subsidiaries—Biotherapeutic Laboratories, Inc. in Van Nuys, California and Mid-Florida Biologicals, Inc. in Altamonte Springs, FL and Frederick, MD—as well as at the Rh Plasma Center in Winnipeg.

Cangene’s lead hyperimmune product, WinRho® SDF, is approved widely for preventing hemolytic disease of the newborn, which is a serious blood-type incompatibility between a pregnant woman and the fetus. It is also approved in certain jurisdictions for treating ITP, an autoimmune condition. During fiscal 2004, Cangene began studying its use as a treatment for dengue hemorrhagic fever, a severe sequela of the mosquito-borne infection, dengue fever.

Cangene has a research and development agreement with Apotex Inc. (a member company of the Apotex Group, Cangene’s majority shareholder) to support the development of certain recombinant biopharmaceuticals through to initial regulatory filing. In return, Apotex will receive a 12% royalty on net sales of certain products developed pursuant to the research and development agreement and a further right to distribute the products. Apotex and Cangene will share profits equally after deducting royalty expenses. During the year ended July 31, 2004, the Corporation recorded revenue of \$9.3 million under this agreement. At December 10, 2004, the Apotex Group<sup>1</sup> controlled approximately 81% of issued and outstanding common shares of the Company. The Apotex Group has its head office in Toronto and is one of Canada’s largest domestically-owned pharmaceutical companies. It is a fully-integrated manufacturer and distributor of over 250 generic drugs in more than 115 countries, and has more than 5,300 employees across Canada.

(1) The Apotex Group includes: Apotex Inc., which holds 2,350,000 common shares of Cangene Corporation, Apotex Holdings Inc., which holds 37,707,808 common shares of Cangene Corporation and the Sherman Foundation, which holds 11,807,979 common shares of Cangene Corporation. The Apotex Group is indirectly controlled by Bernard Sherman through the Bernard and Honey Sherman Family Trust, of which he is the Trustee. Bernard Sherman is a director and president of the Sherman Foundation and as such controls the Foundation’s shareholding indirectly. Bernard Sherman also holds 110,000 common shares of Cangene Corporation directly.

Effective January 31, 2001, the Company completed the acquisition of Baltimore, Maryland based-Chesapeake Biological Laboratories, Inc. for consideration of \$52.8 million. Chesapeake is an established contract service-provider of pharmaceutical and biopharmaceutical product development and filling services for injectable and other sterile products. Cangene has paid down a significant portion of the debt that resulted from the Chesapeake acquisition during the last two years, and total debt outstanding at the end of fiscal 2004 was \$8.9 million.

Chesapeake serves a broad range of customers, from major international pharmaceutical firms to emerging biotechnology companies. The specialized development services it provides include: research and development on sterile product formulations, test method development and validation, process design and manufacturing validations, regulatory and compliance consulting, preparation of clinical trial and toxicology materials, container-closure system design, and accelerated and ongoing stability studies. During fiscal 2004, contract research and manufacturing revenue surpassed product sales and made up 58% of the Company's product and service revenue.

During fiscal 2002, Chesapeake was selected to provide the final filling, freeze-drying and finishing services for 155 million doses of smallpox vaccine that were being produced by Acambis Inc. and Baxter BioSciences for the U.S. Centers for Disease Control and Prevention ("CDC"). Also during fiscal 2002, Chesapeake constructed a viral vaccine-filling facility, which was used for filling the smallpox vaccine and expands Chesapeake's capabilities in working with viral products and vaccines.

On August 12, 2002, Cangene was selected by the CDC to develop and supply Vaccinia immune globulin ("VIG") for use in treating and preventing severe reactions that may be brought on by the administration of the smallpox vaccine. Under the five-year contract, Cangene will supply the U.S. government up to 100,000 doses of VIG on an as-needed basis. During fiscal 2004, activity on both CDC contracts wound-down as Cangene fulfilled its responsibilities or supplied the requirements of the initial order.

In March 2003, Cangene signed a marketing agreement with Acambis plc under which Acambis will market Cangene's VIG in jurisdictions outside North America and Israel.

Cangene was also awarded CDC contracts to develop a clinical-grade hyperimmune to be used as an adjunct to antibiotic therapy in critically ill patients with anthrax and a hyperimmune to counteract botulinum toxin (the toxin that causes botulism). Subsequent to the year-end, the CDC and U.S. Department of Health and Human Services identified Cangene as the only prospective contractor that possessed the necessary experience, capability and capacity to fulfil its requirements for up to 200,000 doses of botulinum toxin immune globulin. A contract has yet to be negotiated, but this could represent a significant opportunity for Cangene.

Cangene has entered a European marketing and distribution agreement with Baxter Healthcare S.A. Under the agreement, Baxter will market and distribute WinRho® SDF in Europe, excluding Portugal, for treating a blood clotting disorder called immune thrombocytopenic purpura ("ITP"). Baxter has already launched the product in the United Kingdom. Cangene is expanding this arrangement to include the United States through the affiliated Baxter Healthcare Corporation. Cangene has announced that it will not renew its WinRho® SDF distribution agreement with Nabi Biopharmaceuticals when the agreement expires in March 2005 and Baxter will become the U.S. distributor.

Cangene also entered a marketing and distribution agreement with BioGeneriX AG for Cangene's recombinant human growth hormone. Under the agreement, BioGeneriX will be the sole distributor of the product in the European market. BioGeneriX AG was founded in June 2000 by one of Europe's leading generic drug companies to develop biopharmaceutical drugs with known modes of action and established markets.

Resulting from an earlier licensing agreement, Cangene receives 50% of any net profits worldwide on a drug called deferiprone that Apotex developed and markets. As part of the same agreement, Apotex received warrants to purchase 5,300,000 common shares of Cangene at an exercise price of \$2.32 per share. One half of these warrants expired unexercised on November 5, 2001. The remaining warrants became exercisable when the Company's share of the profits reached \$2.0 million in a 12-month period; Cangene's received \$3.4 million from sales of deferiprone during fiscal 2003. Apotex exercised the remaining 2,650,000 warrants on October 30, 2003.

Cangene also conducts research and development aimed at the discovery of new therapeutic agents both in-house and through outside collaborations. It has continued to conduct R&D directed towards discovering innovative products and technologies and to further develop existing ones. For the year ended July 31, 2004, the Company's research and development expenditures, before taking into account investment tax credits, aggregated to approximately \$32.4 million.

Effective February 29, 2004, Alex Glasenberg retired from his position as Cangene's Chief Financial Officer and from its board of directors. Mr. Glasenberg was replaced on the board and audit committee by J. Robert Lavery, FCA, who comes to Cangene with extensive public company and Canadian board experience. Subsequent to the 2004 year-end, the Company hired a full-time CFO, Michael Graham, another experienced member of Canada's corporate community. In July, Edward Sonshine, also stepped down from the board due to competing time commitments. The board is seeking a new outside board member to replace Mr. Sonshine; meanwhile, existing board member, Craig Baxter, replaces Mr. Sonshine on the Audit Committee.

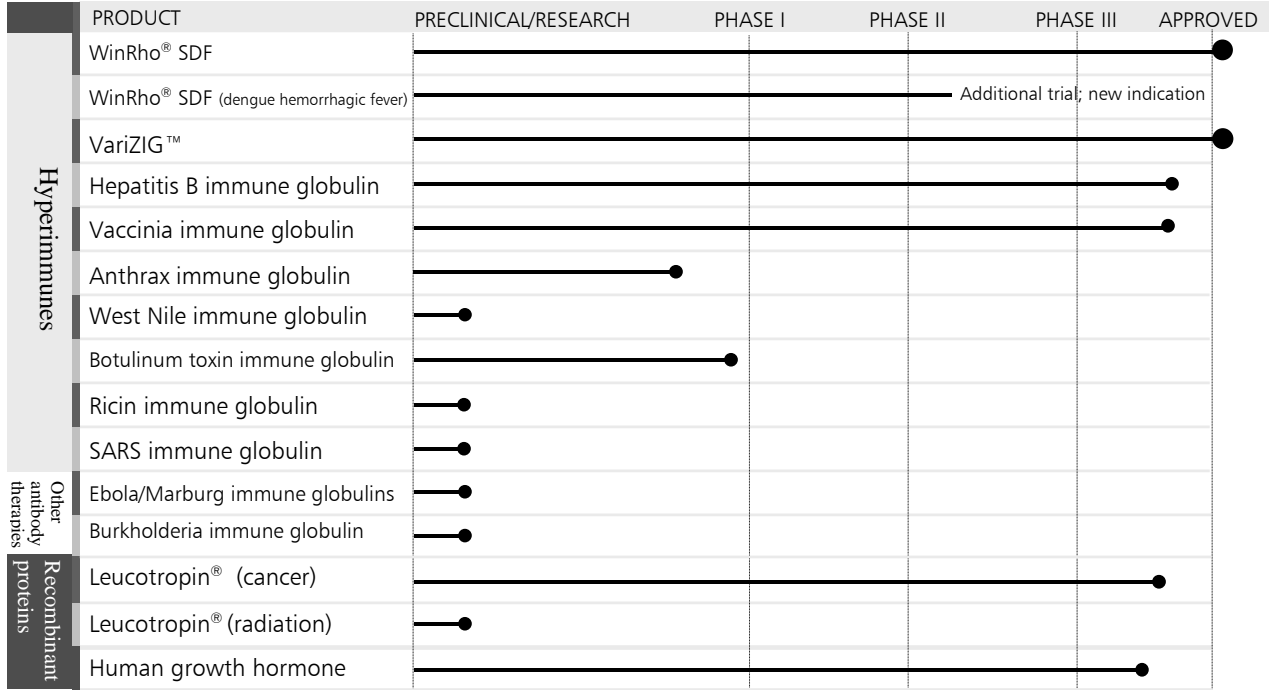
## **NARRATIVE DESCRIPTION OF THE BUSINESS**

### **General**

Cangene is a profitable Canadian biopharmaceutical company that develops, manufactures and markets specialty plasma products (hyperimmunes) and recombinant therapeutic products for international markets. A growing contract R&D and manufacturing initiative capitalizes on the Company's proven manufacturing expertise and adds to near-term revenue. Although down somewhat in 2004 after the exceptional results recorded in 2003, Cangene's revenues and profits have grown significantly over the last five years. In 2003, contract research and manufacturing revenue exceeded biopharmaceutical sales for the first time and that trend continued in 2004, with contract revenues accounting for nearly 60% of the total. To continue developing new products and technologies, Cangene also maintains substantial R&D activities both internally and through collaborations with third parties.

For its hyperimmunes, the Company uses an innovative approach to manufacturing traditional plasma products giving it a high yield and excellent product purity. Cangene is also developing biopharmaceuticals, and for certain products being developed under an R&D commitment from Apotex Inc., Cangene is pursuing a follow-on product strategy (biogenerics). The Apotex Group, of which Apotex Inc. is a member, is Cangene's majority shareholder and is one of Canada's largest pharmaceutical companies and a world leader in the generic drug industry. Cangene uses its own efficient manufacturing processes to build on the successes of known commercial products. The independent revenue streams from product sales, and contract R&D and manufacturing contribute to Cangene's profitability and stability.

The Company’s pipeline consists of a number of products with significant commercial potential, and along with two approved products, several are in late-stage clinical trials, including three that have been submitted for regulatory review.



The Company’s first hyperimmune product, WinRho® SDF has been sold in about 40 countries globally, including Canada and the United States. WinRho® SDF accounted for nearly all the Company’s \$66 million biopharmaceutical sales in 2004, an increase of approximately 6% over 2003 sales.

Cangene has been listed since 1991 on the Toronto Stock Exchange under the symbol CNJ. Its majority shareholder, the Apotex Group controlled 81% of the issued and outstanding common shares of Cangene at December 10, 2004.

**Business Strategy**

Cangene’s approach to product development differs from many biopharmaceutical companies—rather than concentrating on a single product or even a single disease area, Cangene develops products that arise from platform manufacturing technologies. Its strength is in its technology and the ability to turn that technology into products. This approach diversifies risk and minimizes some of the difficulties of new product development, and helps Cangene build a solid product pipeline with steady growth potential.

With the exception of certain innovative drugs in its discovery research program, Cangene’s pharmaceutical products can be classed into two different technology categories. The first category is hyperimmunes: concentrated antibody preparations made from plasma. These products lend themselves to fighting infectious disease, and the Company is focused on several such targets, including a number of biodefence projects. The second technology area is biopharmaceuticals: recombinant proteins—proteins that are made by introducing a specific gene into a host-cell system where the desired protein is produced.

Consequently, the Company's product development strategy is two-fold: firstly, to develop a number of new hyperimmunes, which will enhance its leadership position in the speciality antibody-based products market and secondly, to develop biopharmaceuticals including several follow-on or biogeneric recombinant products.

Manufacturing new hyperimmunes is based on the established manufacturing process used for WinRho® SDF; production depends on the availability of commercial quantities of the appropriate plasma. For the biogenics, the Company believes they offer a lower level of development risk than innovative drugs, and intends to capitalize on Apotex's extensive marketing contacts worldwide.

In addition to new product development, in fiscal 1998 Cangene began marketing its services for contract research and manufacturing. By February 1, 2001, Cangene had completed the acquisition of Chesapeake Biological Laboratories, Inc., an established contract-service provider of pharmaceutical and biopharmaceutical product development and filling services for injectable and other sterile products. Chesapeake's cGMP production facilities are located in Baltimore, Maryland. Its operation serves a broad range of customers, from major international pharmaceutical firms to emerging biotechnology companies. The specialized development services it provides include: research and development on sterile product formulations, test method development and validation, process design and manufacturing validations, regulatory and compliance consulting, preparation of clinical trial and toxicology materials, container-closure system design, and accelerated and ongoing stability studies. The combination of Cangene's existing contract research and manufacturing business and the Chesapeake operation makes contract services a significant contributor to the Company's revenue stream, and in fiscal 2004 contract R&D and manufacturing services accounted for 58% of total revenues.

Cangene's expertise in developing and manufacturing hyperimmune products that can be used in biodefence programs has allowed the Company to compete for major U.S. government contracts, including the VIG project that contributed significantly to the exceptional financial results Cangene recorded in 2003. The Company has established a group within the marketing and business development department to focus on further opportunities in the government contract business.

The Company is also maintaining certain innovative research programs through internal and external efforts. Cangene believes it can build on its successful hyperimmune business and expertise in protein therapeutics to develop a number of innovative products.

In summary, the key elements of the Company's business development strategy include:

- i) Building on the successful hyperimmune business; focusing new product development on infectious disease and bioterrorism targets
- ii) Continue increasing contract R&D and manufacturing operations
- iii) Capitalizing on Cangene's proprietary technologies and manufacturing expertise to become a world leader in the development and manufacture of follow-on biopharmaceuticals

None of Cangene's business is seasonal in nature.

## **Pharmaceutical Products**

### **Hyperimmunes**

#### *Background*

One class of Cangene's pharmaceutical products are plasma-derived products known collectively as hyperimmunes. These products are specific polyclonal antibodies isolated from plasma that contains enhanced levels of a desired antibody (specialty plasma). These levels may be boosted by a process similar to vaccination. Cangene believes hyperimmune products offer great potential in treating infectious disease. Plasma donors can donate more frequently than donors of whole blood. Therapeutic use of hyperimmunes confers immediate, passive immunity to the recipient or can be used to block an unwanted immune response, as in the case of Cangene's lead hyperimmune, WinRho® SDF. Cangene has two approved hyperimmunes; the first of these, WinRho® SDF, generated most of Cangene's biopharmaceutical revenue in 2004.

Cangene relies on a specialized column-chromatographic method for fractionating plasma, a process that is ideally suited for producing high-quality, small-batch speciality products like hyperimmunes.

#### *WinRho® SDF*

Cangene's lead plasma product, WinRho® SDF, was initially developed as a treatment for hemolytic disease of the newborn ("HDN"), and has virtually eliminated deaths from the condition in Canada since it was introduced to the market in 1980. HDN can occur when a woman with Rh<sup>-</sup> blood, e.g. Type O<sup>-</sup>, carries a fetus that is Rh<sup>+</sup>, e.g. O<sup>+</sup>. The mother's blood recognizes a foreign surface protein (D) on the fetal blood cells and can mount a severe immune response against them, causing HDN. In 1993 Rh Pharmaceuticals licensed (a company that amalgamated with Cangene in 1995), on a non-exclusive basis from New York Blood Center, Inc., a solvent-detergent process to inactivate lipid-enveloped viruses (e.g. hepatitis B, hepatitis C, and HIV) that may be present in the plasma used to make WinRho®. This second version of the product, WinRho® SD, was licensed in Canada for preventing HDN in 1993 and launched in the U.S. in 1995. Cangene has since added a special filtration (nanofiltration) step to its manufacturing process, resulting in a new version of the product, WinRho® SDF. In each case, the new version ultimately replaced its predecessor. WinRho® SDF has been sold in about 40 countries worldwide.

In the 1980's, Cornell Medical College started studying the use of WinRho® in treating an autoimmune platelet disorder called immune thrombocytopenic purpura ("ITP"), where platelets are destroyed by a patient's own immune system. Since platelets are required for blood clotting, the disorder can result in uncontrolled bleeding, either spontaneously or as a result of even minor trauma. The bleeding can be life-threatening. ITP can occur as either a primary disease with no other associated condition, or secondary to another underlying disease, such as HIV infection. Unless associated with HIV infection, ITP in children is generally an acute condition that resolves within six months, with or without therapy. In adults, whether primary or secondary to HIV infection, the disease is usually chronic. The original work on ITP led to treatment of HIV-related ITP, which affects a significant portion of AIDS patients. WinRho® SDF was licensed for ITP treatment in 1995 by the FDA.

