



**CANGENE CORPORATION**

**RENEWAL ANNUAL INFORMATION FORM**

**for the fiscal year ended July 31, 2005**

**October 27, 2005**

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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/ 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>Cangenus™</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>CDC</b>	Centers for Disease Control and Prevention; an agency of the U.S. Department of Health and Human Services
<b>CRTI</b>	CBRN Research and Technology Initiative; a Canadian government initiative
<b>cGMP</b>	Current Good Manufacturing Practices; a set of international quality guidelines for 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 a 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>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; used to treat certain adverse reactions to smallpox vaccination

## **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 AND MAJORITY SHAREHOLDER**

### **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 (“Cangene U.S.”), which is incorporated in the State of Delaware in the United States. Cangene U.S. 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. Cangene U.S. also owns 100% of Biotherapeutic Laboratories, Inc. in California and Mid-Florida Biologicals, Inc. that has operations in Florida and Maryland. Cangene operates an office in the U.K., Cangene Europe Limited (U.K.).

**Majority Shareholder**

Bernard Sherman controls the Apotex Group, which includes Apotex Holdings Inc, Apotex Inc, Apotex Research Inc. and other subsidiary companies, as well as related entities such as Sherman Foundation. He controls Apotex Inc. and Apotex Holdings Inc. indirectly through the Bernard and Honey Sherman Family Trust, of which he is the Trustee. Dr. Sherman is a director and President of Sherman Foundation and as such controls its holdings indirectly. At October 27, 2005, Dr. Sherman held or controlled 80% of Cangene's common stock as follows:

Apotex Inc.	2,350,000 common shares
Apotex Holdings Inc.	37,707,808 common shares
Sherman Foundation	11,807,979 common shares
Barry Sherman	110,000 common shares (held directly)

**GENERAL DEVELOPMENT OF THE BUSINESS****Overview and 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.

Hyperimmunes are purified antibodies that are used therapeutically, and Cangene uses its own innovative approach to manufacturing these products, which results in a high yield and excellent product purity. The Company has three approved hyperimmune products, one more that has been submitted for regulatory review in the U.S. and Canada, and others in various stages of development.

The Company is pursuing a follow-on strategy for certain recombinant protein products it is developing and manufacturing using its own efficient processes. The Company believes that using this type of strategy to capitalize on the success of known commercial products eliminates one area of development uncertainty. One of these products has been submitted for regulatory review in Canada, and Cangene is preparing for a U.S. filing of a second product.

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 U.S. 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 maternal and fetal blood. WinRho® SDF is also approved in certain jurisdictions for treating an autoimmune condition, called immune thrombocytopenic purpura ("ITP"), that results in a clotting deficiency due to a drop in blood platelets. Interim results from a recent clinical trial investigating the potential use of WinRho® SDF to treat dengue hemorrhagic fever, a severe sequela of the mosquito-borne infection, dengue fever, showed the drug met its study endpoint, which indicates it may also be useful for treating other infectious diseases that cause dangerously low platelet counts. During fiscal 2005, a liquid version of WinRho® SDF was approved by the United States Food and Drug Administration. Liquid versions of injectable drugs rather than freeze-dried product that must be reconstituted before use can offer greater convenience for physicians and healthcare providers.

Thirty-four percent of Cangene's revenue in fiscal 2005 resulted from biopharmaceutical product sales, the majority of which is WinRho® SDF.

In addition to its biopharmaceutical business segment, Cangene offers contract R&D and manufacturing services through its main Winnipeg facility and its wholly owned subsidiary, Chesapeake Biological Laboratories, Inc. located in Baltimore, MD. 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 of sterile product formulations, test method development and validation, process design and manufacturing validations, regulatory and compliance consulting, and fill/finishing of viral vaccines. During fiscal 2005, contract R&D and manufacturing revenue made up 48% 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").

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. In March 2005, the Canadian government awarded Cangene a \$3.2 million contract to supply VIG. And during fiscal 2005, Cangene submitted VIG to the United States Food and Drug Administration ("FDA") for review; the product was subsequently approved in May 2005. Subsequent to the year-end, the U.K. Department of Health awarded Cangene a contract to supply VIG. The contract has an estimated value of \$17.0 million. Cangene expects to complete delivery during fiscal 2006. The U.S. department of Defense has indicated that it intends to contract with Cangene as the sole source for a supply of VIG for a period of up to five years.

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 who have anthrax and to develop a hyperimmune to counteract botulinum toxin (the toxin that causes botulism). In October 2004, 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.

Subsequent to the year-end, Cangene was awarded a contract by the Office of Public Health Emergency Preparedness, in the office of the Secretary of U.S. Department of Health and Human Services ("DHHS") to supply Cangene's anthrax immune globulin for preliminary efficacy testing. Based on the outcome of this testing and several other factors, the DHHS has an option, within a year of the award date, to purchase between 10,000 and 100,000 doses of AIG over a period of three years. If the DHHS exercises this option, Cangene will be required to undertake the steps necessary for licensure by the FDA.

Cangene has entered into two marketing and distribution agreements for WinRho® SDF. Under an agreement with Baxter Healthcare S.A., Baxter will market and distribute WinRho® SDF in Europe for treating a blood clotting disorder called immune thrombocytopenic purpura ("ITP"). Baxter has already launched the product in the United Kingdom. In December 2004, European approval for WinRho® SDF was expanded to eleven countries through the European Mutual Recognition Procedure ("MRP"). In addition, Baxter (through Baxter Healthcare Corporation) assumed exclusive marketing and distribution rights for WinRho® SDF in the U.S. in March 2005 when a previous

marketing arrangement with Nabi Biopharmaceuticals expired.

Cangene has also entered a marketing and distribution agreement with BioGeneriX AG for Cangene's recombinant human growth hormone. Under the agreement, BioGeneriX AG 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.