In 2004, Cangene initiated a clinical study to investigate the use of WinRho® SDF to treat dengue hemorrhagic fever, an often fatal sequela of dengue fever, a mosquito-borne disease of the tropics. A pilot study on 19 gravely ill children showed positive results. This application for WinRho® SDF would be an extension of its ITP indication and may expand its market. Further, it may similarly be effective in other infectious diseases that result in bleeding due to platelet destruction.

Cangene has developed a liquid formulation of WinRho® SDF that is pending approval. The Company believes this new formulation may have some advantage in ease of use for its customers.

### Other Hyperimmunes

Cangene's second hyperimmune, VariZIG™, specifically reacts with Varicella zoster virus, the agent that causes chicken pox and that can lead to shingles. The Company completed a Phase I clinical trial with the product in January 1996 and, in September 1996, began a Phase III trial in pregnant women who were not immune to V. zoster and who had been accidentally exposed to the virus. In January 2001, VariZIG™ was approved in Canada for preventing chicken pox during pregnancy. As most North American adults have developed immunity to chickenpox, this product has a small market and the Company is not actively marketing the product.

Cangene has developed a Vaccinia hyperimmune globulin ("VIG") for use in treating and preventing severe reactions that may be brought on by the administration of the smallpox vaccine. Cangene developed the product under a contract with the United States Centers for Disease Control and Prevention ("CDC"). The five-year contract specifies a maximum of 100,000 doses of VIG, which the CDC will order on an as-needed basis. This product was developed under a modified regulatory program that allows preclinical studies and certain additional data to be used to support the approval of new drug and biological products for use in treating exposure to chemical, biological, radiological or nuclear agents where controlled clinical trials are not feasible or ethical. Cangene completed supply of the initial order from this contract primarily during fiscal 2003 and the remainder during fiscal 2004; revenues for fiscal 2004 reflect the decline in revenue from the project. Cangene submitted VIG to the FDA for regulatory review in July.

Cangene has developed anti-hepatitis B for international markets. This product completed a pivotal clinical trial during 2000, and the Company filed a Biologics License Application with the FDA and a New Drug Submission with Health Canada in 2001.

Cangene is also developing several other hyperimmune globulins, including one for use as an adjunct to antibiotic therapy in critically ill patients with anthrax and one for counteracting botulinum toxin. As discussed more fully under contract research and manufacturing, these products are being developed under contract with the CDC. In addition, the CDC recently announced that they intended to negotiate a sole-source agreement with Cangene for supply of up to 200,000 doses of botulinum toxin immune globulin. A contract has not been awarded but this represents a significant opportunity for the Company. Other targets for hyperimmunes under development include: West Nile, Ricin toxin and SARS.

In 2003, the Company began a program in conjunction with the Chemical, Biological, Radiological or Nuclear incident Research and Technology Initiative (CRTI), a federal Canadian initiative, to develop therapeutic antibodies to Ebola and Marburg viruses. Both viruses cause hemorrhagic fever and there is no effective therapeutic or prophylactic treatment. Cangene will be developing both polyclonal (hyperimmunes) and monoclonal (produced in the laboratory) antibodies under this project.

### Manufacturing and Supply of Raw Materials

Cangene manufactures its hyperimmune products at its facilities at 104 Chancellor Matheson Road in Winnipeg. The facility received an establishment licence from Health Canada in 1984, and was licensed by the FDA to produce WinRho® for distribution in the United States in March 1995. Expansion, and subsequent Health Canada and FDA licensure in 1998 increased plant capacity to >50,000 litres of plasma.

Manufacturing of WinRho® SDF and other hyperimmunes depends on the availability of commercial quantities of specialty plasma (primarily human plasma). Cangene brought a portion of its plasma needs under its own control by opening an expanded collection facility in Winnipeg in February 1996, which increases its ability to access Canadian plasma, and through acquisition of two U.S. facilities, Biotherapeutic Laboratories, Inc. in Van Nuys, CA (July, 1996), and Mid-Florida Biologicals, Inc. in Altamonte Springs, FL (June, 1997). Cangene obtains the majority of its plasma through supply contracts with commercial plasma collectors, and does not anticipate supply problems in the foreseeable future. However, there can be no guarantee that it would not experience shortages of plasma of an acceptable quality, which would have a detrimental effect on its ability to produce hyperimmunes.

### Marketing and Sales

WinRho® has been sold in about 40 countries, including Canada and the United States, and generated almost all the of the Company's biopharmaceutical revenue in 2004. And while the product is being successfully marketed internationally, Cangene is pursuing a broadened distribution network worldwide.

Cangene has marketed WinRho® SDF in the U.S. through a licence and distribution agreement with Nabi Biopharmaceuticals (originally signed in 1992, and restated in 1995). Under this agreement Nabi received exclusive WinRho® SDF distribution rights in the United States and its territories for 10 years commencing March 1995; that being the date WinRho® was approved for sale in the United States by the FDA. The agreement expires March 2005 and the Company has announced that Baxter Healthcare Corporation, an affiliate of Cangene's European distribution partner, will distribute WinRho® SDF in the United States, beginning in March 2005. Under Cangene's marketing agreement with Baxter Healthcare S.A., Baxter will market WinRho® SDF in Europe for the ITP indication. The product has already been launched in the United Kingdom.

Since its introduction to American markets in 1995, WinRho® has been listed on many of the hospital formularies in the United States. It has also been listed under the federal Medicare and Medicaid reimbursement programs. In the United States, sales of WinRho® SDF are almost entirely for the ITP indication; the U.S. represents Cangene's largest market.

The Company also has marketing arrangements in various other jurisdictions.

Cangene's foreign sales are transacted mainly in U.S. dollars.

### Competition

There are a number of competitors for the Anti-D immunoglobulin market (i.e. WinRho® SDF's market). The competition differs in various jurisdictions depending on the nature and stage of regulatory approval. WinRho® was the first licensed Anti-D product that could be administered intravenously, giving it access to the ITP-treatment market, which is especially significant in the United States and constitutes WinRho®'s largest market. Cangene

initially received Orphan Drug status for WinRho for treating ITP; this market exclusivity expired during 2002. A competitive product, made by ZLB Bioplasma AG, that can be administered intravenously, is now on the market but is not currently licensed for ITP treatment.

WinRho currently accounts for nearly 100% of the existing Canadian Anti-D market, but a much smaller share in the United States. In the U.S., competition comes from major pharmaceutical companies: ZLB Behring, Ortho-McNeil Pharmaceuticals Inc. and Bayer AG. WinRho® SDF sales in the U.S. are almost exclusively for the ITP indication. Cangene hopes to increase the total market through an aggressive educational campaign aimed at physicians and providing information about WinRho's use in treating ITP. In Western Europe, Northern Africa and the Middle East, competing products are manufactured by a number of other companies.

WinRho® SDF enjoys a significant market share in some jurisdictions in which it is available, but there can be no guarantee that the entry of new competition would not affect WinRho® SDF sales in those markets.

There are several licensed competitors in various jurisdictions for the hepatitis B immune globulin market also.

In the 1970's researchers began developing technologies for making monoclonal antibodies: specific and homogenous antibodies, produced under controlled conditions, independent of a supply of human plasma. It seemed at first like these antibodies would replace their naturally produced, polyclonal counterparts. However, their efficacy proved to be limited and the plasma business continued to thrive. Recently, there has been a resurgence of research into monoclonal technology and this wave may prove more successful. Cangene has begun an in-house program directed at developing monoclonal antibody technology.

## **Recombinant Biopharmaceuticals**

### *Background*

Many of the proteins produced naturally in the body have proved to be therapeutically useful if administered in appropriate doses. Producing these complex proteins is often most easily accomplished by using recombinant DNA technology—using the biological machinery in living cells to produce, or express, the protein of interest. Because these products arise from biological processes or sources, they are referred to as biopharmaceuticals. Cangene has developed a number of expression technologies with different characteristics that it believes will allow it to make a wide variety of recombinant products.

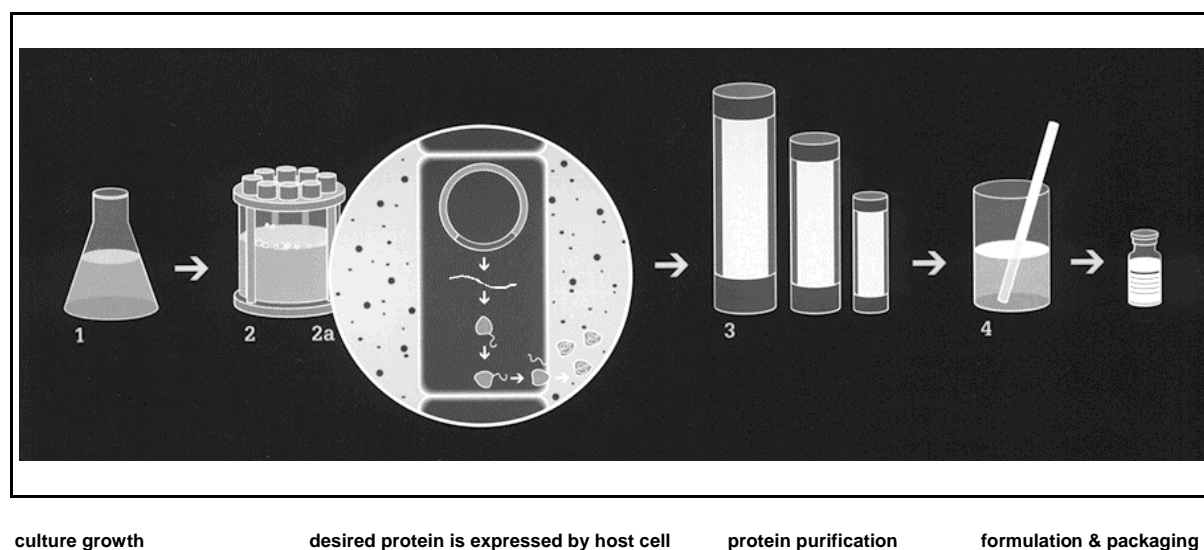
Biopharmaceutical products offer the potential for tremendous growth and large markets. Many companies compete to develop new biopharmaceutical products and technologies. However, the possibility of failure of products or technologies at an early development stage is significant. Cangene believes that its strategy to develop proprietary methods of manufacturing follow-on biopharmaceuticals eliminates some of the uncertainty associated with new drug development. Many of the products currently on the market will come off patent in the next few years. In an increasingly cost-conscious healthcare environment, the ability to compete on the basis of price may be an asset.

### *Production Technologies—Cangenus™*

Cangene developed and patented a novel gene expression system based on the soil bacterium, *Streptomyces*. The resulting technology, Cangenus™, allows economically feasible production of commercial amounts of many therapeutic proteins. Cangenus™ offers benefits that may not be shared by other bacterial, yeast or animal cell

expression technologies. In particular, for certain proteins, Cangenus™ produces the precise biological shape required for activity. It also exports the product into the surrounding fermentation media, eliminating the need to break open the cells for harvest. Finally, it readily yields a product of high purity. Like other expression systems, Cangenus™ suffers from certain limitations, and some commercially valuable proteins cannot be produced using it. Nevertheless, Cangene has cost-effectively produced certain proteins using Cangenus™, including its lead biopharmaceutical product, Leucotropin®.

Schematic diagram of protein expression using Cangenus™



Production Technologies—Other Expression Systems

Cangene also has an established *E. coli* bacterial expression system that provides an easily manipulated, cost-effective system with which to produce certain products. Cangene’s second most advanced recombinant biopharmaceutical, human growth hormone (“hGH”), is its first product made using this system.

Cangene has developed a patented technology that it calls SAR (scaffold attachment region) that alleviates some of the technical problems associated with other mammalian expression systems. Certain proteins must be expressed using mammalian cells. Unlike bacterial cells, genes introduced into mammalian cells may integrate at random within the cell’s own DNA, which produces variable levels of protein expression or may decrease cell viability. Cangene’s SAR technology improves expression of the desired protein in transfected mammalian cells. In 1999, Cangene received two U.S. patents with respect to this technology and a Canadian patent issued in 2003.

Biopharmaceutical Development Program

Follow-on approvals

The development of a biopharmaceutical product is a multi-step process. The first step can be categorized as R&D, which involves developing and producing the desired product as described earlier. The next step, preclinical development, involves producing the protein in larger amounts and using it in preclinical studies. The third step is

clinical development and involves scaling up the production technology to generate a sufficient quantity of the product for further testing, which is generally clinical trials with human volunteers. There are typically three phases of clinical trials, and following the successful completion of these three phases, a pharmaceutical product may be submitted for regulatory review for licensure. In certain cases, the phases may be combined. At the same time, if deemed appropriate, scale-up to commercial levels of production would be commenced. However, marketing and sale of the biopharmaceutical product may not occur until regulatory approval is obtained. [See Government Regulation].

The approval process differs in the case of follow-on or generic products. The classical generic approach is to compare the generic product to an approved drug through bioequivalency tests. That is, to show that the generic product performs within a specified range compared to an approved product. If the generic product performs outside the range, even if it is better, the new product cannot be approved as a generic. This approach to drug development is generally faster and consequently less expensive than the full clinical trial approach.

The development of a biopharmaceutical product generally takes many years and throughout that process there cannot be guarantees of the success of the product. However, Cangene's approach of pursuing a generic-style approach removes one element of risk; the products themselves have already demonstrated commercial success and utility. As well, with products that are already on the market, significant data exists and may reduce the amount of new data that must be collected before Cangene's products can be submitted for regulatory approval.

Many key biopharmaceuticals will come off patent in the next few years, making this an excellent time to pursue a generic-style strategy, although currently, no regulatory process exists for the approval of generic biologics. The United States Food and Drug Administration has announced its intention to prepare draft guidance for the development of follow-on protein pharmaceutical products and the European Medicines Agency has already adopted guidelines for determining the comparability of medicinal products containing biotechnology-derived proteins as active ingredients. However, these moves are still preliminary and are further complicated by intellectual property issues regarding biotechnology-derived drugs. Consequently, there can be no assurance that regulatory agencies will accept a bioavailability approach or that the products would be considered substitutable. If the biogeneric approach were found unacceptable by regulatory agencies, the Company would have to follow a full clinical trial program for its biopharmaceutical drugs, which could materially slow their commercialization.

Cangene is developing several products under an R&D agreement with Apotex using this strategy. For Leucotropin®, one of the lead drugs in its recombinant pipeline, the Company has completed clinical trials and in October 2003, announced its regulatory submission of Leucotropin® in Canada.

Human growth hormone is a good candidate for a follow-on approach because several versions of human growth hormone are currently on the market and the protein is well characterized. The Company completed the bioequivalence trial of hGH at the end of calendar 1999 and completed patient recruitment for subsequent Phase III trials during fiscal 2001. These Phase III studies provide data to assess the drug's ability to combat short stature in children with growth hormone deficiency and in girls with Turner Syndrome for regulatory submission in Canada, the U.S., and other jurisdictions.

### Markets for Biopharmaceuticals

Biopharmaceuticals address many of the complex diseases that have baffled medical science for years, and their use has grown dramatically in the short time they have been available. Every year the list of approved products gets longer and their respective market size continues to increase as new indications are discovered and as they gain acceptance within the medical community. Biological products with estimated sales aggregating \$10 billion U.S. are expected to come off patent over the next five years (The Generic Pharmaceutical Association)

### Leucotropin® (Granulocyte-Macrophage Colony-Stimulating Factor; GM-CSF)

Many cancer therapies in current medical use involve treatments that result in the destruction of some normal cells, particularly those that are actively growing and dividing, such as white blood cells. Cancer patients undergoing such treatments risk contracting infections that would normally be controlled by white blood cells. Accordingly, a desirable component of cancer treatment in many cases includes the stimulation of the stem cells that produce new blood cells.

Colony-stimulating factors (“CSFs”) are a family of proteins that induce stem cells in the bone marrow or circulating in the blood to produce mature white blood cells. Each member of the CSF family stimulates the growth or the maturation of certain specific white-blood-cell types. Granulocyte-macrophage CSF (“GM-CSF”) is a type of CSF that controls the growth and differentiation of granulocytes (white blood cells that specifically focus on destroying viruses and bacteria) and macrophages (white blood cells that destroy a variety of infectious agents). Cangene’s lead biopharmaceutical product is the GM-CSF protein, which the Company has named Leucotropin®.

Cangene believes that the use of its recombinant GM-CSF (“rGM-CSF”) will stimulate granulocyte and macrophage development in patients undergoing certain anti-cancer treatments, thus possibly permitting the use of higher or more frequent dose regimens. In either case, the Company expects that the use of its rGM-CSF could control or reduce the risk of contracting an infection that intensive drug therapy might otherwise elevate. Cangene also expects that rGM-CSF may be useful in some other conditions where increasing the white blood cell count is desirable, including exposure to radiation, certain AIDS treatments, serious burns, and various types of bacterial and viral infections.

Midway through 1997, Cangene began a Canadian Phase III clinical trial of Leucotropin® in patients undergoing bone marrow transplantation. Patient enrolment in the Canadian trial slowed as clinical practice shifted away from the use of bone marrow transplantation. In August 1999, Cangene began a new Phase III trial investigating use of Leucotropin® to assist white-blood-cell recovery following chemotherapy. The trial was expanded to include sites in Europe; patient recruitment was completed in fiscal 2001. The original Canadian trial was closed. The Company filed a Canadian New Drug Submission for Leucotropin® in 2003. The submission seeks approval from the Biologics and Genetic Therapies Directorate for use of the drug in enhancing recovery of certain white blood cells in patients with Hodgkin’s disease and non-Hodgkin’s lymphoma following stem cell transplantation. Cangene developed this product with the Apotex Group, which plans to market it in Canada.

Cangene has also begun a project, which will be funded by the Chemical, Biological, Radiological or Nuclear Incident Research and Technology Initiative (“CRTI”), to develop Leucotropin® as a treatment for white-blood-cell damage resulting from radiation exposure. CRTI is an interdepartmental Canadian federal government initiative mandated to improve Canada’s ability to respond to chemical, biological, radiological or nuclear incidents.

### *Competition*

Leucotropin's market is dominated by a functionally similar product, Granulocyte Colony-Stimulating Factor ("G-CSF"), called Neupogen® (Granulokine® in certain markets) and Neulasta® a chemically-modified, second-generation product. Neupogen® and Neulasta® are owned by Amgen Inc. and are two of the top-selling biopharmaceuticals in the world, with combined annual sales of US\$2.5 billion during Amgen's 2003 fiscal year.

Two versions of GM-CSF, owned by large multinational companies, are approved for marketing—Leukine®, marketed by Berlex Laboratories, Inc., a division of Schering AG generated net sales equivalent to approximately \$70 million in Schering's 2003 fiscal year, and Leucomax®, owned by Schering-Plough Corp. Other companies may also be developing alternative versions of GM-CSF or functional analogues. As yet, although two GM-CSF products have been approved, neither Leukine® nor Leucomax® is actively marketed in Canada, leaving the Canadian market poorly served.

Cangene has been issued patents in Canada, the U.S. and Europe on its Cangenus® expression system for the production of Leucotropin®. Although patents with claims to GM-CSF exist in the U.S., Cangene has obtained favourable legal opinions from external legal counsel in respect of such patents. There can be no guarantee that these opinions will be upheld by any court of law. Cangene is not aware of any dominating product claims for GM-CSF that have been issued in Canada to date, but there can be no guarantees that none will issue in the future.

### *Human Growth Hormone*

The most advanced product made in Cangene's E. coli expression system is a protein normally produced by the human pituitary gland, human growth hormone ("hGH"). Normally, hGH performs a number of physiological functions, including growth to normal stature through its action on the long bones of the body until the onset of puberty. A deficiency in this hormone during childhood results in abnormally small stature. Human growth hormone is used to treat hGH deficiency and Turner Syndrome (a genetic condition that causes abnormal physical development in girls, including short stature). Human growth hormones are also approved for use in chronic renal insufficiency, children born small for gestational age, Prader-Willi Syndrome (a genetic disorder), and idiopathic short stature. Growth hormones have been shown useful in alleviating cachexia, the profound wasting that often accompanies AIDS or some cancers, and they may be useful in geriatric applications.

Cangene has completed a bioequivalence trial that compared its hGH to a commercially available human growth hormone product. The Company followed with pivotal trials in Europe in children diagnosed with growth hormone deficiency or girls with Turner syndrome. The Company completed patient recruitment for the pivotal trials during the second quarter of fiscal 2001 and is preparing for regulatory filing in North America in 2005.

In 2003, Cangene announced it had entered an exclusive marketing and distribution agreement with BioGeneriX AG of Mannheim, Germany for Cangene's hGH. Under the agreement, BioGeneriX will be the sole distributor of the product in Europe, giving Cangene significant access to the European market, especially through the sales force of BioGeneriX' parent company, one of the largest generic drug companies in Europe. Cangene and BioGeneriX will pursue regulatory approval from the European Medicines Agency and any other authority necessary for sales in the region.

### *Competition*

Several versions of human growth hormone, including a sustained release product, have been approved for sale and are marketed throughout the world. The protein has been the subject of intense legal wrangling over the patent rights; nonetheless, many different pharmaceutical manufacturers continue commercializing human growth hormone. These include Genentech Inc., Eli Lilly and Co., Savient Pharmaceuticals, Inc., Novo Nordisk A/S, Serono SA, Pfizer Inc., and Ferring Pharmaceuticals. In the U.S., Eli Lilly's Orphan Drug protection for its version of hGH expired in 1994. Current marketers of the drug claim a world market that exceeds \$1 billion annually.

### *Innovative Products*

In addition to products already discussed, the Company maintains research programs in innovative drugs and technologies, both through in-house research and outside collaborations. Most of these initiatives are still at a relatively early stage, but Cangene believes they may promise future commercial value.

## **Contract R&D and Manufacturing**

### *Background*

As stated earlier, Cangene began marketing its manufacturing capability early in fiscal 1998. With the expansion of the FDA-licensed Winnipeg manufacturing facility, the Company has sufficient capacity to make its expertise available to others. Cangene offers one of the few FDA-licensed manufacturing facilities in Canada. Well known in the industry and recognized for its commitment to quality, Cangene boasts several successful contracts using varied technologies. In recent years, the Company's expertise in developing and manufacturing hyperimmune products and its focus on biodefence-related products attracted significant contracts from the U.S. government. Cangene has subsequently established a business development unit to maximize the potential opportunities in this area. Cangene's contract R&D and manufacturing segment generated 58% of the Company's revenue in fiscal 2004.

### *Chesapeake Biological Laboratories, Inc.*

Effective January 31, 2001, Cangene completed the acquisition of Chesapeake Biological Laboratories, Inc. ("Chesapeake") for a consideration of \$52.8 million. Chesapeake is an established contract service provider of pharmaceutical and biopharmaceutical product development and filling services for injectable and other sterile products. Chesapeake's cGMP production facilities are located in Baltimore, Maryland. Chesapeake serves a broad range of customers, from major international pharmaceutical firms to emerging biotechnology companies. The combined Cangene and Chesapeake contract research and manufacturing operations have serviced more than 90 customers. Chesapeake has particular experience and expertise in providing product development services and filling sterile, process-sensitive biopharmaceutical injectable products. Biopharmaceutical products are derived from biological materials and typically involve larger, more complex molecules than traditional pharmaceutical products, which generally are based upon smaller, more stable, synthetic organic molecules. The complexity, inherent instability and process-sensitivity of biopharmaceutical products require the application of specialized technology and expertise in their development, production and analysis. The specialized development services Chesapeake provides include: research and development of sterile product formulations, test method development and validation, process design and manufacturing validations, regulatory and compliance consulting, preparation of clinical trial and toxicology materials, container-closure system design, and accelerated and ongoing stability studies.

### *Government Contracts*

On November 29, 2001, Cangene announced that Chesapeake would do the filling for 155 million doses of smallpox vaccine being manufactured by Acambis Inc. and Baxter BioSciences. The primary manufacturing contract was awarded to Acambis and Baxter by the U.S. Department of Health and Human Services. Chesapeake provided the final filling, lyophilization (freeze-drying) and finishing stages of the manufacturing process at its specialized viral vaccine fill/finishing facility. Delivery on this contract was completed in the first quarter of fiscal 2005. Cangene and Chesapeake are currently assessing new contract manufacturing opportunities for this specialized operation while the facility is temporarily idle and undergoing maintenance and cleaning.

On August 12, 2002, Cangene was awarded a second major contract when it was selected by the CDC to develop and supply Vaccinia immune globulin (“VIG”) for use in treating and preventing severe reactions that may be brought on by the administration of the smallpox vaccine. Under the five-year contract, Cangene could supply the U.S. government up to 100,000 doses of VIG on an as-needed basis. Cangene has completed supply on the initial order under this contract.

The two smallpox-related contracts contributed significantly to the exceptional revenues recorded by the Company in fiscal 2003 and earnings for fiscal 2004 and into 2005 reflect the decline from this revenue source. While the Company anticipates the award of future contracts there can be no guarantees on the magnitude or timing of such contracts.

During 2002, Cangene was also awarded a contract to develop a clinical-grade hyperimmune globulin to be used as an adjunct to antibiotic therapy in critically ill patients with anthrax. Under this initial program, the hyperimmune will be used for preclinical studies, and human compassionate use and safety testing. This innovative hyperimmune will initially be used under an Investigational New Drug application. The goal of the program is to develop an FDA-licensable product. Subsequently, during 2003, the CDC awarded Cangene a similar contract to develop a hyperimmune globulin specific for botulinum toxin (the toxin that causes botulism). In October 2004, the CDC announced that it intends to negotiate a sole-source agreement with Cangene to provide up to 200,000 doses of botulinum toxin immune globulin. Cangene was identified as the only prospective contractor with the necessary experience, capability and capacity to fulfil these requirements. Both anthrax and botulism were key targets identified by the U.S. Congress when it enacted the US\$5.6 billion BioShield legislation for the creation and stockpiling of products to protect the U.S. from biological attack.

### *Competition*

The Company competes for its contract R&D and manufacturing business with several pharmaceutical product development organizations, contract manufacturers of biopharmaceutical products and university research laboratories. Although many of these pharmaceutical product development organizations, contract manufacturers and university research laboratories do not offer the same range of service offered by the Company, they can and do compete effectively against certain segments of the Company’s business, including its pharmaceutical production capabilities. The Company also competes with in-house research, development and support service departments of pharmaceutical and biotechnology companies. Certain of these competitors, particularly the larger, established pharmaceutical and biotechnology companies, have significantly greater resources and better name recognition than the Company. As the demand for biopharmaceutical-manufacturing capacity escalates, more competitors are attracted to the market. Competitive factors include reliability, turnaround time, reputation for innovation and quality performance, capacity to perform numerous required services, financial and regulatory strength, and price.

The Company believes it can compete favourably in these areas. As well, as a greater number of biopharmaceutical products move into clinical testing and commercial production, the need for validated manufacturing facilities grows.

Cangene's contract research and manufacturing business relies heavily on several significant contracts with a small number of government agencies; there can be no assurance that these contracts will continue at current levels or that other competitors would not enter the market. By their nature, these contracts call for Cangene to supply such products to a national stockpile, to be used only in the event of an actual incident or attack. Accordingly, demand for these products should be expected to fluctuate significantly.

### Segment Information

The Corporation manages its business and evaluates performance based on two operating segments: biopharmaceutical operations, and contract R&D and manufacturing. The products and services provided by biopharmaceutical operations include in-house licensed product sales and royalties, as well as related party research and development. Contract R&D and manufacturing provides products and services to third party clients. There are no significant inter-segment transactions. The following presents segment operating results for the years ended July 31, 2004 and July 31, 2003, and identifiable assets as at July 31, 2004 and July 31, 2003:

|                                                          | <b>2004</b>                          |                                           |                | <b>2003</b>                          |                                           |                |
|----------------------------------------------------------|--------------------------------------|-------------------------------------------|----------------|--------------------------------------|-------------------------------------------|----------------|
|                                                          | Biopharm-<br>aceutical<br>operations | Contract<br>R&D and<br>manufac-<br>turing | Total          | Biopharm-<br>aceutical<br>operations | Contract<br>R&D and<br>manufac-<br>turing | Total          |
| Revenues                                                 | \$ 65,688                            | \$ 91,215                                 | \$ 156,903     | \$ 59,283                            | \$ 126,930                                | \$ 186,213     |
| Expenses                                                 |                                      |                                           |                |                                      |                                           |                |
| Cost of sales                                            | 12,050                               | 53,024                                    | 65,074         | 11,818                               | 77,261                                    | 89,079         |
| Research and development                                 | 15,086                               | 10,525                                    | 25,611         | 10,925                               | 7,145                                     | 18,070         |
| Selling, general and administrative                      | 2,483                                | 7,206                                     | 9,689          | 2,796                                | 9,619                                     | 12,415         |
| Amortization                                             | 2,572                                | 4,389                                     | 6,961          | 1,857                                | 4,261                                     | 6,118          |
| Interest                                                 | 97                                   | 719                                       | 816            | 312                                  | 2,190                                     | 2,502          |
| Foreign exchange loss (gain)                             | 673                                  | (3,166)                                   | (2,493)        | (3)                                  | (4,124)                                   | (4,127)        |
|                                                          | <b>32,961</b>                        | <b>72,697</b>                             | <b>105,658</b> | <b>27,705</b>                        | <b>96,352</b>                             | <b>124,057</b> |
| Income before income taxes                               | <b>32,727</b>                        | <b>18,518</b>                             | <b>51,245</b>  | 31,578                               | 30,578                                    | 62,156         |
| Income taxes expense (recovery)                          |                                      |                                           |                |                                      |                                           |                |
| Current                                                  | 14,852                               | 9,180                                     | 24,032         | 11,091                               | 9,909                                     | 21,000         |
| Future                                                   | —                                    | (5,329)                                   | (5,329)        | —                                    | 1,066                                     | 1,066          |
|                                                          | <b>14,852</b>                        | <b>3,851</b>                              | <b>18,703</b>  | 11,091                               | 10,975                                    | 22,066         |
| Net income for the year                                  | \$ 17,875                            | \$ 14,667                                 | \$ 32,542      | \$ 20,487                            | \$ 19,603                                 | \$ 40,090      |
| Tangible assets                                          | \$ 83,087                            | \$ 77,425                                 | \$ 160,512     | \$ 77,287                            | \$ 68,324                                 | \$ 145,611     |
| Goodwill                                                 | \$ 3,216                             | \$ 37,298                                 | \$ 40,514      | \$ 3,216                             | \$ 38,779                                 | \$ 41,995      |
| Additions to property, plant and equipment, and goodwill | \$ 12,278                            | \$ 11,755                                 | \$ 24,033      | \$ 5,594                             | \$ 12,110                                 | \$ 17,704      |

### Major Customers or Geographic Segments

For the period August 1, 2003 to July 31, 2004, sales to one customer represent 51% [2003 – 56%] of the revenue of the biopharmaceutical operating segment. Sales to another customer represent 68% [2003 – 80%] of the revenue of the contract R&D and manufacturing segment.

Geographic information about the Corporation's revenue is based on the product shipment destination or the location of the contracting organization. Assets are based on their physical location as at July 31, 2004 and July 31, 2003:

|               | 2004              |                                             | 2003              |                                             |
|---------------|-------------------|---------------------------------------------|-------------------|---------------------------------------------|
|               | Revenue           | Property, plant and equipment, and goodwill | Revenue           | Property, plant and equipment, and goodwill |
| Canada        | \$ 29,641         | \$ 59,934                                   | \$ 20,435         | \$ 47,225                                   |
| United States | 116,382           | 83,346                                      | 156,674           | 82,425                                      |
| Eurasia       | 10,880            | —                                           | 9,104             | —                                           |
|               | <b>\$ 156,903</b> | <b>\$ 143,280</b>                           | <b>\$ 186,213</b> | <b>\$ 129,650</b>                           |

### PATENTS AND TRADE SECRETS

Cangene actively seeks to protect the intellectual property arising from its research and development by all means possible. In general, the Company pursues patent protection for new and inventive processes and products that it develops. In some cases, the Company may decide that the best protection is to retain proprietary information as trade secrets rather than to apply for patents, which would involve disclosure of proprietary information to the public. However, Cangene cannot be certain that others will not independently develop or acquire same or similar technologies, or that its issued patents will not be circumvented or invalidated by a competitor or rendered obsolete by new technology.

Cangene has filed patent applications in all jurisdictions in which it believes it is necessary to protect its inventions. In particular, patents for the Cangenus™ technology have been issued by patent offices in Canada, in the United States, in Europe (designating major European countries). These patents specifically claim a number of biopharmaceuticals including GM-CSF produced by Cangenus™, which effectively means Cangene now has patent protection in these countries for use of the Cangenus™ system to produce Leucotropin®. Cangene has obtained favourable legal opinions from external legal counsel in respect of U.S. patents with claims to GM-CSF. However, there can be no guarantees on whether such opinions would be shared by any court of law. Cangene cannot be certain that any of its pending or future applications will result in issued patents, or that any patent rights granted thereunder would confer competitive advantage to Cangene or its licensees.

In 1999, Cangene also received two patents for a novel mammalian expression system, known as SAR, from the U.S. Patent and Trademark Office. Cangene also has numerous patents issued and pending relating to its plasma and innovative products.

Cangene has acquired title to a number of patents. In particular, it acquired, from the Winnipeg Rh Institute, two patents relating to human plasma fractionation for preparing purified immune globulin (IgG). Cangene also licenses non-exclusive patent rights and technology relating to the solvent-detergent viral inactivation step, used in the manufacture of WinRho® SDF, from New York Blood Center, Inc. Under an agreement expiring in 2006, Cangene has the right to use this technology and pays royalties to New York Blood Center, Inc. based on 3% sales

of WinRho® SDF, Vaccinia immune globulin, Anthrax immune globulin, and Botulinum toxin immune globulin. During the year ended July 31, 2004, these royalties amounted to \$3.1 million [2003 – \$3.5 million]. In 1999, Cangene also acquired exclusive licence rights to patents owned by the University of Manitoba relating to the Receptor for Hyaluronan-Mediated Motility (RHAMM) and has an issued patent entitled Enhanced Affinity Hyaluronan Peptides.