Cangene has a research and development agreement with Apotex Inc. (a member company of the Apotex Group; Cangene's majority shareholder; see page 6) 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. Apotex 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 to more than 115 countries, and has approximately 5,200 employees across Canada.

Resulting from an earlier licensing agreement, Cangene receives 50% of any net profits worldwide on a drug called Ferriprox™ (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 received \$3.4 million from sales of Ferriprox™ 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.

Cangene made no acquisitions during the 2005 fiscal year.

## **NARRATIVE DESCRIPTION OF THE BUSINESS**

### **General**

Cangene is a Canadian biopharmaceutical company that develops, manufactures and markets specialty plasma products (hyperimmunes) and recombinant therapeutic products for international markets. Both product classes fall within the segment identified as biopharmaceuticals in the financial statements. It also offers various contract R&D and manufacturing services to biopharmaceutical and pharmaceutical companies.

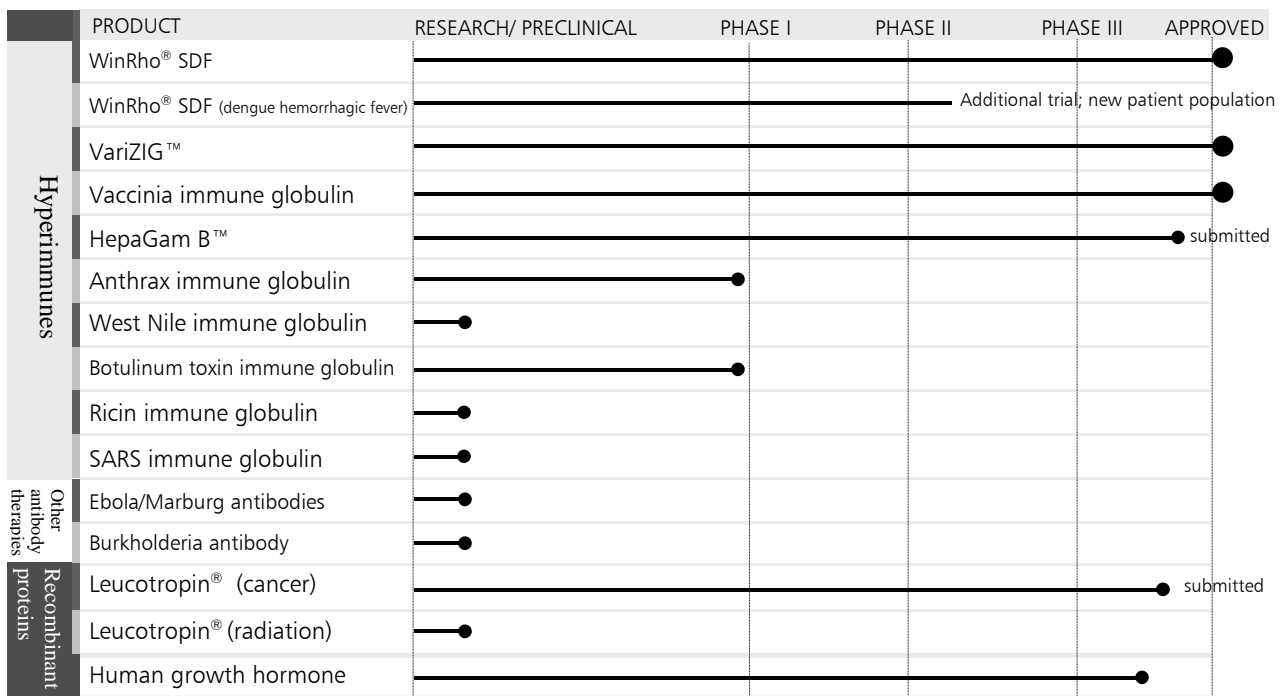
Cangene has been listed since 1991 on the Toronto Stock Exchange under the symbol CNJ. The Apotex Group controlled 80% of the issued and outstanding common shares of Cangene at October 27, 2005 (see page 6). Having two independent revenue streams diversifies the Company's risk somewhat, although the nature of the Company's contract business, which tends to rely on a small number of large contracts, does generate an uneven revenue flow. Generally, the Company has been increasingly profitable, although results for 2005 did not follow the growth trend set by the previous ten years, and the Company reported a loss in the second and fourth quarters of 2005. After the exceptional results recorded in 2003, the results for 2004 appeared disappointing, yet they followed the growth trend seen in years prior to 2003. In the absence of major government contracts during fiscal 2005, contract R&D and manufacturing revenues still accounted for 48% of the total revenues for the year. To continue

developing new products and technologies, Cangene also maintains substantial independent R&D activities both internally and through collaborations with third parties.

For its hyperimmunes, which are purified antibodies used for therapeutic purposes, the Company uses an innovative approach to manufacturing that gives it a high yield and excellent product purity. Cangene is also developing recombinant 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, which is Cangene’s majority shareholder, includes Apotex Inc., which is one of Canada’s largest pharmaceutical companies and a world leader in the generic drug industry.

The Company’s pipeline consists of a number of products with significant commercial potential, including three approved products, and two 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 most of the Company’s \$35 million in biopharmaceutical product sales in 2005. WinRho® SDF sales decreased in fiscal 2005, reflecting the impact of reduced U.S. sales, as Cangene transitioned to a new distributor, and a weaker U.S. dollar.

**Pipeline**



**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 biopharmaceutical 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 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 R&D 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, USA. 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 for 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 R&D and manufacturing business, and the Chesapeake operation makes contract services a significant contributor to the Company's revenue stream, and in fiscal 2005 contract R&D and manufacturing services accounted for 48% 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 (see pages 14 and 25) 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. Such contracts, while beneficial to the Company, can result in a certain degree of volatility in revenue and cash flow.

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.

## **Biopharmaceutical Segment**

### **Hyperimmunes and other Antibody-based Therapies**

#### 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 a significant portion of Cangene's biopharmaceutical revenue in 2005.