It is possible that any patents that issue in Europe may be opposed. The nature of any such possible opposition cannot be determined at this time. Consequently, no assurance can be given that the patents will confer upon Cangene a preferred position with respect to the processes or products claimed. Neither the application for, nor the granting of, a patent is any assurance that the claimed invention will not infringe any claimed patent rights of third party patentees or that third parties will not attempt to infringe patents belonging to Cangene. Furthermore, in several jurisdictions there are a number of important unresolved general legal issues about the extent to which patent protection may be afforded to biotechnological and biopharmaceutical inventions. These include, for example, issues relating to the difficulty in describing living organisms.

The patent positions in the pharmaceutical and biotechnology industries can be uncertain and the possibility and breadth of patent claims allowed in competitive patents cannot be predicted. Patent disputes are frequent and can preclude commercialization of products and technologies. There can be no guarantee that Cangene will not be involved in material patent litigation in the future and cannot predict with certainty the eventual outcome of any patent litigation. Patent litigation is costly and could subject the Corporation to significant liabilities to third parties. In addition, if decided adversely, Cangene may need to obtain third-party licenses at a material cost or terminate the use/commercialization of the technology or product in dispute. The presence of patents or other proprietary rights belonging to other parties may lead to the termination of the development or commercialization of a particular product or technology.

As noted above, the Company attempts to protect trade secrets and know-how involving ideas and processes that may not, in themselves, be patentable. This information is protected by confidentiality agreements signed by the Company's employees and third parties with whom the Company desires to discuss possible business proposals. These agreements require the employees and those third parties to refrain from disclosing confidential information. There can be no assurance, however, that these agreements will be effective.

## **FACILITIES**

Cangene's head office and FDA-licensed, cGMP, ISO 9001-registered manufacturing facilities comprises 121,000 square feet and is located at 104 Chancellor Matheson Road in Winnipeg, Manitoba. The facility received an establishment licence from the FDA to produce WinRho® SDF for distribution in the United States in March 1995.

Cangene currently leases approximately 18,500 square feet of industrial space at 3403 American Drive in Mississauga, Ontario. Approximately 10,500 square feet is finished and equipped as biotechnology research laboratories with the rest used as warehouse and office space. The Company's lease for these premises expires September 30, 2005.

Chesapeake Biological Laboratories, Inc. operates a 70,000-square-foot building on 3.48 acres of land in the Camden Industrial Park, located at 1111 South Paca Street in Baltimore, Maryland, USA. This cGMP facility is presently operational, providing contract manufacturing services to the biopharmaceutical industry. The Company's nearby viral vaccine-filling facility is currently undergoing cleaning and maintenance as the Company evaluates new contract manufacturing opportunities.

The Company owns two medium-sized plasma collection operations in the United States: Biotherapeutic Laboratories, Inc. in Van Nuys, CA, and Mid-Florida Biologicals, Inc. in Altamonte Springs, FL. And the Company leases approximately 1,410 square feet of space in the Medical Arts Building in Winnipeg where it operates The Rh Plasma Center.

In January 1999, Cangene officially opened a 35,000-square-foot research and development facility in Winnipeg, located at 26 Henlow Bay. As well as providing needed laboratory space, the expansion will ultimately allow the Company to perform all its biopharmaceutical manufacturing operations in-house. The Company has completed construction of the second phase—30,000 square feet of manufacturing facilities—which houses the fermentation and down-stream processing stages of manufacturing for its biopharmaceutical products, and provides capacity for the rapidly growing contract research and manufacturing commitments.

The Company believes that its current facilities comply with all material zoning requirements and that it has all necessary permits and authorizations for such facilities.

## **HUMAN RESOURCES**

As of July 31, 2004, Cangene and its subsidiaries employed 598 persons in full-time positions; 153 of those were employees at Chesapeake. None of Cangene's employees is covered by collective bargaining agreements and the Company believes that it has a good relationship with its employees.

## **FOREIGN OPERATIONS**

Cangene's wholly-owned subsidiary, Chesapeake Biological Laboratories, Inc., operates in Baltimore, Maryland and comprises the bulk of Cangene's contract-manufacturing business. And as previously mentioned, Cangene also operates two plasma centres in the U.S. The Company is not aware of any risks associated with this foreign operation and believes that its U.S. location adds visibility in its target market. The majority of Cangene's international sales are transacted in U.S. dollars. The strengthening Canadian dollar over the past year has negatively impacted translation of international sales into Canadian dollars.

## **GOVERNMENT REGULATION**

The manufacture, sales and marketing of pharmaceutical products using the Company's biological processes are governed by a variety of statutes and regulations in Canada and by comparable laws and regulations in foreign countries.

In Canada, these activities are regulated by Health Canada ("HC"). The law requires licensing of manufacturing facilities, carefully controlled research and testing of pharmaceutical products, government review and/or approval of results prior to marketing and strict adherence to current Good Manufacturing Practices ("cGMP") during production. Although the Company has successfully operated in this stringent regulatory environment and believes its experience is an advantage over some of its competitors, compliance with these regulations is a continuous process. These regulations apply to all phases of drug manufacturing, testing and record keeping, including personnel, facilities, equipment, control of materials, processes and laboratories, packaging, labelling and

distribution. Non-compliance with cGMP by the Company could result in regulatory sanctions, and in severe cases, could result in a mandated closing of the Company's facilities. Any of these sanctions would materially and adversely affect the Company's business and prospects. Revised or new regulations would likely to increase the Company's operating costs and could require capital expenditure.

The issuance of a Notice of Compliance ("NOC") by Health Canada to sell pharmaceutical products requires proof of safety, purity, potency and efficacy, which is established through preclinical and clinical trials. These procedures may require substantial funding and may take several years before approvals are obtained. The first step in the approval process requires the filing of an Investigational New Drug submission ("IND") with HC requesting approval to conduct clinical trials. The IND consists of toxicology data obtained from preclinical trials, manufacturing data showing that the product has been properly made under cGMP conditions, a summary of the published literature of the product, and a detailed description of all relevant aspects of the proposed clinical trials.

Clinical trials traditionally involve three phases. In Phase I, the product's effect on, and safety in patients or healthy volunteers is assessed. In Phase II, the product's efficacy, dosage, side effects and safety are established in a small number of patients with the condition that the product is intended to treat. In Phase III, controlled clinical trials are conducted in which the product is administered to a large number of patients who have the condition the product is intended to treat, and in which further information relating to the safety and efficacy is gathered. Further, after Phase III, an applicant would file with HC a New Drug Submission ("NDS") with respect to the proposed product, for marketing approval. The NDS includes a comprehensive summary and analysis of the results of the clinical trials, information relating to proposed labelling and packaging materials, and data relating to the proposed manufacturing and quality control procedures. If, and when, HC finds the NDS to be satisfactory, it issues a Drug Identification Number ("DIN") and an NOC permitting sale of the proposed product in Canada under the conditions specified in the NOC. A similar process in the United States is regulated by the Food and Drug Administration ("FDA"), an agency within the Department of Health and Human Services.

Cangene is producing certain follow-on proteins under an R&D agreement with Apotex. Essentially a strategy of this type would follow that of the generic drug business in which Apotex has been very successful. The basis of this approach is to prove that the product being developed will be similarly bioavailable and therefore substitutable for an innovative product that is currently on the market. After the patent for the innovative product expires, the generic alternative can rapidly enter the market. Most regulatory agencies in the world are considering this strategy for biologics at some level. Cangene's approach was discussed earlier in this document.

Both Health Canada and the FDA have indicated that they believe licensing of protein therapeutics through a generic-style strategy will occur, but they are unclear as to the timing and the technologies required and how they will deal with the intellectual property issues that may arise. Cangene will pursue the licensing of certain protein therapeutics through this approach with various regulatory groups, but there is no guarantee that this approach will be successful. Cangene believes that proof of therapeutic equivalence of different proteins will expedite the review of clinical trial data. This information may result in fewer requirements for regulatory approval due to the extensive clinical experience available for established products.

Manufacturing of the Company's own products as well as contract-manufacturing services performed by the Company are also subject to extensive regulatory requirements designed to ensure the quality and integrity of pharmaceutical products. Regulatory agencies perform inspections of the Company's manufacturing facilities and documentation on a regular basis. In addition, Cangene has several R&D and manufacturing contracts with U.S. government agencies, these contracts have specific requirements defined by these agencies.

## **BUSINESS RISK FACTORS**

In addition to risk factors discussed elsewhere in this document the reader should be aware that the Company's businesses are subject to risks and uncertainties that cannot be predicted or quantified; consequently, actual results may differ materially from past results and those expressed or implied by any forward-looking statements. Factors that could cause or contribute to such risks or uncertainties include, but are not limited to: the regulatory environment including the difficulty of predicting regulatory outcomes; changes in the value of the Canadian dollar; the Company's reliance on a small number of customers including government organizations; the demand for new products and the impact of competitive products, service and pricing; cost of raw materials, especially the cost and antibody concentration in plasma; fluctuations in operating results; government policies or actions; progress and cost of clinical trials; reliance on key strategic relationships; costs and possible development delays resulting from use of legal, regulatory or legislative strategies by the Company's competitors; uncertainty related to intellectual property protection and potential cost associated with its defence; the Company's exposure to lawsuits and uncertainties related to estimates and judgments used in preparation of financial statements in accordance with GAAP and related standards and other matters beyond control of management.

## **SELECTED CONSOLIDATED FINANCIAL INFORMATION**

### **Summary of Selected Consolidated Financial Information for the Last Three Fiscal Years**

*in thousands of Canadian dollars except share-related data*

|                                                         | <b>Year ended<br/>July 31, 2004</b> | <b>Year ended<br/>July 31, 2003</b> | <b>Year ended<br/>July 31, 2002</b> |
|---------------------------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|
| <b>Revenues</b>                                         | <b>\$ 156,903</b>                   | \$ 186,213                          | \$ 88,314                           |
| <b>R&amp;D expenses (net of investment tax credits)</b> | <b>25,611</b>                       | 18,070                              | 13,157                              |
| <b>Income tax expense</b>                               | <b>18,703</b>                       | 22,066                              | 10,214                              |
| <b>Net income for the year</b>                          | <b>32,542</b>                       | 40,090                              | 10,434 <sup>1</sup>                 |
| <b>Earnings per common share, basic</b>                 | <b>0.52</b>                         | 0.67                                | 0.18 <sup>1</sup>                   |
| <b>Earnings per common share, fully-diluted</b>         | <b>0.50</b>                         | 0.62                                | 0.16 <sup>1</sup>                   |
| <b>Total assets</b>                                     | <b>201,026</b>                      | 187,606                             | 176,523                             |
| <b>Debt</b>                                             | <b>8,902</b>                        | 36,715                              | 73,942                              |
| <b>Dividends</b>                                        | <b>n/a</b>                          | n/a                                 | n/a                                 |

1. 2002 net income reflects an expense of \$5.0 million or \$0.08 per share related to a charge against goodwill.

### **Dividend Policy and Restrictions**

As provided in the *Business Corporations Act* (Ontario), Cangene and its directors are not permitted to declare or pay a dividend if there are reasonable grounds for believing that such payment would render the Company insolvent. There are no other restrictions that would prevent the Company from paying dividends. However, Cangene does not intend to pay dividends on its common shares in the foreseeable future as earnings are expected to be retained to finance the growth of Cangene's business and to expand its research and product development activities.

## **MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

October 6, 2004

*This review contains management's discussion of the Company's operational results and financial condition, and should be read in conjunction with the accompanying audited financial statements and associated notes.*

### **Forward-looking statements**

*Management's discussion and analysis contains certain forward-looking statements that are subject to risks and uncertainties that may cause actual results or events to differ materially from the results or events predicted in this discussion. In addition to the risks outlined in the Risk and Uncertainties section within the MD&A, factors which could cause actual results or events to differ include, but are not limited to: the regulatory environment including the difficulty of predicting regulatory outcomes; changes in the value of the Canadian dollar; the Company's reliance on a small number of customers including government organizations; the demand for new products and the impact of competitive products, service and pricing; cost of raw materials, especially the cost of and the antibody concentration in plasma; fluctuations in operating results; government policies or actions; progress and cost of clinical trials; reliance on key strategic relationships; costs and possible development delays resulting from use of legal, regulatory or legislative strategies by the Company's competitors; uncertainty related to intellectual property protection and potential cost associated with its defence; the Company's exposure to lawsuits and uncertainties related to estimates and judgments used in preparation of financial statements in accordance with GAAP and related standards; and other matters beyond control of management. Forward-looking statements can be identified by the use of words such as "expects", "plans", "will", "believes", "estimates", "intends", "may", "bodes", and other words of similar meaning. Should known or unknown risks or uncertainties materialize, or should management's assumptions prove inaccurate, actual results could vary materially from those anticipated.*

### **Overview**

Cangene Corporation ("the Company" or "the Corporation") is a leading Canadian biopharmaceutical company in the business of developing, manufacturing, and commercializing products and technologies for global markets. Revenues are generated by product sales, contract manufacturing, contract research and development, and royalties.

The Company manages its business and evaluates performances based on two operating segments: biopharmaceutical operations, and contract research and manufacturing. Cangene has two different categories of products in development: hyperimmune products, which are concentrated specialty antibody preparations made from plasma; and recombinant biopharmaceuticals, which are therapeutic proteins made by introducing a particular gene into a host organism, which in turn produces the protein of interest. The Company has particular expertise in manufacturing technically complex and sterile injectable products, and offers contract R&D and manufacturing services to other biopharmaceutical organizations. Cangene has an ongoing innovative R&D program, which provides further opportunities for long-term future growth.

Apotex Holdings Inc., the parent company of Apotex Inc. (a leader in the Canadian generic drug industry), held approximately 81% of Cangene's common stock at October 6, 2004.

Revenues from the biopharmaceutical operations segment have increased steadily over the last few years, primarily related to continued sales growth of the Company's flagship product, WinRho® SDF, which the Company has sold in over 40 countries worldwide. WinRho® was Cangene's first licensed product and established a core competency in the development and manufacture of hyperimmunes. The revenue from this product has funded an

ongoing research and development program of new hyperimmune products—an essential cornerstone of the business strategy. Regulatory submissions for three additional hyperimmune products have either been approved or filed. Research and development of several other hyperimmunes, a majority of which is being funded under various contracts, is underway.

Within the biopharmaceutical operations segment, Cangene is developing certain recombinant biopharmaceutical products as follow-on biologics. The Company has filed for regulatory approval of its leading product in this category, Leucotropin® (“GM-CSF”), in Canada and expects to file an application for its second follow-on product, human growth hormone, in the U.S. in the coming months. Funding to support the research and development of these products through to their initial regulatory filing comes from cash generated from operations and through an R&D agreement with Apotex Inc. During fiscal 2004, Cangene received funding revenues of \$9.3 million through this agreement.

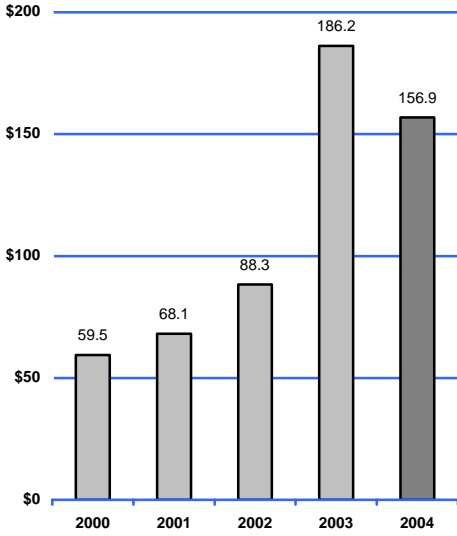
Cangene continues to seek additional geographic markets for WinRho® SDF, while also making efforts to increase penetration in existing markets through new distribution relationships and the application of the product to new medical indications. For the European market, WinRho® SDF is currently licensed in the U.K., Ireland and Poland. In conjunction with its distribution partner, Baxter Healthcare S.A., the Company is using the Mutual Recognition Procedure to prepare additional filings for several more jurisdictions in Europe where a significant market opportunity exists. In efforts to increase penetration in the competitive U.S. market, Cangene has decided to re-align its distribution of WinRho® SDF in the U.S. by selecting Baxter as its new distribution partner, beginning in March 2005.

The Company has also initiated clinical studies to assess the use of WinRho® SDF for treating dengue hemorrhagic fever, which may expand use of the product to new indications. The Company will continue to employ similar market expansion strategies for other hyperimmunes and its recombinant products as they move through the development pipeline.