Cangene is considered a leader in developing and manufacturing hyperimmune products. Based on its twenty-year history manufacturing WinRho® SDF, it 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

Status	Approved for both ITP and HDN (see below) in major jurisdictions, including: Canada, United States, eleven countries in the European Union, India, Pakistan and Egypt. WinRho® SDF is more widely approved for HDN alone and has been sold in about 40 countries. WinRho® SDF generated the most of Cangene's \$35 million biopharmaceutical product sales in 2005.
Description/ Background	Cangene's lead plasma product, WinRho® SDF [ <i>Rho(D) Immune Globulin Intravenous (Human)</i> ] is a purified polyclonal human immunoglobulin or antibody, specific for Rh+ red blood cells.

It was initially developed as a preventative 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 subsequent pregnancies. By reacting with any fetal blood in the mother’s blood stream, WinRho® SDF can prevent the immune reaction, preventing future complications.

In 1993, Rh Pharmaceuticals Inc. (a company that amalgamated with Cangene in 1995) licensed, 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 1993 in Canada for preventing HDN, and was 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.

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. WinRho® SDF was licensed by the FDA for treating ITP in the United States in 1995.

#### Marketing/ 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 2005. While the product is being successfully marketed internationally, Cangene continues pursuing a broadened distribution network worldwide.

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.

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 for treating ITP. Baxter has already launched the product in the United Kingdom. In December 2004, European approval for WinRho® SDF was expanded to eleven countries through the European Mutual Recognition Procedure (“MRP”). In addition, Baxter (through Baxter Healthcare Corporation) assumed exclusive marketing and distribution rights for WinRho® SDF in the U.S. in March 2005 when a previous marketing arrangement with Nabi Biopharmaceuticals expired.

Total WinRho® SDF sales were down in the 2005 fiscal year reflecting both weaker U.S. sales and the effect of translating the weaker U.S. dollar. The change in distributors part way through the year negatively affected sales initially; however, Baxter has committed to increasing U.S. sales and launching the drug in the European countries where it is newly licensed.

The Company also has marketing arrangements in various other jurisdictions.

#### Recent

**Developments** In 2004, Cangene initiated a clinical study to investigate the use of WinRho® SDF to treat dengue hemorrhagic fever (“DHF”), 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 expansion of its ITP indication into a new patient population. In February 2005, Cangene completed analysis of interim data from this trial, which indicated the drug met its primary endpoint of increasing platelet counts by 20,000 at 48 hours after dosing. The Company plans to use these results to assess the potential for WinRho® SDF to treat other common and economically significant diseases that also cause reduced platelet levels.

In April 2005, the United States FDA approved a liquid formulation of WinRho® SDF. WinRho® SDF Liquid provides an alternative to the freeze-dried version and eliminates the need for reconstitution prior to administration. This provides increased convenience to healthcare providers administering the drug. Baxter is committed to launching WinRho® SDF Liquid in the U.S. in calendar 2005.

**Competition** There are a number of competitors for the Anti-D immunoglobulin market. The competition differs in various jurisdictions and for different indications, depending on the nature and stage of regulatory approval. WinRho® SDF 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 for the HDN market comes from major pharmaceutical companies: Ortho-Clinical Diagnostics (a Johnson & Johnson company), ZLB Behring (a subsidiary of CSL Limited), and Talecris Biotherapeutics, Inc. (formerly Bayer Healthcare Biologicall plasma products). However, WinRho® SDF sales in the U.S. are almost exclusively for the ITP indication. 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.

In Western Europe, Northern Africa and the Middle East, competing products are manufactured by a number of other companies.

WinRho® SDF also competes in the ITP market with non-anti-D therapies such as intravenous immune globulin (“IVIG”), immunosuppressants and chemotherapies.

WinRho® SDF enjoys a significant market share in some jurisdictions, but there can be no guarantee that new competitors or aggressive marketing strategies by existing competitors will not affect WinRho® SDF sales in the future.

Vaccinia Immune Globulin (“VIG”)

Status Approved in the U.S. by the FDA in May 2005.

Description/  
Background

Vaccinia Immune Globulin (Human) Intravenous is a purified polyclonal human immunoglobulin (antibody) specific for Vaccinia virus, the virus used to make smallpox vaccine. Vaccinia is not the virus that causes smallpox but it is similar enough to elicit a protective immune response when used as a vaccine. However, susceptible individuals may incur a Vaccinia infection from the vaccination, which requires the administration of VIG as a therapy. A stockpile of VIG is a prudent component of a smallpox vaccination program. VIG is the lead product in Cangene’s biodefence program.

In August 2002, the United States Centers for Disease Control and Prevention awarded Cangene a significant contract to develop and supply VIG for use in treating and preventing certain 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 completed supply on the initial order under this contract during fiscal 2004 (see page 25). As part of the contract, Cangene undertook to take VIG through regulatory approval in the U.S. 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 submitted the drug to the FDA in July 2004, and it was approved in May 2005, making it Cangene’s first licensed biodefence product and the first licensed product in the U.S. biodefence stockpile.

Market/  
Sales

Cangene developed and manufactured this product under contract with the U.S. government and has already supplied the initial order. VIG sales began in the second quarter of fiscal 2003, reaching a peak of \$31.1 million in the third quarter of that year. It completed the order with sales of \$11.2 million in the third quarter of fiscal 2004. While additional VIG product could be ordered under the initial five-year contract, future revenue from this product may depend on Cangene’s ability to market the product to other governments.

In March 2005, the Health Canada Centre for Emergency Preparedness and Response awarded Cangene a \$3.2 million contract to supply VIG. Under the terms of the agreement, Cangene intends to seek Health Canada approval for the product.

Cangene anticipates that having an FDA licence for VIG may enhance its ability to market the drug internationally. Other governments are establishing smallpox vaccination programs and are expected to seek a VIG product as part of those programs.

Recent Developments	The FDA licensed VIG in May 2005. Subsequent to the year-end, the U.K. Department of Health awarded Cangene a contract to supply VIG. The contract has an estimated value of \$17.0 million. Cangene expects to complete delivery during fiscal 2006. The U.S. Department of Defense has indicated that it intends to contract with Cangene as the sole source for a supply of VIG for a period of up to five years.
Competition	DynPort Vaccine Company LLC manufactures a VIG product that was approved by the FDA in February 2005. DynPort developed its product in conjunction with the U.S. Department of Defense Joint Vaccine Acquisition Program and is largely focused on the military. To Cangene's knowledge, Dynport is not marketing the product internationally. Cangene and Dynport have agreed to share Orphan Drug Status for the product.

### VariZIG™

Status	Cangene's VariZIG™ received Canadian approval in January 2001 for preventing chicken pox during pregnancy, but the product has not been actively marketed. Cangene has submitted further information to Health Canada to update its regulatory file and is also seeking U.S. licensure. A former competitor, Massachusetts Biological Laboratories ceased production of its Varicella zoster immune globulin and existing supplies will be exhausted early in 2006; Cangene is preparing to respond to this unmet medical need.
Description/ Background	VariZIG™ or Varicella zoster Immune Globulin (Human) Intravenous is a purified polyclonal human immunoglobulin (antibody) specific for Varicella zoster virus, the agent that causes chicken pox and that can cause shingles. Cangene's VariZIG™ is formulated for intramuscular or intravenous administration. Chicken pox can cause serious complications during pregnancy, and pregnant women who are not already immune may be particularly susceptible.
Market/ Sales	As most North American adults have developed immunity to chickenpox, this product has a small market, estimated at about \$2.3 million annually. While a vaccine against chicken pox exists, certain at-risk patients would require treatment with a Varicella zoster immune globulin in the event of exposure, because of this, there is ongoing medical need, which will be unserved when current supplies of the competitive product run out.
Competition	No currently manufactured competitive product is licensed for the North American market.

HepaGam B™

Status	Submitted for regulatory review in United States and Canada.
Description/ Background	<p>HepaGam B™ is Cangene's Hepatitis B Immune Globulin (Human) Intravenous, and is a purified polyclonal human immunoglobulin or antibody, specific for hepatitis B surface antigen. It is formulated for intramuscular or intravenous administration. Hepatitis B is a highly infectious virus that can be spread through contact with blood or other bodily fluids from a person who is positive for hepatitis B, or can be transmitted from an infected mother to a newborn during birth. It is approximately 50–100 times more infectious than HIV, and the infection can become chronic and produce severe liver problems.</p> <p>Cangene completed a pivotal clinical trial with this product during 2000, and subsequently filed a Biologics License Application with the FDA and a New Drug Submission with Health Canada in 2001.</p>
Market/ Sales	<p>Hepatitis B is a major disease worldwide and a significant public health problem. Approximately two billion people worldwide have been infected with the virus; more than 350 million of these have chronic infections. In the developing world, most people become infected in childhood and hepatitis B infection in young children is most likely to become chronic, leading to severe liver disease. Currently, approximately 8,500 new cases are reported annually in the U.S. While an effective vaccine is now available and has begun to decrease the incidence of new infections in North America, children in many countries where the disease is prevalent do not receive vaccination. Hepatitis B positive recipients of liver transplants who usually receive immunosuppressive therapies may benefit from hyperimmune therapy to prevent re-infection of the transplanted liver. The worldwide market for hepatitis B immune globulin products is currently estimated at approximately \$135 million annually.</p>
Recent Developments	<p>Cangene has provided additional data regarding its HepaGam B™ to North American regulatory authorities since its original submissions in Canada and the U.S. However, it is difficult to predict time or cost that will be required to bring a new drug product to market. Cangene does not anticipate being required to conduct further clinical trials, but should regulators request additional data, the time taken and costs incurred could be significant.</p>
Competition	<p>Two competitive products are marketed in North America, Nabi-HB®, manufactured by Nabi Biopharmaceuticals, and HyperHEP B™ S/D manufactured by Talecris Biotherapeutics, Inc. (formerly Bayer Healthcare Biological plasma products).</p>

Other Hyperimmunes

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. These are discussed more fully under contract R&D and manufacturing as they are being developed under contract with the United States Centres for Disease Control and Prevention ("CDC"). In addition, the CDC announced in October 2004 that it 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 potential opportunity for the

Company.

Additional targets for hyperimmunes under development include: West Nile, Ricin toxin (a deadly toxin derived from castor beans for which there is no antidote; considered to be a possible agent of bioterrorism) and SARS.

At present, all of these new hyperimmune projects are considered to be in the R&D phase. To bring these products to commercialization would involve scaling-up manufacturing and a program of preclinical/clinical testing, the extent of which could vary depending on the product and may be costly. Biodefence products may undergo a shortened program to establish safety of the drug in humans and infer efficacy from testing in model systems, as it would be impossible to test efficacy in humans directly due to the nature of the targets. Several years are generally necessary to bring new hyperimmunes to commercialization. Cangene's VIG product was developed and licensed very rapidly, taking only 32 months from the beginning of the contract with the CDC to fast-tracked product approval by the FDA.

### Monoclonal Antibodies

Monoclonal antibodies are made in the laboratory from a single source or clone of cells that recognize only one kind of antigen. Naturally occurring antibodies, those isolated from plasma to produce hyperimmunes, are known as polyclonal. 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.

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 and monoclonal antibodies under this project.

In October 2003, Cangene received funding from the National Institute of Allergy and Infectious Diseases ("NIAID"), part of the United States National Institutes of Health ("NIH"), for a project aimed at developing monoclonal antibodies to a pathogenic type of bacteria called *Burkholderia*. The CDC has identified two species of *Burkholderia* as Category B agents of bioterrorism. Cangene will partner with Defence R&D Canada and Los Alamos National Laboratory for the project.