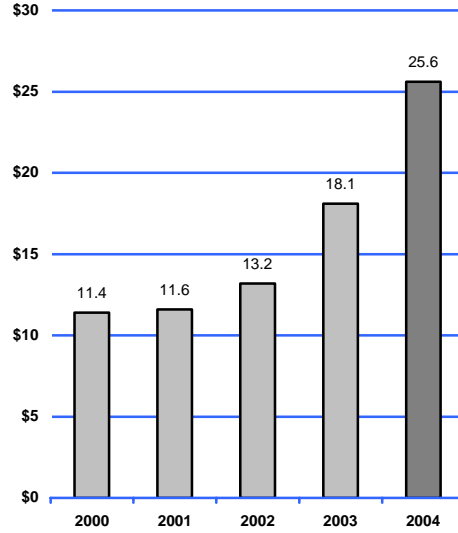
The contract R&D and manufacturing segment continues to contribute significant revenues to the overall business. However, this segment is subject to significant fluctuations in activity as contracts are completed and new contracts initiated. Segment revenues in fiscal 2003 increased \$92.0 million over fiscal 2002 due to a major contract for the supply of Vaccinia immune globulin (“VIG”) to the U.S. government and a significant subcontract to fill/finish smallpox vaccine at Cangene’s U.S.- based Chesapeake Biological Laboratories, Inc. (“Chesapeake”) subsidiary. During 2004, contract R&D and manufacturing revenues declined 28% as the Company completed supply of the initial order for the major contract to supply VIG to the U.S. government and the Company’s U.S. contract manufacturing facilities faced weaker customer demand. Revenues were also affected as the U.S. dollar weakened in relation to the Canadian dollar. Cangene is aggressively pursuing new contract R&D and manufacturing opportunities, including significant contracts with the U.S. government to develop and provide products under the *Bioshield Act*. These contracts, if awarded, would not only provide Cangene with revenues from the development and supply of products to the U.S. government over the next few years as anti-biological warfare stockpiles are built, but could also provide potential to expand product sales to other foreign governments. The Company is currently marketing the VIG product to other foreign governments and has experienced some limited early success. Cangene also continues to seek contract R&D and manufacturing agreements with other biopharmaceutical industry partners, particularly at Chesapeake.

**Selected Annual Information**

**Revenues**  
(in millions)

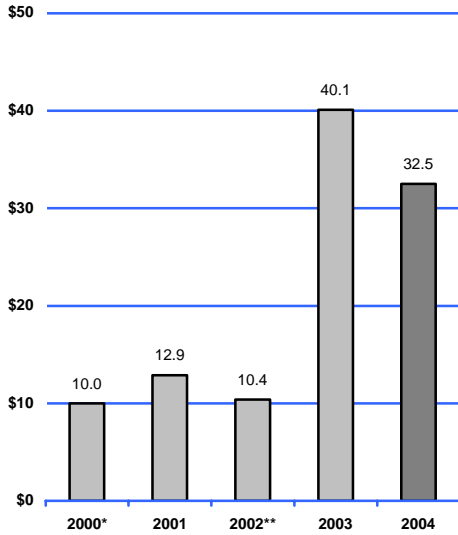


**Research and Development Expenses\***  
(in millions)



\* After applying investment tax credits

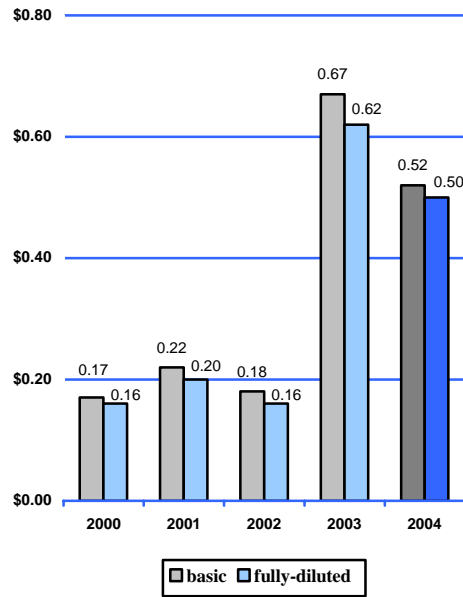
**Net Income**  
(in millions)



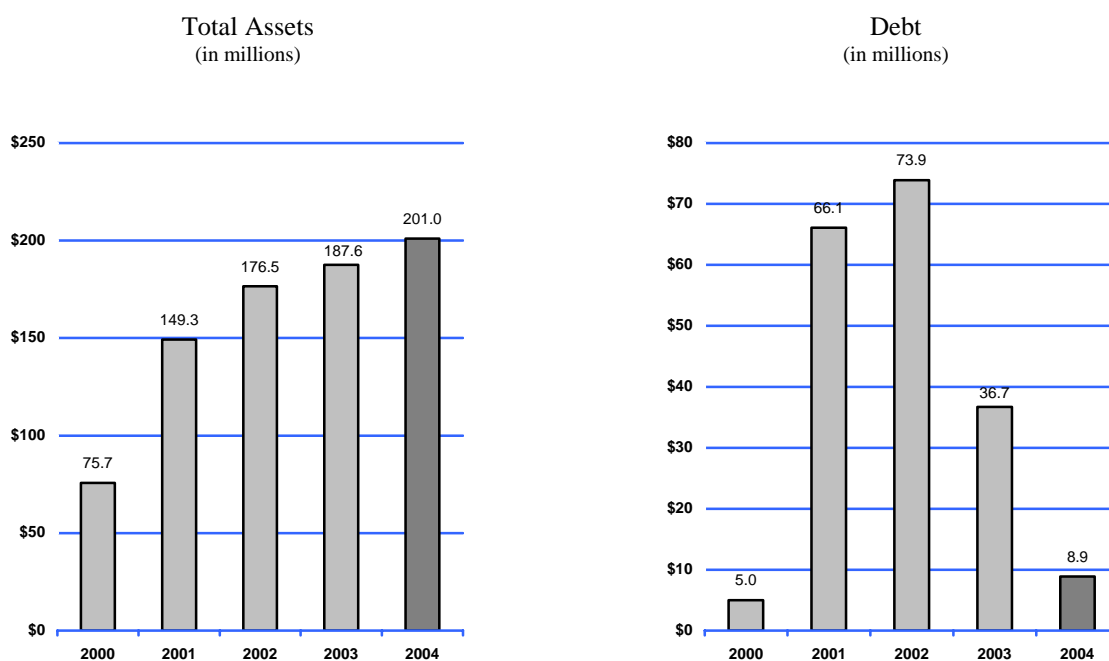
\* Includes special, non-recurring charges of \$4.5 million after tax

\*\* Includes a \$5.0-million charge against goodwill

**Earnings per Share**  
(in millions)



■ basic ■ fully-diluted



The selected annual information presented above is extracted from the Company's financial statements, which are prepared in accordance with Canadian generally accepted accounting principles and reported in Canadian dollars. A significant portion of the Company's revenues are denominated in U.S. dollars and the Company has significant operations in the U.S., requiring translation of these revenues and operations to the reporting currency.

Revenue fluctuations within the contract R&D and manufacturing segment, as discussed above, coupled with a trend toward increasing research and development efforts to expand the Company's product pipeline, have contributed to fluctuations in profitability over the last five years. In the period from fiscal 2000 through 2002, the Company's profitability primarily resulted from WinRho® SDF sales in the biopharmaceutical segment. Net income in fiscal 2002 was reduced as a result of recording a \$5.0-million goodwill impairment related to the Chesapeake contract-manufacturing operation. The dramatic increase in revenue and earnings in 2003 resulted directly from the VIG contract in the Canadian operations and the smallpox vaccine fill/finishing contract at Chesapeake. In fiscal 2004, the Company completed supply of the initial order pertaining to the VIG contract midway through the year, while the volume of fill/finishing activity for smallpox vaccine at the U.S. subsidiary was diminishing as that contract neared completion. While contract-manufacturing volume declined in 2004, the number and magnitude of contract research and development projects increased, along with Cangene's own new product research and development efforts, reflecting a rising trend in research and development expenditures and related contract revenues. Earnings per share over the period reflects the fluctuations in earnings, while the number of shares outstanding has continued to grow gradually over the period, due primarily to the exercise of stock options.

### **New Developments**

In October 2003, the Company announced that it had filed a Canadian New Drug Submission for Leucotrocin®. The submission seeks approval from the Biologics and Genetic Therapies Directorate for use of the drug in enhancing recovery of certain white blood cells in patients with Hodgkin's disease and non-Hodgkin's lymphoma, following stem-cell transplantation. Cangene developed Leucotrocin® with the Apotex Group, which plans to market and distribute the product in Canada upon licensure. Apotex will be entitled to receive a 12% royalty on net

sales after which the two parties will share profits equally. Leucotropin® is Cangene's granulocyte-macrophage colony-stimulating factor ("GM-CSF"), which is a protein that stimulates the production of certain infection-fighting white blood cells. White-blood-cell levels can be depleted by cancer treatments and drug therapies for other conditions, possibly leaving patients susceptible to harmful infections and requiring cessation of treatment. This is the first of Cangene's recombinant biopharmaceutical products to be filed for regulatory approval. The Company will consider seeking licensure in other jurisdictions in the future.

Later in October 2003, the Company also announced that it had signed a research and development contract with the National Institute of Allergy and Infectious Diseases ("NIAID"), part of the United States National Institutes of Health ("NIH"), to develop a hyperimmune specific for the virus associated with severe acute respiratory syndrome ("SARS"). NIAID will supply the plasma and funding for the project. To date, NIAID has supplied a limited amount of plasma in quantities as yet insufficient to allow the Company to undertake further development of this hyperimmune.

At the end of October 2003, Cangene announced that it had entered into an exclusive marketing and distribution agreement with BioGeneriX AG of Mannheim, Germany for Cangene's recombinant human growth hormone. Under the agreement, BioGeneriX will be the sole distributor of the product in Europe, giving Cangene significant access to the European market, especially through the sales force of BioGeneriX' parent company, one of the largest generic drug companies in Europe. Cangene and BioGeneriX will pursue regulatory approval from the European Medicines Agency and any other authority necessary for sales in the region and will share in the costs and profits throughout the life of this agreement. The parties have developed a clinical plan to support submission of a licence application to the European authorities.

Effective the end of February 2004, Mr. Alex Glasenberg retired from his position as Chief Financial Officer of Cangene, having served in that capacity since 1995. Mr. Glasenberg, who will devote his attention to his responsibilities with Apotex Pharmaceutical Holdings Inc., also left Cangene's board. Mr. John McMillan assumed the role of CFO on an interim basis until September, while continuing his role as General Manager with responsibilities for sales, marketing, business development and general administration.

In March, Cangene announced plans to initiate a clinical trial to investigate a new indication for WinRho® SDF in a new patient population. Findings from a pilot study indicate that administration of WinRho® SDF may improve patient survival in cases of dengue hemorrhagic fever ("DHF"). In the pilot study, conducted at Philippine Children's Medical Center and three other hospitals, critically ill young patients showed rapid improvement and were discharged from hospital soon after receiving treatment with WinRho® SDF. The Company plans a six-month trial in two hospitals in the Philippines where DHF places a severe burden on the medical system. The study is currently underway and patient recruitment is ongoing. Positive results could lead to a broader market for WinRho® SDF. DHF is characterized by fever and an extremely low platelet count, which causes increased bleeding and can lead to circulatory failure and shock. Worldwide, 50–100 million cases of dengue fever and several hundred thousand cases of DHF are reported annually, with 250,000 and 7,000 respectively in the Americas. In children under 15 years old, the risk of severe or fatal disease is increased.

Cangene announced in April that it will partner with Defence R&D Canada ("DRDC") on two projects under a Canadian government biodefence initiative. This Chemical, Biological, Radiological and Nuclear Research & Technology Initiative ("CRTI") will invest in twenty-four new projects aimed at developing Canadian counter-terrorism science and technology. Cangene and the University of British Columbia will collaborate with DRDC to identify important structural information about the anthrax antigen to allow development of diagnostic tests and anti-infective treatments. The second project, in partnership with Health Canada as well as DRDC, will aim to leverage Cangene's expertise in developing antibody-based therapeutics to investigate potential new treatments for smallpox exposure. In both instances, the contractual arrangements are being negotiated.

In June, the Company announced a new addition to its board of directors when J. Robert Lavery, FCA joined the board. Mr. Lavery spent 16 years with Ernst & Ernst, now part of KPMG LLP, before co-founding Winpak Ltd. in 1977. Mr. Lavery retired from his position as President and CEO of Winpak in December 2003. He remains on its board as well as serving on the boards of a number of other public and private companies. Mr. Lavery's appointment will strengthen Cangene's board and audit committee. In further board developments, Mr. Edward Sonshine resigned from Cangene's board in July, citing competing time commitments. Mr. Sonshine, president and CEO of Riocan Real Estate Investment Trust, brought a legal perspective to the board. The Company will endeavor to replace Mr. Sonshine as soon as practicable.

In July, Cangene announced that it will change the U.S. distributor for its lead product, WinRho® SDF, when the current distribution agreement with Nabi Biopharmaceuticals expires in March 2005. The new distributor in the United States will be Baxter Healthcare Corporation, which is an affiliate of Cangene's European distribution partner, Baxter Healthcare S.A. The Company believes that having the same distributor in both major markets will enhance its worldwide marketing efforts and allow better coordination of sales and inventory.

At the end of July, Cangene submitted a Biological License Application ("BLA") to the United States Food and Drug Administration ("FDA") for Cangene's VIG product. The Company's application was given fast-track designation by the FDA, which is a program designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions, and that demonstrate the potential to address unmet medical needs. The fast-track designation also allows for a rolling review of the BLA, allowing Cangene to submit data as the trial progresses. Cangene has already manufactured VIG under a five-year supply and development agreement with the United States Centers for Disease Control and Prevention ("CDC") that began two years ago. The Company believes that the granting of an FDA license for the VIG product will enhance its marketability internationally.

The Company has an ongoing agreement with the Apotex Group for the drug known as deferiprone. Under the agreement, Apotex is responsible for manufacturing and marketing the product worldwide and Cangene receives 50% of any net profits from the sales. In return, Apotex received warrants to purchase 5,300,000 common shares of the Company. One half of these warrants expired unexercised on November 5, 2001 and the remaining warrants were exercised on October 30, 2003. During the year ended July 31, 2004, the Corporation earned revenue of \$7.6 million (2003 – \$3.4 million) from the worldwide sales of deferiprone, representing its share of the net profits.

Subsequent to the year-end, the Company announced that it will process plasma to be collected from anthrax-vaccinated military personnel. The U.S. Department of Defense announced that the military will support a Health and Human Services and CDC effort to create a new antibody-based medication against anthrax. An anthrax immune globulin ("AIG") could become a critical medical countermeasure in the event of an anthrax attack.

Also subsequent to the year-end, Cangene announced that it had hired Mr. Michael Graham as its new Chief Financial Officer. Mr. Graham, a chartered accountant, has nearly 20 years of senior management and finance experience with public and privately-held corporations. Mr. John McMillan, who had been interim CFO since the retirement of Mr. Alex Glasenberg in February, continues with his responsibilities for sales, marketing and business development as Vice President of Commercial Development.

### **Competition and Markets**

The Company continues to seek expansion of its market for the sale of WinRho® SDF in all jurisdictions. The majority of the product's sales in Canada are for the suppression of Rh isoimmunization in pregnant, non-sensitized, Rh-negative women (hemolytic disease of the newborn, "HDN"). The product is also licensed for the

treatment of ITP, a clotting disorder, and additional sales opportunities exist within this indication. Conversely in the United States, the majority of sales for WinRho® SDF are for ITP. Nabi Biopharmaceuticals, the Company's current U.S. distributor, has continued to expand the market. The Company believes that its new distribution partner, Baxter Healthcare Corporation, will continue to expand the market when it assumes responsibility for distribution after March 2005. Ongoing product developments will hopefully also lead to expanded sales opportunities in the United States.

Internationally, Cangene continues to market its products aggressively. Although WinRho® SDF is currently licensed in limited jurisdictions in Europe, the Company is using the Mutual Recognition Procedure to seek expanded market opportunities across Europe. Baxter Healthcare S.A., the Company's European distribution partner, will pursue these opportunities as they become available. Cangene will continue to file licence applications in additional jurisdictions throughout the rest of the world as well. In addition, the Company is actively looking at possible opportunities to expand the market for WinRho® SDF by undertaking clinical trials to investigate possible new indications.

Cangene will continue to pursue a growing government contract portfolio, particularly in the United States where the greatest opportunities exist. Accordingly, the Company has put together a group within the business development department that will focus on maximizing opportunities in this area.

The Company continues to pursue a generic-style strategy for certain products in its recombinant biopharmaceutical pipeline. As such, it will compete with already established products in the marketplace. Cangene believes that cost-containment issues within healthcare institutions make the environment favourable for competing on the basis of price. It believes that its manufacturing expertise and cost-effective production technologies will allow it to manufacture products of the highest quality at competitive prices. Cangene's human growth hormone and Leucotropin® will compete with similar products manufactured by other companies; however, both markets are very large. The Company filed a license submission for Leucotropin® during the year; it is the first of the Company's recombinant biopharmaceutical products to be filed for regulatory approval. This represents a significant milestone for Cangene.

## **Results of Operations**

### **Revenues**

Total revenues, from both biopharmaceutical operations and the contract research and manufacturing segment, for the year ended July 31, 2004 were \$156.9 million, a decline of 15.7% from \$186.2 million in the prior year. Revenues from the biopharmaceutical operations segment, consisting primarily of sales of WinRho® SDF, increased to \$65.7 million in the current fiscal year, up 10.8% from \$59.3 million in the prior year. Contract R&D and manufacturing revenues, after the extraordinary results in fiscal 2003, declined 28.1% to \$91.2 million in the current year.

Growth in revenues from the biopharmaceutical segment are primarily attributable to continued strong sales of WinRho® SDF in Canada, the U.S. and international markets. Product sales growth averaged 5.9% overall, and product sales to the U.S. market, comprising 68.7% of total product sales, also grew 5.9% even after considering the impact of translation of \$U.S. revenues at weaker exchange rates. Increased royalty revenue, consisting primarily of Cangene's share of the profits from the sale of deferiprone, the product described earlier that is marketed by Apotex, accounted for the remaining growth in the biopharmaceutical segment.

Contract R&D and manufacturing revenues declined \$35.7 million due to completion of initial requirements of the VIG manufacturing contract midway through the current fiscal year, reduced volume of contract manufacturing at Chesapeake and translation of \$U.S. revenues at weakening exchange rates. The Company anticipates that contract R&D and manufacturing revenues may continue to fluctuate in the future, as major new R&D contracts and manufacturing contracts with the U.S. government, if awarded, would significantly affect revenues from period to period.

Two significant contract research and development projects with the CDC contributed to segment revenue in fiscal 2004. In 2003, the Company was awarded a contract to develop a clinical-grade hyperimmune to be used as an adjunct to antibiotic therapy in critically ill patients with anthrax. Product has been manufactured and supplied to the CDC for non-clinical testing. The program has been expanded to allow for the collection of plasma from personnel at additional military bases. In 2003, the Company was also awarded a contract to develop a clinical-grade hyperimmune to counteract botulinum toxin. To date, assays have been developed and Good Manufacturing Practices (“GMP”) pilot runs undertaken. The Company expects to continue to incur expenditures and record revenue, on a cost-plus basis, in respect of these contracts.

#### **Cost of sales**

Total cost of sales for the year ended July 31, 2004 decreased to \$65.1 million or 41.5% of revenue compared to \$89.1 million or 47.8% in fiscal 2003. Gross profit margins improved in both the biopharmaceutical and the contract R&D and manufacturing segments. Improved margins in biopharmaceuticals resulted from higher WinRho® SDF margins and an increase in royalty revenue from Apotex. Reduced gross profit specific to reduced production volumes of VIG in Canada and viral fill/finishing operations at Chesapeake, and a shift to lower margin manufacturing contracts, was offset by increased R&D revenue and margins from U.S. government research and development contracts.

#### **Research and development**

The Company’s research revenues, included in total revenues, are derived through research agreements with Apotex as well as through other contract research agreements, including agreements with the Canadian and U.S. governments. Research and development expenses for fiscal 2004 increased to \$25.6 million, an increase of 41.7% compared to \$18.1 million in the prior year. Increased research expenses in the biopharmaceutical segment reflect the increased effort and focus on several follow-on biological products. Increased research and development expenditures in the contract research and manufacturing segment are due principally to the impact of a contract research agreement with the CDC for a botulism antitoxin.

#### **Selling, general and administrative expense**

Total selling, general and administrative (“SG&A”) expenses for the year decreased to \$9.7 million, a decrease of 22.0% from \$12.4 million the prior year. Lower SG&A costs in the biopharmaceutical segment resulted from reductions in marketing and selling costs, relating primarily to WinRho® SDF. Lower SG&A expenses in the contract research and manufacturing segment reflect reductions in regulatory filing fees, as well as reductions in salaries and benefit costs in the Chesapeake contract-manufacturing operation as activities were reduced.

**Amortization**

Amortization for the year ended July 31, 2004 increased to \$7.0 million from \$6.1 million in the prior year. Higher amortization costs in 2004 reflect increased investment in plant and equipment for both research and manufacturing, primarily in the biopharmaceutical operations. The increase in amortization costs for the contract research and manufacturing segment was much less pronounced due to minimal growth in investment in new plant and equipment.

**Interest**

Interest costs during fiscal 2004 decreased to \$0.8 million from \$2.5 million in the prior year, due to both reduction in the balance of outstanding bank debt and lower market rates of interest. The Company did not employ any interest rate hedging during the current fiscal year and allowed outstanding bank debt to generally float at short-term market rates of interest.

**Income taxes**

Income tax expense for the year ended July 31, 2004 decreased to \$18.7 million from \$22.1 million in the prior year. The reduction in income tax expense reflects the reduction in pre-tax income for the year, as well as the benefit of recognizing U.S. tax losses recorded in the year.

**Net income**

Net income for the year ended July 31, 2004 was \$32.5 million, compared to \$40.1 million recorded for the prior year. Net income was impacted by reduced revenue in the contract R&D manufacturing segment and increases in research and development expenditures, partly offset by lower SG&A costs and lower income taxes.

**Basic EPS and diluted EPS**

Basic earnings per share for the year ended July 31, 2004 was \$0.52 per share compared to \$0.67 per share in the prior year, reflecting the effect of reduced net earnings and an increase in the number of common shares outstanding. Diluted earnings per share equalled \$0.50 per share for fiscal 2004 compared to \$0.62 per share last year. Diluted earnings per share is calculated under the treasury stock method, which assumes that all outstanding stock options and warrants, where the exercise price is less than current market price, are exercised and the proceeds of such exercise are used to repurchase shares at the current market price.

**Summary of Quarterly Results**

| Quarters ended<br><i>in thousands of Canadian dollars except per-share data</i> | July 31,<br>2004<br>(Q4 2004) | April 30,<br>2004<br>(Q3 2004) | January 31,<br>2004<br>(Q2 2004) | October 31,<br>2003<br>(Q1 2004) | July 31,<br>2003<br>(Q4 2003) | April 30,<br>2003<br>(Q3 2003) | January 31,<br>2003<br>(Q2 2003) | October 31,<br>2002<br>(Q1 2003) |
|---------------------------------------------------------------------------------|-------------------------------|--------------------------------|----------------------------------|----------------------------------|-------------------------------|--------------------------------|----------------------------------|----------------------------------|
| Revenues                                                                        | \$ 32,988                     | \$ 39,193                      | \$ 45,524                        | \$ 39,198                        | \$ 47,188                     | \$ 61,243                      | \$ 49,077                        | \$ 28,705                        |
| Research and development expense <sup>1</sup>                                   | 8,477                         | 7,429                          | 5,743                            | 3,962                            | 5,973                         | 4,804                          | 3,913                            | 3,380                            |
| Net income                                                                      | 7,753                         | 6,247                          | 8,707                            | 9,835                            | 11,225                        | 13,816                         | 9,567                            | 5,482                            |
| Earnings per share                                                              |                               |                                |                                  |                                  |                               |                                |                                  |                                  |
| Basic                                                                           | \$ 0.12                       | \$ 0.10                        | \$ 0.14                          | \$ 0.16                          | \$ 0.19                       | \$ 0.23                        | \$ 0.16                          | \$ 0.09                          |
| Diluted                                                                         | \$ 0.12                       | \$ 0.10                        | \$ 0.13                          | \$ 0.15                          | \$ 0.17                       | \$ 0.22                        | \$ 0.15                          | \$ 0.08                          |

<sup>1</sup> Net of investment tax credits

Variations in quarterly revenues over the past eight quarters illustrate the impact of the VIG contract on total revenues over the last half of 2003 and early 2004. VIG sales to the U.S. government began in the second quarter of 2003 and reached a peak of \$31.1 million in the third quarter of 2003, with final deliveries of \$11.2 million completed in the third quarter of fiscal 2004. The third and fourth quarters of 2004 reflect the impact of reduced contract-manufacturing activity at Chesapeake as the fill/finishing contract for smallpox vaccine concluded and the effect of the weakened U.S. dollar on foreign currency translation. Research and development expenditures continued trending upward throughout the period as a result of increases in the number of contract research and development projects, for which contract revenues are being generated, and from internal research and development of biopharmaceutical products that the Company is undertaking. Net income and earnings per share over the eight quarters directly reflect the impact of fluctuations in revenues and earnings from the contract-manufacturing activities.

**Fourth Quarter**

Total revenues for the fourth quarter of 2004 declined from previous quarters due to reduced contract-manufacturing activity, following initial order completion of the VIG contract, and reduced smallpox vaccine fill/finishing activity at Chesapeake.

Research and development expenditures continued to increase in the quarter compared with previous quarters as the Company intensified internal new product development efforts.

Net income for the fourth quarter of 2004 declined compared with the same quarter of the previous year, but showed improvement over the prior quarter. Net income and earnings per share in the fourth quarter of 2004 were favourably impacted by foreign exchange gains and year-end adjustments to income taxes.

## **Liquidity and capital resources**

### **Operating activities**

Cash at July 31, 2004 was \$4.0 million, a decrease of \$2.3 million from the previous fiscal year. Cash generated from operating activities of \$39.1 million decreased from \$47.6 million in the prior year, due to lower contract-manufacturing revenues; the decrease was offset partially by reductions in working capital balances.

Net non-cash working capital decreased to \$16.7 million at July 31, 2004 compared to \$22.1 million a year earlier, generating cash of \$5.4 million in the current year. Reduced working capital levels resulted from reductions in outstanding accounts receivable and increased financing of income taxes, partially offset by an \$8.5-million increase in inventory that resulted primarily from an increase in raw material and finished goods inventories for the VIG product, which the Company anticipates will be used to meet future U.S. government and international orders.

### **Financing activities**

Cash used in financing activities decreased to \$17.0 million in fiscal 2004 compared to \$25.2 million in the prior year. The reduced use of cash for financing activities reflects a reduction in repayment of long-term debt and increased proceeds from the exercise of warrants and stock options during the current year.

### **Equity**

The Corporation's authorized share capital consists of an unlimited number of non-voting preferred shares with a 4% non-cumulative dividend entitlement; Class A preferred shares, to be issued in series with rights to be determined at issuance by the Board of Directors; and common shares. No preferred shares have been issued. The following is a continuity of the common shares issued and outstanding:

| <i>in thousands of Canadian dollars except share-related data</i> | Number of Shares |           |
|-------------------------------------------------------------------|------------------|-----------|
| Share capital as at July 31, 2002                                 | 59,795,945       | \$ 11,532 |
| Stock options exercised                                           | 911,625          | 4,531     |
| Share capital as at July 31, 2003                                 | 60,707,570       | 16,063    |
| Stock options exercised                                           | 625,650          | 2,505     |
| Warrants exercised                                                | 2,650,000        | 6,148     |
| Share capital as at July 31, 2004                                 | 63,983,220       | \$ 24,716 |

The Corporation, through the Board of Directors, may authorize the grant of options to acquire up to 8 million common shares under terms of the stock option plan, provided that the number of options issued and outstanding to any one individual at any time does not exceed 5% of the outstanding common shares. At July 31, 2004, 0.8 million (2003 – 0.8 million) options remained available to be granted under the existing plan. The exercise price of options granted under the plan cannot be lower than the market price of the Corporation's common shares on the date that the options are granted. These options expire no later than five and eight years after the date they are granted for directors and employees, respectively, and vest evenly over a period of four fiscal years.

During the current year, the Corporation granted 50,000 (2003 – 752,200) new options to acquire common shares at a weighted-average price of \$11.11, and cancelled 73,200 options (2003 – 188,100). Employees and directors of the Corporation exercised 625,650 options at a weighted-average exercise price of \$4.15 per share during the year. The Corporation anticipates that employees and directors will continue to exercise options in the future as such options vest, to the extent that exercise prices are less than the market price of the common shares. The

Corporation is currently considering alternatives to the existing stock option plan, and depending upon the outcome of such deliberations, may not grant any additional options under the existing plan.

On November 5, 1996, the Corporation acquired the rights to a new drug, deferiprone, from Apotex Research Inc., a company under common control, and in exchange issued warrants to purchase 5.3 million shares of the Corporation. A total of 2.65 million of the warrants expired unexercised during the year ended July 31, 2002. Apotex Inc. exercised the remaining 2.65 million warrants on October 30, 2003 at an exercise price of \$2.32 per common share acquired. As a result, no warrants are currently outstanding.

The following table illustrates the expected and maximum number of common shares outstanding as at November 12, 2004, assuming exercise of all exercisable outstanding stock options:

|                          | Exercise Price | Number of securities outstanding | Weighted-average remaining contractual life | Number of options outstanding and exercisable | Number of common shares upon conversion or exercise <sup>1</sup> |
|--------------------------|----------------|----------------------------------|---------------------------------------------|-----------------------------------------------|------------------------------------------------------------------|
| Common shares            |                | 64,257,320                       |                                             |                                               | 64,257,320                                                       |
| Stock options            | \$ 2.04        | 368,000                          | 0.7 years                                   | 368,000                                       | 368,000                                                          |
|                          | 3.50           | 398,500                          | 1.9                                         | 398,500                                       | 398,500                                                          |
|                          | 3.55           | 445,925                          | 1.3                                         | 445,925                                       | 445,925                                                          |
|                          | 4.65           | 325,275                          | 2.9                                         | 325,275                                       | 325,275                                                          |
|                          | 8.03           | 549,300                          | 3.2                                         | 549,300                                       | 549,300                                                          |
|                          | 6.25           | 678,700                          | 4.0                                         | 678,700                                       | 678,700                                                          |
|                          | 7.04           | 90,100                           | 4.5                                         | 90,100                                        | 90,100                                                           |
|                          | 9.31           | 580,250                          | 5.0                                         | 580,250                                       | 580,250                                                          |
|                          | 10.60          | 625,200                          | 5.8                                         | 468,900                                       | 468,900                                                          |
|                          | 11.55          | 40,000                           | 7.1                                         | 30,000                                        | 30,000                                                           |
|                          | 9.33           | 10,000                           | 7.7                                         | 5,000                                         | 5,000                                                            |
|                          | \$ 9.33        | 7,500                            | 7.7 years                                   | 1,875                                         | 1,875                                                            |
| Subtotal – Stock options |                | 4,118,750                        |                                             | 3,941,825                                     | 3,941,825                                                        |
| <b>Total</b>             |                | <b>68,376,070</b>                |                                             |                                               | <b>68,199,145</b>                                                |

<sup>1</sup> Assuming exercise of all exercisable options whether in the money or not. Closing price for Cangene's common shares on the Toronto Stock Exchange November 12, 2004 was \$11.05.

The Corporation anticipates that it could raise new equity where there is a requirement for new capital funding for growth, and where and when, a market opportunity exists.

## Debt

Effective January 1, 2003, the Corporation renewed its senior credit facilities, consisting of a \$15-million revolving operating line of credit and \$38.1 million U.S. of non-revolving term loans with its principal banker, a Canadian chartered bank. The non-revolving-term loans consisted of a \$29.5-million U.S. loan that was originally drawn to fund a portion of the Chesapeake acquisition and an \$8.6-million U.S. loan that was originally advanced to fund certain equipment and facility capital expenditures in 2002. During the period January 1, 2003 to December 31, 2003, the Corporation repaid \$25.6 million U.S. of total principal on the outstanding term loans, of which \$9.9 million U.S. was paid during the first five months of the current fiscal year. On January 1, 2004, the Corporation once again renewed its senior credit facilities, consisting of a \$15-million revolving operating line of credit and

\$12.5 million U.S. of non-revolving-term loans, representing the remaining outstanding balances of these term loans at that time. The renewal of the term loans consisted of a \$5.9-million U.S. balance outstanding on the loan for the Chesapeake acquisition and a \$6.6-million U.S. balance remaining on the loan to fund 2002 capital expenditures.

Advances under the operating line of credit bear interest at variable rates, either at Canadian prime, U.S. base rate or LIBOR plus 1.25%, at the Corporation's option. The revolving facility is collateralized by a general security agreement in respect of all assets and the agreement expires on December 31, 2004 unless otherwise renewed at the option of the bank. As at July 31, 2004, the Corporation had no advances (2003 – Nil) outstanding on the revolving operating facility. Cangene anticipates that the existing revolving operating line of credit will be renewed on or before the December 31, 2004 maturity date.

Since the January 1, 2004 renewal, the Corporation has repaid the remaining \$5.9-million U.S. balance on the loan for the Chesapeake acquisition and has repaid approximately \$3.2 million U.S. of the term loan used to fund the 2002 capital expenditures. As at July 31, 2004, \$3.3 million U.S. (\$4.3 million Cdn) of the term loan used to fund capital expenditures remained outstanding. The remaining term loan outstanding is collateralized by a general security agreement and bears interest at LIBOR plus 1.5%. The Corporation is continuing to repay the outstanding balance through monthly principal instalments of \$165,000 U.S. (\$218,000 Cdn), with final repayment of any outstanding principal amount due on April 30, 2007.

In 1996, the Corporation's U.S. subsidiary, Chesapeake, received funding from the Maryland Industrial Development Financing Authority in the form of a \$7.0-million U.S. Economic Development Revenue Bond for the construction of its main production facility. The bond is secured by the subsidiary's real property, matures on August 1, 2018, and bears interest at LIBOR, except for \$2.0 million U.S. (\$2.6 million Cdn) with the interest payable at a fixed rate of 6.99% to November 2005. Chesapeake is required to make quarterly principal repayments on the bond of \$150,000 U.S. (\$198,210 Cdn). As at July 31, 2004 there was a balance of \$3.5 million U.S. (\$4.6 million Cdn) outstanding under the bond.

Chesapeake has a \$1.0-million U.S. revolving line of credit with a regional U.S. bank, secured by the subsidiary's inventory and accounts receivable. The revolving line of credit bears interest at LIBOR plus 2.25% and the facility matures on December 31, 2004. As at July 31, 2004, there was \$0.4 million U.S. (2003 – Nil) outstanding under the revolving line of credit.

The Corporation has available a \$5.0-million revolving term loan from its majority shareholder, Apotex Holdings Inc. Interest on the loan is payable at the Canadian prime rate plus 1% and the facility matures in 2005. As at July 31, 2004, no balance (2003 – Nil) was outstanding under this revolving term facility.