All projects within Cangene's monoclonal antibody program are in the early research phase. Extensive lab, preclinical and clinical testing would be required to bring these to commercialization, requiring many years of development time and substantial development expense.

### Hyperimmune 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 potential plant capacity to more than 50,000 litres of plasma annually.

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 California (July, 1996), and Mid-Florida Biologicals, Inc. in Florida (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.

As the main raw material for hyperimmune manufacture, cost of plasma significantly impacts the cost of manufacturing. Each product requires its own specific plasma that has an enriched supply of the particular antibody of interest. Certain types of plasma are more plentiful than others and cost may vary accordingly.

## **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.

Recombinant biopharmaceuticals address many of the complex diseases that have baffled medical science for years, and their use has grown dramatically in the relatively short time they have been available. Every year, the list of approved products gets longer and their collective market size continues to increase as new indications are discovered and as they gain acceptance within the medical community. Various sources estimate that biological products with estimated sales aggregating more than \$10 billion U.S. will come off patent over the next five years.

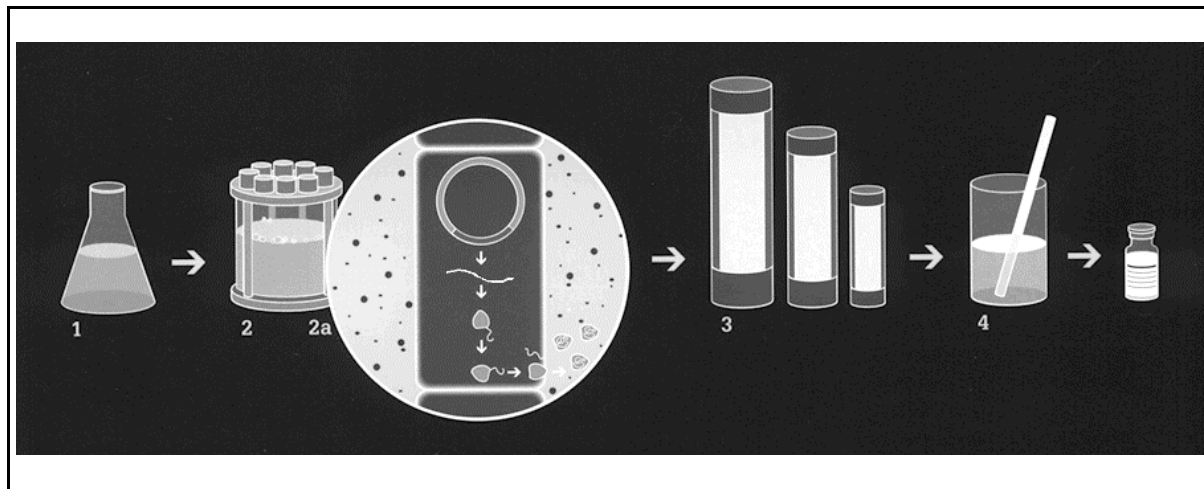
Recombinant biopharmaceutical products offer the potential for tremendous growth and large markets. Many companies compete to develop new biopharmaceutical products and technologies. However, the possibility of failure of products or technologies at an early development stage is significant. Cangene believes that its strategy of developing proprietary methods of manufacturing follow-on recombinant 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,

Cangene™ suffers from certain limitations, and some commercially valuable proteins cannot be produced using it. Nevertheless, Cangene has cost-effectively produced certain proteins using Cangene™, including its lead recombinant biopharmaceutical product, Leucotropin®.

Schematic diagram of protein expression using Cangene™



culture growth

desired protein is expressed by host cell

protein purification

formulation & packaging

Production Technologies—Other Expression Systems

Cangene also has an *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.

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 has developed a patented technology that it calls SAR (scaffold attachment region) that alleviates some of the technical problems associated with other mammalian cell expression systems. 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 was issued in 2003.

Follow-on Biopharmaceutical Development Program

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 generally involves 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, Page 31].

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 follow-on or 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 has hosted industry workshops to discuss the issues related to approval of biogenerics or biosimilar products. 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 a follow-on product strategy. Under the agreement Apotex, is supporting research and development of these products through to their initial regulatory filing.

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. Cangene completed a bioequivalence trial of hGH at the end of calendar 1999 and completed patient recruitment for subsequent Phase III trials during fiscal 2001. These completed 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.

Leucotropin® (recombinant Granulocyte-Macrophage Colony-Stimulating Factor (Human); “rGM-CSF”)

Status Submitted to Health Canada for regulatory review

Description/  
Background

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 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.

Leucotropin® is one of the products that Cangene is developing under an agreement with the Apotex Group.

Market/  
Sales

Cangene developed this product with the Apotex Group, which plans to market it in Canada upon licensure. Under the agreement, Apotex will be entitled to receive a 12% royalty on net sales, after which Cangene and Apotex will share profits equally. Cangene expects to compete in the GM-CSF market as well as the related Granulocyte Colony-Stimulating Factor (“G-CSF”) market. The prominent G-CSFs, Neupogen® (Granulokine® in certain markets) and Neulasta® (a chemically-modified, second-generation product) are owned by Amgen Inc. G-CSF was the first colony-stimulating factor licensed and dominates this market. Amgen’s G-CSF products are two of the top selling biopharmaceuticals in the world. In 2004 the combined global market for G-CSF and GM-CSF global market exceeds \$3 billion U.S.; Amgen commanded approximately 97% of this in 2004.

## Recent

**Developments** The Company filed a Canadian New Drug Submission for Leucotropin® in October 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 has also begun a project, which will be funded by 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. Under the project, the Company is also investigating a longer-acting version of the protein that has been modified by coupling it with a molecule of polyethylene glycol ("PEG"). Longer-lasting action and enhanced stability could increase the drug's utility in military or emergency settings.

**Competition** Leucotropin's market is dominated by the functionally similar product, G-CSF (discussed above), with 2004 sales of \$2.9 billion U.S.