The following table summarizes the Corporation's long-term debt and other contractual obligations:

| <i>in thousands of Canadian dollars</i>  | <b>Total at<br/>July 31, 2004</b> | <b>Payments Due by Period</b> |                 |                 |                  |
|------------------------------------------|-----------------------------------|-------------------------------|-----------------|-----------------|------------------|
|                                          |                                   | Less than 1<br>year           | 1–3 years       | 4–5 years       | After 5<br>years |
| Long-term debt                           | \$ 8,902                          | \$ 3,324                      | \$ 3,398        | \$ 1,090        | \$ 1,090         |
| Capital lease obligations                | –                                 | –                             | –               | –               | –                |
| Operating leases                         | 6,454                             | 2,468                         | 2,487           | 500             | 999              |
| Purchase obligations <sup>1</sup>        | –                                 | –                             | –               | –               | –                |
| Other long-term obligations <sup>2</sup> | –                                 | –                             | –               | –               | –                |
| <b>Total contractual obligations</b>     | <b>\$ 15,356</b>                  | <b>\$ 5,792</b>               | <b>\$ 5,885</b> | <b>\$ 1,590</b> | <b>\$ 2,089</b>  |

1 "Purchase obligation" means an agreement to purchase goods or services that is enforceable and legally binding on the Company and that specifies all significant terms, including: fixed or minimum quantities to be purchased; fixed, minimum or variable price provisions; and the approximate timing of the transaction.

2 "Other long-term obligations" means other long-term liabilities reflected on the Company's balance sheet.

### **Investing activities**

Cash used in investing activities increased to \$24.4 million for the year ended July 31, 2004, compared to \$17.6 million in the prior year. The increase in investing activity is entirely due to increased capital expenditures on plant and equipment as the Corporation continues with plans to expand its research and manufacturing facilities to address new business opportunities.

### **Summary**

The Company's ability to generate funds from operating activities, including product sales, contract research and manufacturing, as well as debt financing from its bank and parent, are expected to provide sufficient liquidity to meet anticipated needs of existing projects, absent the occurrence of any unforeseen events.

### **Related-party transactions**

The Corporation has an agreement with Apotex Inc., a company under common control, to support the development of certain biopharmaceutical products through to initial regulatory filing. In fiscal 2004, the Corporation recorded revenue of \$9.3 million (2003 – \$10.2 million) under the terms of this agreement, of which \$1.2 million (2003 – \$1.0 million) was included in accounts receivable at the year-end. Research revenue received pursuant to this contract is based on the direct research costs plus a contribution to overhead. Under the terms of the agreement, Apotex Inc. will be entitled to receive a 12% royalty on net sales of the biopharmaceutical products developed by the Corporation and will hold the right to distribute these products. Apotex Inc. and the Corporation will share profits equally after deducting royalty payments. No sales of biopharmaceutical products developed pursuant to this agreement have been made to July 31, 2004.

On November 5, 1996, the Corporation acquired the rights to a new drug, deferiprone, from Apotex Research Inc., in exchange for issuing warrants to purchase 5.3 million common shares. Under the terms of the agreement, warrants to purchase 2.65 million shares of the Corporation expired unexercised on November 5, 2001. The

remaining 2.65 million warrants were exercised by Apotex Inc. on October 30, 2003 at an exercise price of \$2.32 per common share. The Corporation receives 50% of any net profits from sales of the drug worldwide. During the year ended July 31, 2004, the Corporation earned revenue of \$7.6 million (2003 – \$3.4 million) from the worldwide sales of deferiprone, of which \$2.2 million (2003 – \$1.2 million) was included in accounts receivable at July 31, 2004.

The Corporation has separate agreements with Apotex Inc., a company under common control, to conduct contract research on two products being developed by Apotex Inc. for future licensure and commercialization. In fiscal 2004, the Corporation earned and recorded \$4.7 million (2003 – \$2.1 million) of contract-research revenue under the terms of these agreements, \$0.5 million (2003 – \$1.9 million) of which was included in accounts receivable at July 31, 2004. The terms of these agreements are representative of normal commercial terms for the type of contract research being undertaken. The Corporation has no future rights or obligations, beyond the current agreements, with respect to these products.

Cangene has entered into a rental agreement with Apotex Fermentation Inc. for the use of certain facilities and equipment in order to conduct certain research activities. Under the terms of this agreement, the Corporation paid rent of \$0.5 million during fiscal 2004 (2003 – \$0.4 million).

### **Critical accounting estimates**

The preparation of financial statements that present fairly the financial position, financial condition and results of operations in accordance with Canadian generally accepted accounting principles requires that the Corporation make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the balance sheet date and reported amounts of revenues and expenses during the reporting period. Actual results could differ materially from these estimates. The following is a summary of critical accounting estimates and assumptions that the Corporation believes could materially impact its reported financial position, financial condition or results of operations:

### **Goodwill valuation and impairment**

The Corporation acquired Chesapeake Biological Laboratories, Inc., a U.S.-based contract-manufacturing business, on January 31, 2001 and recorded goodwill at the time of acquisition with a book value and a fair value of \$51.8 million. The Corporation, in accordance with *CICA Handbook Section 3062 – Goodwill and Other Intangible Assets* (“Section 3062”), effective January 1, 2002, has established a process for testing the valuation of goodwill on an annual basis for purposes of determining any potential impairment. In order to establish that the carrying value of net assets, including goodwill, for a particular business reporting unit exceeds the fair value, the Corporation is required to make significant estimates and assumptions regarding the timing and magnitude of future cash flows.

When evaluating goodwill, the Corporation uses estimates or forecasts of future cash flows for the next five years, plus estimates of residual cash flows beyond that time, discounted using an estimated discount rate which reflects assumptions regarding its weighted-average cost of capital. Qualitative factors, including market presence and trends, strength of customer relationships, strength of local management, strength of debt and capital markets and degree of variability in cash flows, as well as other factors, are considered in making assumptions with regard to future cash flows and the appropriate discount rate. The Corporation has not changed its approach or method of evaluating goodwill since it adopted this methodology. However, the Corporation believes that its contract manufacturing operations in Canada and the U.S. are essentially identical; consequently, the goodwill was evaluated in the context of an aggregated contract R&D and manufacturing segment.

Goodwill impairment, when determined, reduces the carrying value of goodwill on the balance sheet and is recorded as a separate charge to income. Goodwill impairment would typically be a non-cash charge, since the valuation is being performed on assets acquired and related cash outflows from prior investments. Subsequent to the adoption of Section 3062, and based on greater uncertainty in the marketplace, the Corporation recorded a loss of \$5.0 million with respect to its contract-manufacturing operations for the year ended July 31, 2002. No goodwill impairment was recorded in 2003, and based upon the recent evaluation of goodwill, no impairment was recorded for the year ended July 31, 2004. A change in any of the significant assumptions or estimates used to evaluate goodwill could result in material change to the results of operations.

#### **Impairment of long-lived assets—viral facility**

Subsequent to the acquisition of Chesapeake, the Corporation decided to make an additional investment in the U.S. contract-manufacturing subsidiary to construct a specialized fill/finishing facility to process live viral vaccines. The decision to construct this facility was made in large part as a result of an award of a significant subcontract from a vaccine manufacturer that was a successful bidder on a major contract to supply smallpox vaccine to the U.S. government. The Corporation believed that sufficient future demand for live-virus contract fill/finishing services existed to support the decision to invest.

Subsequent to July 31, 2004, the existing contract to supply fill/finishing services to the smallpox vaccine manufacturer will come to a conclusion, and the Corporation is currently evaluating a number of opportunities to generate revenues and cash flow from this facility.

The Corporation, in accordance with Section 3063 of the *CICA Handbook* and in light of the uncertainty regarding the future cash flows to be generated from this facility, evaluated this long-lived asset for potential impairment. The net book value of this asset was compared to the estimated future undiscounted cash flows to be generated directly from the use or operation of this facility over its expected remaining life. The Corporation was required to make significant estimates and assumptions regarding both the amount and timing of future estimated cash flows.

Impairment relating to long-lived assets, when determined, reduces the carrying value of the asset recorded on the balance sheet and results in a separate charge to income. Impairment relating to long-lived assets is typically a non-cash charge since the valuation is being performed on assets acquired or investments made in prior accounting periods. To date, no impairment with respect to the Chesapeake viral facility, or any other long-lived asset, was recorded. Any change in any of the critical assumptions or estimates used to value the long-lived assets could result in a material change to results of operations.

#### **Future benefit of tax loss carryforwards**

In 2003, the Corporation recorded a deferred tax asset of \$5.0 million to recognize the future benefit of previously unrecorded tax-loss carryforwards and deductible temporary differences arising from its U.S. operations, principally the Chesapeake subsidiary. During 2004, the Corporation recorded an additional future tax asset of \$5.0 million to recognize the future benefit of current year operating losses and deductible temporary differences for tax purposes that are expected to be utilized to offset taxable income, and thereby reduce taxes payable in future years. Existing accumulated operating losses can be carried forward to offset future taxable income for periods of 18–20 years.

In accordance with *CICA Handbook Section 3465 – Income Taxes*, the Corporation should only recognize the future benefit of tax loss carryforwards where it is more likely than not that sufficient future taxable income can be generated in order to fully utilize such losses and deductions. The Corporation is required to make significant estimates and assumptions regarding future revenues and earnings, and its ability to implement certain tax planning

strategies in order to assess the likelihood of utilizing such losses and deductions. These estimates and assumptions are subject to significant uncertainty, and if changed could materially affect the Corporation's assessment of the ability to fully realize the benefit of the future income tax assets. Future tax asset balances would be reduced, and additional income tax expense recorded in the applicable accounting period in the event that circumstances change and the Corporation, based on revised estimates and assumptions, determined that it was no longer likely that future tax assets would be fully realized.

### **Accounting changes, including initial adoption of accounting policies**

The preparation of financial statements that present fairly the financial position, financial condition and results of operations in accordance with Canadian generally accepted accounting principles requires that the Corporation adopt, select and apply the appropriate accounting policies and principles, particularly where alternatives exist, within GAAP. During 2004, the Corporation initially adopted or changed accounting policies and principles as follows:

#### **Revenue arrangements with multiple deliverables**

Effective December 17, 2003, the CICA Emerging Issues Committee issued *Abstract-143 – Revenue Arrangements with Multiple Deliverables* with respect to identification of separate units of accounting for multiple deliverables and allocation of revenues based on the relative fair values of such deliverables. This guidance reflects the same pronouncements already in place in the United States for a number of years and which have been followed by Canadian public companies. The Corporation has expanded the disclosure of its existing revenue recognition policies in the current year to meet the requirements under this new *Abstract*. The Corporation expects these principles to significantly impact the financial statements in the future as it engages in an increasing number of complex and longer-term government and non-government contracts that often include separately identifiable deliverables.

#### **Foreign currency translation of foreign operations**

On April 30, 2004, the Corporation implemented a change to its method of translating foreign currency to Canadian dollars with respect to the assets, liabilities, revenue and expenses of its principal U.S. subsidiary, Chesapeake.

Under Canadian GAAP, issuers of financial statements are required to evaluate whether or not the operations of a foreign subsidiary or division are considered to be integrated or self-sustaining, which would determine the appropriate method of translating foreign currency denominated accounts of foreign operations.

Prior to April 30, 2004, the Corporation was applying the current-rate method of foreign currency translation appropriate to a self-sustaining foreign operation. Under this method, the assets and liabilities of Chesapeake were translated into Canadian dollars using the rate of exchange in effect at the balance sheet dates. Revenues and expenses (including amortization) were translated at the average monthly exchange rates. Exchange gains and losses arising from the translation were included in the cumulative translation adjustment account, a separate component of Shareholders' Equity. As well, the exchange gains and losses arising from the translation of certain U.S. non-revolving loans, recorded on the books of the Corporation and originally used to fund the acquisition of Chesapeake, and which have been designated as a hedge of the net investment in Chesapeake, were also included in the cumulative translation account.

Effective May 1, 2004, the Corporation has concluded that as a result of changes in the economic facts and circumstances, the Chesapeake subsidiary should be designated as an integrated foreign operation for the purposes of foreign currency translation, and accordingly commenced applying the temporal method of foreign currency

translation. The Corporation reached this conclusion on the basis that the day-to-day operations and activities of Chesapeake are essentially similar to and under common management with the Canadian contract-manufacturing operations, the Corporation is providing cash management and operating funding to the operation, and the Corporation is planning on contracting with Chesapeake to provide manufacturing capacity and services in the future. Under the temporal method, monetary assets and liabilities of the subsidiary are translated into Canadian dollars using current rates of exchange at the balance sheet dates while non-monetary assets and liabilities are translated at historical rates of exchange. Revenues and expenses of the operation, other than amortization, are translated at monthly-average exchange rates, while amortization is recorded at the historical rate of exchange applicable to the related non-monetary asset. Exchange gains and losses arising on translation are included in income in the period incurred. The income impact of this change in accounting policy for 2004 was a fourth-quarter recognition of foreign exchange gains of \$3.3 million.

### **Stock-based compensation**

Effective August 1, 2002, the Corporation prospectively adopted the recommendations of the Canadian Institute of Chartered Accountants for Stock-Based Compensation and Other Stock-Based Payments (“Section 3870”). The new recommendations are generally applicable only to awards granted after the date of adoption. The effect of this change is to provide pro forma disclosure of net income and earnings per share as if stock options granted since August 1, 2002 were accounted for using the fair-value method.

In November 2003, Section 3870 was amended to require that all stock-based compensation be measured and expensed using a fair-value based methodology. The Corporation will adopt the new recommendations effective August 1, 2004.

### **Financial instruments**

The current assets and liabilities of the Corporation, which are subject to normal trade terms, are financial instruments for which the recorded carrying values approximate the fair value. The long-term debt obligations of the Corporation, for which no ready market exists, have been evaluated on the basis of discounted cash flows and it is believed that the fair value of these obligations is approximately equal to the current carrying value. The Corporation is, however, exposed to financial market risks, including foreign currency exchange rates and interest rates on long-term debt obligations. The Corporation currently uses derivative financial instruments to manage exposure to changes in foreign currency exchange rates and interest rate risk relating to certain debt obligations.

### **Foreign currency risk**

Cangene operates internationally, and a majority of its revenue and a significant amount of its expenditure activities are denominated in U.S. dollars. The Corporation has entered into forward-exchange contracts to sell U.S. dollars and purchase Canadian dollars at fixed rates of exchange as a means of mitigating its exposure to fluctuations in exchange rates. The Corporation has not applied hedge accounting to these derivative instruments. The forward-exchange contracts are marked to market at each reporting date and both realized and unrealized gains and losses resulting from settlement of these contracts and changes in exchange rates are recorded in income in the current period. Assets or liabilities arising from the unrealized gains or losses on these contracts are recorded on the balance sheets as current amounts receivable or payable. The Corporation uses these derivative instruments as a risk-management tool and not for trading or speculative purposes.

**Interest rate risk**

The Corporation is exposed to interest rate risk on borrowings under its revolving operating line of credit, non-revolving term loans and a non-revolving industrial development bond, each of which are subject to variable interest rates. A portion of the outstanding balance of the industrial development bond is subject to a fixed interest rate. Reductions in the outstanding balances of these credit facilities during the 2004 fiscal year has significantly reduced the exposure to short-term fluctuations in interest rates. Based on the current levels of debt outstanding, a significant change in short-term interest rates would be necessary to materially impact the Corporation's results of operations.

**Risks and uncertainties**

The Corporation is subject to certain risks and uncertainties inherent in the operation of the business. It attempts to mitigate these risks through a combination of sound management practices, insurance and systems of internal control. Some of the principal risks and uncertainties, although not all inclusive are:

**Risks associated with new product development**

One of the core competencies of the Corporation is research and development of new biopharmaceutical products. Many of the Corporation's products are still under development. Considerable costs are incurred at every stage of identifying, developing, manufacturing and marketing new products.

There can be no assurance during any given research stage that any viable new products will be developed for which a market demand exists. The costs of conducting basic research to identify potential new product opportunities can be significant. There can be no assurance during any development stage that any new products developed will receive regulatory approval. And if approved, some of these products will compete with established products of proven safety and efficacy, the manufacturers of which can be expected to employ intellectual property challenges against commercialization of these products by Cangene. There can be no assurance that the Corporation's products will be commercialized or, if commercialized, that medical centres, hospitals, physicians or patients will accept them in lieu of existing treatments. Accordingly, there can be no assurance that these products can be successfully manufactured and marketed profitably.

**Impact of regulatory delays on generic-style strategy**

The Corporation plans a generic-style approach to the licensing of certain biopharmaceutical products, by which it expects to receive regulatory approval to sell and distribute these products with reduced clinical studies and within shorter time frames than for first-to-market products. There can be no assurance that regulatory agencies in any markets will accept this approach for all or any of the products. If this generic-style strategy cannot be successfully employed to obtain simplified product approval from the regulatory agencies, the Corporation would have to follow a full clinical-trial program for its biopharmaceutical drugs, which could materially slow the commercialization and increase the cost of approval. Longer approval times, leading to a delay in time-to-market, could materially affect the competitiveness of a particular product in terms of market penetration and price.

**Dependence on availability and quality of raw materials**

Cangene's profitable manufacture of WinRho® SDF and its other hyperimmune products is dependent upon the availability of plasma with sufficient antibody levels. Plasma is collected from donors through both company-owned and third-party collection centres, and accordingly, is subject to donor participation. Furthermore, the level of antibodies in the plasma of donors is variable and unless concentrations of antibodies in the plasma are

sufficient, the cost of processing plasma to the end product may not be economically viable. Cangene believes that it has sufficient relationships with third-party plasma collection centres to ensure an adequate supply of plasma in the foreseeable future; however, there can be no assurances that shortages will not develop.