Two versions of GM-CSF, owned by large multinational companies, have been approved for marketing—Leukine®, marketed by Berlex Laboratories, Inc., a division of Schering AG generated net sales equivalent to approximately \$76 million in Schering's 2004 fiscal year, and Leucomax®, owned by Schering-Plough Corp., which is not commercially available currently. Other companies may also be developing alternative or modified versions of GM-CSF, or functional analogues.

Although the two GM-CSF products have received licensure in Canada, neither is actively marketed, 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®. Patents with claims to GM-CSF exist in the U.S. and could prevent Cangene from selling GM-CSF in that market.

### Human Growth Hormone

**Status** Clinical trials complete; Cangene is preparing for U.S. submission, which it expects to file in the 2006 fiscal year.

**Description/  
Background**

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.

Market/  
Sales

In 2003, Cangene 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's 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.

Current marketers of the drug claim a world market of almost \$2 billion U.S. annually. These companies see market growth opportunities in expanding use beyond pediatric growth hormone deficiency to adult growth hormone deficiency as well as growth hormone failure in children with Prader-Willi Syndrome.

Recent

Developments Preparing for U.S. regulatory filing.

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. The leading products are owned by Pfizer Inc., Eli Lilly and Co., Novo Nordisk A/S, Genentech Inc. and Serono SA. Pfizer Inc. (acquired Pharmacia Corporation) was granted Orphan Drug Status for its product, Genotropin®, for use in the long-term treatment of growth failure in children with Prader-Willi Syndrome.

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 and will require varying amounts of time and investment to advance towards commercialization. Cangene will continue to evaluate such projects and will disclose individual information as it becomes known or relevant to Cangene's future pipeline.

**Contract R&D and Manufacturing Segment**

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. 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 48% of the Company's revenue in fiscal 2005, even in the absence of significant government contracts activity during the year.

Cangene receives revenue and records expenses for certain R&D projects with third parties or with Apotex. Depending on the project, Cangene may hold the product licence or the licence may remain the property of the contracting party. More detailed discussion may be found in the 2005 Management's Discussion and Analysis (see Appendix A) as published in the Company's 2005 annual report.

*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 R&D 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.

Subsequent to the acquisition of Chesapeake, Cangene decided to construct a specialized fill/finishing facility to process live viral vaccines adjacent to the main facility. This decision was made largely due to the award of a significant subcontract from a vaccine manufacturer that was producing smallpox vaccine for the U.S. government (see Government Contracts below). Cangene believed there would be sufficient future demand for contract fill/finishing services to support the investment. The subcontract concluded in October 2004. Since that time Chesapeake has been actively pursuing other potential contracts and customers that may have a need for this specialized manufacturing capability. In efforts to minimize the financial impact of maintaining this facility during fiscal 2005, certain utilities and components were decommissioned in late 2004. Although negotiations are continuing with at least one viral vaccine manufacturer for its potential future use of this facility, there can be no assurances of successful negotiations or profitable future operation. Accordingly, the Company recorded an \$18.0-million impairment loss related to the facility during the fourth quarter of fiscal 2005.

### 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.

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 of an initial order under this contract.

The two smallpox-related contracts contributed significantly to the exceptional revenues recorded by the Company in fiscal 2003. 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. In March 2005, the Canadian government purchased \$3.2 million worth of VIG from Cangene. And, subsequent to the year-end, Cangene was awarded a \$17.0-million contract by the U.K. government to supply VIG. This was followed by a U.S. Department of Defense announcement that it intended to purchase VIG from Cangene also.

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. To date, no manufacturing contract has been awarded, however. 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 services 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 Cangene. 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 R&D and manufacturing business relies heavily on 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.

### Segmented Financial 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 as discussed earlier. 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, 2005 and July 31, 2004, and identifiable assets as at July 31, 2005 and July 31, 2004:

	2005			2004		
	Biopharm- aceutical operations	Contract R&D and manufac- turing	Total	Biopharm- aceutical operations	Contract R&D and manufac- turing	Total
<i>in thousands of Canadian dollars</i>						
<b>Revenues</b>						
Product sales and services	\$ 34,993	\$ 20,733	\$ 55,726	\$ 48,827	\$ 64,971	\$ 113,798
R&D services	12,766	28,338	41,104	9,304	26,244	35,548
Royalties	5,895	—	5,895	7,557	—	7,557
	<b>53,654</b>	<b>49,071</b>	<b>102,725</b>	65,688	91,215	156,903
<b>Cost of sales</b>						
Product sales and services	11,457	22,826	34,283	12,050	53,024	65,074
R&D services	8,812	18,379	27,191	7,294	11,278	18,572
	<b>20,269</b>	<b>41,205</b>	<b>61,474</b>	19,344	64,302	83,646
<b>Gross profit</b>	<b>33,385</b>	<b>7,866</b>	<b>41,251</b>	46,344	26,913	73,257
<b>Expenses</b>						
Independent R&D	7,021	—	7,021	7,039	—	7,039
Selling, general and administrative	6,785	9,644	16,429	2,483	7,206	9,689
Amortization	4,268	5,169	9,437	2,572	4,389	6,961
Interest						
Short-term	474	38	512	97	28	125
Long-term	—	400	400	—	691	691
Foreign exchange loss (gain)	407	(1,098)	(691)	673	(3,166)	(2,493)
Facility impairment loss	—	18,000	18,000	—	—	—
	<b>18,955</b>	<b>32,153</b>	<b>51,108</b>	12,864	9,148	22,012
Income (loss) before income taxes	14,430	(24,287)	(9,857)	33,480	17,765	51,245
Income taxes expense (recovery)						
Current	6,093	585	6,678	14,574	9,458	24,032
Future	452	(1,524)	(1,072)	—	(5,329)	(5,329)
	<b>6,545</b>	<b>(939)</b>	<b>5,606</b>	14,574	4,129	18,703
<b>Net income (loss) for the year</b>	<b>\$ 7,885</b>	<b>\$ (23,348)</b>	<b>\$ (15,463)</b>	<b>\$ 18,906</b>	<b>\$ 13,636</b>	<b>\$ 32,542</b>
Tangible assets	\$ 90,633	\$ 78,277	\$ 168,910	\$ 83,087	\$ 77,425	\$ 160,512
Goodwill	\$ 3,216	\$ 37,298	\$ 40,514	\$ 3,216	\$ 37,298	\$ 40,514
Additions to property, plant and equipment, and goodwill	\$ 6,900	\$ 6,492	\$ 13,392	\$ 12,122	\$ 12,761	\$ 24,883