### **Compliance with regulatory requirements**

Cangene's ability to manufacture and ship its products is subject to numerous regulatory requirements and conditions, which are complex and evolving. The supply of product, and hence the revenues generated, could be interrupted should compliance become an issue. There can be no assurances that the Corporation will remain in compliance at all times, although it undertakes a very stringent quality assurance, quality control and regulatory review process internally on a continuous basis to minimize this risk.

### **Reliance on distribution relationships**

A significant portion of Cangene's revenues from its principal product, WinRho® SDF, are derived from sales through existing exclusive distributors in the U.S. and international markets. During 2005, the Corporation plans to change its distribution relationships such that a sole distributor will have the right to distribute WinRho® SDF throughout the U.S. and Europe. As a result, Cangene is relying on the sales and marketing strength, and the distribution channels through which this distributor operates, for a significant portion of its revenues. There can be no assurance that the Corporation will be able to retain this distribution relationship indefinitely and that it will be able to rely upon the sales, marketing and distribution efforts of this distributor to continue to support the sales of this product in these significant markets.

### **Potential liabilities associated with intellectual property claims**

Cangene has adopted a strategy to license and manufacture certain biopharmaceutical products as generic or follow-on alternatives to existing products in the marketplace. Due to the nature of the products being developed and the complexity of law governing intellectual property rights, the Corporation may face increasing exposure to intellectual property claims as it pursues this strategy. Defending intellectual property claims, whether or not such claims have merit, can result in the Corporation incurring significant legal costs. Inability to defend such claims could lead to loss of rights to manufacture and sell a product, even after significant costs have been incurred for development and licensing. There can be no assurances that the Corporation will not become subject to intellectual property claims, nor can there be any assurance that the Corporation will be able to successfully defend such claims.

### **Customer concentration and reliance on contracts**

Cangene is party to significant contracts with Canadian and U.S. government agencies, as well as with a small number of third parties and Apotex Inc., a related party. There can be no assurance that these customers will continue to purchase products or services from the Corporation at current levels or at all.

### **Fluctuations in demand resulting from certain events**

The Corporation has entered into contracts and submitted proposals with the U.S. government to develop and manufacture certain products for use in counteracting the effects of biological agents that could be used by terrorists as biological weapons. By their nature, these contracts call for Cangene to supply such products to a national

stockpile, to be used only in the event of an actual incident or attack. Accordingly, demand for these products should be expected to fluctuate significantly, both at the time of establishing initial stockpiles and in the event of any such subsequent biological warfare event. Should such events not occur, future demand for such products may not materialize.

### **Expansion into foreign markets**

Cangene has sold WinRho® SDF in some 40 countries throughout the world, and views international markets as having significant potential for market expansion of several of its products. Although the Corporation believes that the international political and regulatory environment has not presented a sustained barrier to its ability to ship product in the past, there can be no assurance that future political or regulatory events will not impede distribution of products to these markets in the future.

### **Competition**

Cangene competes in a number of segments within the biopharmaceutical industry, some of which are subject to significant competition. Competition in the contract research and manufacturing segment in North America appears to be intensifying, with a small number of well-positioned organizations attempting to provide a complete suite of services. Cangene anticipates it will compete with a number of larger manufacturers in the production of certain biopharmaceutical products. In addition, the Corporation anticipates facing increasing competition as it attempts to further penetrate existing markets and expand its products into new markets.

Given these industry characteristics, existing or new competitors may be significantly larger and have greater financial, research, manufacturing or marketing resources than Cangene. These competitors may compete with Cangene in providing both products and services in markets in which Cangene currently operates, as well as competing to enter new markets where Cangene desires to expand. Further, competitors may employ tactics, such as intellectual property challenges, to prevent or impede Cangene's progress in expanding its markets. There can be no assurances that the Corporation will be able to maintain or achieve its desired market share in any particular industry segments or markets.

### **Foreign currency risk**

As noted previously, the majority of Cangene's revenues are generated from non-Canadian customers and accordingly are typically transacted in foreign currencies, primarily U.S. dollars. Although the Corporation also incurs significant U.S. dollar-denominated expenses, there has historically been a net inflow of U.S. dollars. In addition, the Corporation's net earnings can be materially affected directly by exchange rate fluctuations as net earnings from U.S. operations are translated to Canadian dollars for reporting purposes. The Corporation has entered into forward exchange contracts in efforts to mitigate the impact of fluctuations in exchange rates on U.S. dollar cash flows.

### **Additional information**

Additional information relating to Cangene Corporation, including the most recently filed Annual Information Form, can be found on the Company's website at [www.cangene.com](http://www.cangene.com) or on SEDAR at [www.sedar.com](http://www.sedar.com).

**MARKET FOR SECURITIES**

The common shares of Cangene are listed and posted for trading on the Toronto Stock Exchange under the symbol CNJ.

| <b>Month</b>   | <b>High</b> | <b>Low</b> | <b>Volume</b> |
|----------------|-------------|------------|---------------|
| August 2003    | 12.60       | 11.27      | 326,248       |
| September 2003 | 12.95       | 11.70      | 450,024       |
| October 2003   | 12.65       | 12.05      | 506,227       |
| November 2003  | 12.29       | 11.10      | 409,018       |
| December 2003  | 12.50       | 10.90      | 636,828       |
| January 2004   | 12.50       | 11.45      | 695,584       |
| February 2004  | 11.75       | 11.11      | 785,160       |
| March 2004     | 11.85       | 11.00      | 1,005,748     |
| April 2004     | 11.29       | 9.65       | 565,222       |
| May 2004       | 10.60       | 9.90       | 289,960       |
| June 2004      | 10.59       | 9.21       | 487,535       |
| July 2004      | 9.74        | 9.25       | 195,615       |

**DIRECTORS AND OFFICERS FISCAL 2004**

| <b>Name and Municipality of Residence</b>                   | <b>Office</b>                                        | <b>Director Since</b>                               | <b>Principal Occupation</b>                                                                                                                                                                                                                                                                                                             |
|-------------------------------------------------------------|------------------------------------------------------|-----------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| R. Craig Baxter <sup>1,3</sup><br>Richmond Hill,<br>Ontario | Director                                             | November 1,<br>1995                                 | President of Apotex International, Inc. and Executive Vice President of Apotex Inc. Prior to that, he was Vice President, Finance and Corporate Development. Mr. Baxter has been employed with Apotex since May 1985. Apotex has its head office in Toronto and is one of Canada's largest domestically-owned pharmaceutical companies. |
| Alex Glasenberg <sup>4</sup><br>Thornhill, Ontario          | Chief Financial Officer <sup>4</sup><br>and Director | November 1,<br>1995 (until<br>February 29,<br>2004) | Senior Vice President – Finance and Chief Financial Officer, Apotex Pharmaceutical Holdings Inc., prior thereto, CFO, Apotex Inc. He joined Apotex in May 1990. Apotex has its head office in Toronto and is one of Canada's largest domestically-owned pharmaceutical companies.                                                       |
| Jack M. Kay <sup>2</sup><br>Richmond Hill,<br>Ontario       | Director                                             | November 1,<br>1995                                 | President and COO of Apotex Inc. Prior thereto, he was Executive Vice-President. Mr. Kay joined Apotex in 1982. Apotex has its head office in Toronto and is one of Canada's largest domestically-owned pharmaceutical companies.                                                                                                       |
| John M. Langstaff <sup>2,3</sup><br>Winnipeg, Manitoba      | President and Chief Executive Officer, and Director  | November 1,<br>1995                                 | President and Chief Executive Officer, Cangene, since November 1, 1995. Prior thereto, President and CEO, Rh Pharmaceuticals Inc. from 1994, and VP Operations and Research, Rh Pharmaceuticals 1990 to 1994.                                                                                                                           |

|                                                           |                                                                                   |                                          |                                                                                                                                                                                                                                                                                                                                         |
|-----------------------------------------------------------|-----------------------------------------------------------------------------------|------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| J. Robert Lavery <sup>12,3,6</sup><br>Winnipeg, Manitoba  | Director                                                                          | June 1, 2004                             | President of Shaunnara Corp., an investment management company he has owned for the 27 years. In December 2003, he retired from his 26-year position as President and CEO of Winpak Ltd., a company he co-founded in 1977. Winpak Ltd. manufactures and distributes high-quality packaging materials and innovative packaging machines. |
| Bernard C. Sherman<br>Toronto, Ontario                    | Chairman                                                                          | November 1, 1995                         | Chief Executive Officer and Chairman of the Board, Apotex Inc. Dr. Sherman has been the Chief Executive Officer of Apotex since he established the corporation in 1974. Apotex has its head office in Toronto and is one of Canada's largest domestically-owned pharmaceutical companies.                                               |
| Edward Sonshine <sup>5</sup><br>Toronto, Ontario          | Director                                                                          | January 29, 2003<br>(until July 9, 2004) | President and CEO of Riocan Real Estate Investment Trust, a TSX-listed organization. He has held this position since the Trust's inception in 1993. Riocan is the leading retail landlord in Canada, and Canada's largest Real Estate Investment Trust.                                                                                 |
| Michael Spino<br>Pickering, Ontario                       | Director                                                                          | November 1, 1995                         | President, ApoPharma Inc. and Senior Vice President – Scientific Affairs, Apotex Inc.<br><br>ApoPharma is part of the Apotex Group and is responsible for the discovery and development of innovative drugs. Apotex has its head office in Toronto and is one of Canada's largest domestically-owned pharmaceutical companies.          |
| Jerry Treppel <sup>1,3</sup><br>Edison, New Jersey<br>USA | Director                                                                          | January 29, 2003                         | General Partner and fund manager at Wheaten HealthCare Partners LP (a hedge fund) in the United States. He was Managing Director of Equity Research at Banc of America Securities, LLC from June 1999 until June 2002. Prior thereto, he was Managing Director of Equity Research at UBS Warburg from 1995 until 1999.                  |
| William Bees<br>Winnipeg, Manitoba                        | Vice President,<br>Operations (Officer)                                           | n/a                                      | Vice President, Operations, Cangene, prior thereto, Vice President Operations, Rh Pharmaceuticals since 1995 and Director of Operations, Rh from 1990 to 1995.                                                                                                                                                                          |
| Wendy M. Johnson<br>Spruce Grove, Alberta                 | Vice President, Research<br>& Development (Officer)                               | n/a                                      | Vice President, R&D, Cangene since 1999. Prior thereto, Dr. Johnson was Acting Director of the Bureau of Microbiology of the Laboratory Centre for Disease Control, a division of Health Canada's Health Protection Branch ("HPB"). Prior to that, she was Associate Director at HPB where she had been employed for over 24 years.     |
| John W. McMillan<br>Winnipeg, Manitoba                    | Vice President –<br>Commercial Operations<br>and Corporate Secretary<br>(Officer) | n/a                                      | Vice President – Commercial Operations and Corporate Secretary of Cangene, effective September 20, 2004. Prior thereto, General Manager and Corporate Secretary. Mr. McMillan also served as interim CFO from March 1, 2004 until September 20, 2004.                                                                                   |

|                                        |                                                                            |     |                                                                                                                                                                                                                                 |
|----------------------------------------|----------------------------------------------------------------------------|-----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Andrew D. Storey<br>Winnipeg, Manitoba | Vice President – Quality Assurance/Clinical & Regulatory Affairs (Officer) | n/a | Vice President, Quality Assurance/Clinical & Regulatory Affairs. Prior thereto, Mr. Storey was Director of Quality Assurance and Regulatory Affairs from 1995 to 1999 and prior thereto, manager of the same from 1993 to 1995. |
|----------------------------------------|----------------------------------------------------------------------------|-----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

- 1 Member of Audit Committee
- 2 Member of Nominating Committee
- 3 Member of Compensation and Governance Committee
- 4 Mr. Glasenberg resigned his position on Cangene's Audit Committee and Board of Directors, as well as his position as CFO effective February 29, 2004.
- 5 Mr. Sonshine resigned his position on Cangene's Audit Committee, Nominating Committee, and the Compensation and Governance Committee along with his position on Cangene's Board of Directors effective July 9, 2004
- 6 Mr. Lavery joined Cangene's board effective June 1, 2004

Each director of Cangene is elected annually and holds office until the next annual meeting of shareholders unless that person ceases to be a director before then. Cangene's annual meeting of shareholders for fiscal 2004 is scheduled for January 12, 2005. Cangene is currently seeking a new board member to replace Mr. Sonshine who resigned from the board in July 2004.

#### **Shareholdings by directors and officers as a group**

At December 10, 2004, the directors and senior officers of Cangene, as a group, beneficially owned, directly or indirectly, or exercise control or direction over, 52,310,929 common shares or approximately 81.4% of Cangene's outstanding common shares.

#### **Board committees**

Cangene does not have an Executive Committee but is required under the *Business Corporations Act* (Ontario) to have an Audit Committee. Until February 29, 2004, the members of Cangene's Audit Committee were Alex Glasenberg, Edward Sonshine and Jerry Treppel. Mr. Glasenberg retired from his Board position, including the Audit Committee, effective February 29, 2004. He was replaced, effective June 1, 2004, by J. Robert Lavery. On July 9, 2004, Mr. Sonshine also stepped down from his Board and Committee positions. Cangene is currently seeking a new board member to replace Mr. Sonshine; in the interim, Mr. Baxter has joined the Audit Committee. As a result, Cangene's Audit Committee comprises Messrs. Baxter, Lavery and Treppel, all of whom are outside, unrelated directors, and all of whom have expertise in financial matters. Mr. Baxter is an officer of Apotex-Group member companies and Messrs. Lavery and Treppel are free of any interest in the Apotex Group, Cangene's majority shareholder. Mr. Glasenberg was also the Company's chief financial officer until February 29, 2004.

In addition to the Audit Committee, Cangene has a Nominating Committee, comprising Dr. Langstaff, and Messrs. Lavery and Kay. Dr. Langstaff is an inside director; Mr. Lavery is an outside, unrelated director; and Mr. Kay is an outside, unrelated and is an officer of an Apotex-Group member company.

Cangene also has a Compensation and Governance Committee comprising Dr. Langstaff and Messrs. Baxter, Lavery and Treppel. As described earlier, Dr. Langstaff is an inside director, Messrs. Lavery and Treppel are outside, unrelated directors and Mr. Baxter is an outside, unrelated director and also an officer of Apotex-Group member companies.

Craig Baxter, Alex Glasenberg, Jack Kay, Bernard Sherman and Michael Spino are officers of companies belonging to the Apotex Group. Specifically, Messrs. Baxter and Kay, and Dr. Sherman are directors and officers of Sherfam Inc. the parent company of Apotex Holdings Inc. (Apotex Holdings Inc. is Cangene's majority

shareholder; it is a member of the commonly-controlled Apotex Group, which collectively holds 81% of Cangene's outstanding shares). Mr. Baxter and Dr. Sherman are also directors and officers of Apotex Holdings Inc. Mr. Kay and Dr. Sherman are directors and officers of Apotex Inc., a member of the Apotex group and a company with which Cangene has an ongoing R&D agreement. Mr. Baxter is also an officer of Apotex Inc. Apotex Inc. is an integrated Canadian pharmaceutical company, focused primarily on developing generic medicines and a member of the Apotex Group. Edward Sonshine is an officer of RioCan Real Estate Investment Trust and Jerry Treppel is an officer of Wheaten HealthCare Partners LP, a hedge fund. Mr. Lavery is President of Shaunnara Corporation, an investment management company he has owned for the past 27 years.

**Corporate cease trade orders or bankruptcies**

Not applicable

**Penalties or sanctions**

Not applicable

**Personal bankruptcies**

Not applicable

**Conflicts of interest**

See Board committees

**ADDITIONAL INFORMATION**

If Cangene securities are in the course of a distribution under a preliminary short form prospectus or a short form prospectus and upon request to the Secretary, Cangene will provide at no charge a copy of this Annual Information Form, the comparative financial statements for the year ended July 31, 2004 and accompanying auditor's report, the most recently filed interim financial statements for any period following that year end, the Management Information Circular dated November 26<sup>th</sup>, 2004 issued in respect of the Company's 2004 Annual Meeting of Shareholders, and any other documents that may be incorporated by reference into the preliminary short form prospectus or the short form prospectus. At any other time, Cangene will provide the above documents but may require the payment of a reasonable charge if a request is made by a person or company who is not a security holder of Cangene.

Additional information, including the director's and officer's remuneration and indebtedness, principal holders of Cangene's securities, options to purchase securities and interests of insiders in material transactions, where applicable, as at the end of the Company's fiscal year ended July 31, 2004, is contained in Cangene's Management Information Circular dated November 26<sup>th</sup>, 2004, prepared for its 2004 Annual Meeting of Shareholders. Additional financial information is provided in Cangene's comparative financial statements for its most recently completed financial year, which are included in Cangene's 2004 Annual Report. Information about the Company's product development pipeline is also contained in its 2004 Annual Report. Copies of the Circular, Annual Report, or additional public information may be obtained upon request from the Investor Relations department at Cangene Corporation, 3403 American Drive, Mississauga, Ontario, L4V 1T4 or by email at [jcompton@cangene.com](mailto:jcompton@cangene.com). Investor information is also available from the Company's website, [www.cangene.com](http://www.cangene.com).