### Major Customers or Geographic Segments

For the period August 1, 2004 to July 31, 2005, sales to two customers represent 63% [2004 –one customer, 51%] of the revenue of the biopharmaceutical operating segment. Sales to two customers represent 53% [2004 – one customer, 68%] of the revenue from 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, 2005 and July 31, 2004:

	2005		2004	
	Revenue	Property, plant and equipment, and goodwill	Revenue	Property, plant and equipment, and goodwill
Canada	\$ 38,471	\$ 66,549	\$ 29,641	\$ 59,934
United States	50,751	62,686	116,382	83,346
Eurasia	13,503	—	10,880	—
	<b>\$ 102,725</b>	<b>\$ 129,235</b>	<b>\$ 156,903</b>	<b>\$ 143,280</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 innovative 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 the 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™.

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 filed an international patent application under the Patent Cooperation Treaty for the use of WinRho® SDF to treat dengue hemorrhagic fever.

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 has licensed non-exclusive patent rights and technology relating to the solvent-detergent viral inactivation step, which is used in the manufacture of WinRho® SDF, from New York Blood Center, Inc. and pays royalties until early 2006 based on 3% sales of WinRho® SDF, Vaccinia immune globulin, Anthrax immune globulin, and Botulinum toxin immune globulin.

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.

Uncertainty regarding the patent positions of certain biopharmaceutical drugs has also impacted the establishment of a regulatory process for follow-on biologics in the United States. Regulators seem unwilling to step in until legal issues have been settled. Such uncertainty could impact Cangene's strategy of developing follow-on biological products, particularly in the United States.

As noted above, the Company attempts to protect trade secrets, 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, Canada. The facility received an establishment licence from the FDA to produce WinRho® SDF for distribution in the United States in March 1995. The Company currently has 36,000 square feet of additional fractionation capacity under construction at this location; it expects to have the new area operational by the end of 2006.

Cangene currently leases approximately 18,500 square feet of industrial space at 3403 American Drive in Mississauga, Ontario, Canada. 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, 2010.

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. that has locations in Altamonte Springs, FL. and Frederick, MD. 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. 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. This facility came into operation early in fiscal 2005.

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, 2005, Cangene and its subsidiaries employed 598 persons in full-time positions; 97 of these 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.

Of Cangene's 598 full-time employees, approximately 35% work in the Contract R&D and Manufacturing segment and 65% in the Biopharmaceutical segment.

The nature of Cangene's business demands a significant percentage of employees with specialized skills. Typically a high percentage (approximately 30%) have a Bachelor's degree or higher. Certain operations people have particular skills developed from years of experience in Cangene's business. Generally the Company has found no difficulty in recruiting qualified individuals, at times using the services of professional recruiting firms specialized in R&D and pharmaceutical areas. As well, the Company places a high priority on retaining skilled employees that has led to a low turnover rate. The Company promotes from within wherever possible. Cangene has been the recipient of several awards for its human resource practices.

## **FOREIGN OPERATIONS**

Cangene's wholly-owned subsidiary, Chesapeake Biological Laboratories, Inc., operates in Baltimore, Maryland and comprises the bulk of Cangene's contract R&D and manufacturing business. And as previously mentioned, Cangene also operates plasma centres at three locations in the U.S. Cangene also maintains an office in the U.K., Cangene Europe Limited (U.K.).

The Company is not aware of any risks associated with these foreign operations and believes that its U.S. location adds visibility in its target market. However, the majority of Cangene's international sales are transacted in U.S. dollars and the strengthening Canadian dollar over the past two years has negatively impacted translation of international sales into Canadian dollars.

## **GOVERNMENT REGULATION**

The manufacture, sales and marketing of pharmaceutical products 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 be 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, efficacy and manufacturing compliance, which is established through preclinical and clinical trials, and site inspections. 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.

As discussed earlier (Recombinant Biopharmaceutical, Follow-on Biopharmaceutical Development Program, page 19) 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.

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, including in the Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") for the year ended July 31, 2005 as published in Cangene's 2005 Annual Report (the MD&A follows this Annual Information Form as Appendix A), 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 of 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.

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

Management's Discussion and Analysis of Financial Condition and Results of Operations for the year ended July 31, 2005 is included as Appendix A as published in Cangene Corporation's 2005 Annual Report. Cangene's complete 2005 Annual Report is available on the SEDAR website at [www.sedar.com](http://www.sedar.com).

## **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.

## **DESCRIPTION OF CAPITAL STRUCTURE**

The Corporation's authorized share capital comprises an unlimited number of non-voting preferred shares with a 4% non-cumulative dividend entitlement; Class A preferred shares, issuable in series with rights to be determined at issuance by the Board of Directors; and common shares.

Issued share capital comprises common shares as follows:

In thousands of Canadian dollars	Number of shares	
July 31, 2003	60,707,570	\$ 16,063
Stock options and warrants exercised	3,275,650	8,653
July 31, 2004	63,983,220	24,716
Stock options exercised	1,037,750	4,321
July 31, 2005	65,020,970	\$ 29,037

## **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 2004	9.40	9.00	243,808
September 2004	10.00	9.00	353,222
October 2004	11.10	9.40	592,502
November 2004	11.45	9.86	429,746
December 2004	11.40	8.25	1,211,471
January 2005	10.75	9.76	776,266
February 2005	10.29	9.51	749,628
March 2005	10.50	8.50	454,070
April 2005	8.44	7.76	629,013
May 2005	8.10	7.20	367,482
June 2005	8.05	7.50	115,879
July 2005	8.95	7.40	183,762

**DIRECTORS AND OFFICERS FISCAL 2005**

<b>Name and Province/State of Residence</b>	<b>Office</b>	<b>Director Since</b>	<b>Principal Occupation</b>
R. Craig Baxter <sup>1,3</sup> Ontario, Canada	Director	November 1, 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.
Jack M. Kay <sup>2</sup> Ontario, Canada	Director	November 1, 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 Manitoba, Canada	President and Chief Executive Officer, and Director	November 1, 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>1,3</sup> Manitoba, Canada	Director	June 1, 2004	President of Shaunnara Corp., an investment management company he has owned for the past 28 years. In December 2003, he retired from his 26-year position as President and CEO of Wimpak Ltd., a company he co-founded in 1977. Wimpak Ltd. manufactures and distributes high-quality packaging materials and innovative packaging machines.
Bernard C. Sherman Ontario, Canada	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.
Michael Spino <sup>2</sup> Ontario, Canada	Director	November 1, 1995	President, ApoPharma Inc. and Senior Vice President – Scientific Affairs, Apotex Inc. 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> New Jersey, USA	Director	January 29, 2003	General Partner and fund manager at Wheaten HealthCare Partners LP (a hedge fund) and Principal of Wheaten Capital Management LLC 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.
John Vivash <sup>2</sup> Ontario, Canada	Director	June 8, 2005	President and Chief Executive Officer, Tesseract Financial Inc. (Financial Services Consulting) since 1989.
William Bees Manitoba, Canada	Vice President, 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.
Michael Graham Manitoba, Canada	Chief Financial Officer (Officer)	n/a	Chief Financial Officer, Cangene since September 20, 2004. Prior thereto, since January 2000, he was Vice President and Chief Financial Officer of The Boyd Group Inc. (operator of collision-repair centres).
Wendy M. Johnson Alberta, Canada	Vice President, Research & 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 Manitoba, Canada	Vice President – Commercial Operations and Corporate Secretary (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 Manitoba, Canada	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 Governance and Nominating Committee; this committee was reorganized October 12, 2005

3 Member of Compensation Committee; this committee was reorganized October 12, 2005

For a more detailed discussion of board committees please refer to the Management Information Circular dated October 21, 2005 available on SEDAR at [www.sedar.com](http://www.sedar.com)

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 2005 is scheduled for December 7, 2005.

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

At October 27, 2005, the directors and senior officers of Cangene, as a group, beneficially owned, directly or indirectly, or exercise control or direction over, 52,483,507 common shares or approximately 80.7% of Cangene's outstanding common shares.

**Corporate cease trade orders or bankruptcies**

Jerry Treppel was a director of Able Laboratories, Inc., a public company in the United States, which filed a petition to re-organize under *Chapter 11 of the United States Bankruptcy Code* on July 18, 2005. Mr. Treppel is no longer on Able's Board of directors.

**Penalties or sanctions**

Not applicable

**Personal bankruptcies**

Not applicable

**Conflicts of interest**

Mssrs. Baxter and Kay, and Drs. Sherman and Spino are officers of companies belonging to the Apotex Group (described on page 6). Mssrs. Baxter and Kay, and Dr. Sherman are also directors of companies within the Apotex Group. Through the Apotex Group, Dr. Sherman controls 80% of Cangene's outstanding common stock. Further discussion of Cangene's Board and its Corporate Governance practices is contained within the Company's Management Information Circular dated October 21, 2005, available from the SEDAR website at [www.sedar.com](http://www.sedar.com)

**INTEREST OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS**

Cangene has agreements with companies controlled by the Apotex Group (described on page 6). A discussion of these agreements is contained in the MD&A (Appendix A) and in the Notes to the Financial Statements for the year ended July 31, 2005 in Cangene's 2005 Annual Report (available on the SEDAR website at [www.sedar.com](http://www.sedar.com)).

**TRANSFER AGENT AND SHARE REGISTRAR**

Cangene's transfer agent and share registrar is Computershare Investor Services Inc., located at 100 University Avenue, 9<sup>th</sup> Floor, Toronto, ON, M5J 2Y1. The Company's share register is maintained in Toronto.

**INTERESTS OF EXPERTS**

Cangene's auditors for the year ended July 31, 2005 were Ernst & Young LLP; they have provided a report on the Company's financial statements as they appear in the 2005 Annual Report and which are available along with the Auditors' Report on the SEDAR website at [www.sedar.com](http://www.sedar.com).

## **AUDIT COMMITTEE INFORMATION (Form 52-110F1)**

### **Audit Committee Charter**

The Audit Committee Charter is attached as Appendix B to this Annual Information Form.

### **Composition of Audit Committee**

The Audit Committee of the Company is chaired by J. Robert Lavery and also includes R. Craig Baxter and Jerry Treppel. Mr. Lavery and Mr. Treppel are independent directors as defined under *Multilateral Instrument 52-110 – Audit Committees* (“MI 52-110”) and do not receive any compensation from the Company, either directly or indirectly, other than for service as a member of the Board of Directors and its committees. Mr. Baxter is exempt from the independence requirement by virtue of section 3.3(2) of MI 52-110. All members of the Audit Committee are financially literate as defined under MI 52-110

### **Relevant Education and Experience**

The members of the Company’s Audit Committee possess considerable education and business experience relevant to the performance of their audit committee responsibilities, as described below:

**J. Robert Lavery** is the Chair of the Audit Committee. Mr. Lavery, a Chartered Accountant, is President of Shaunnara Corp., an investment management company he has owned for the past 28 years. In December 2003, he retired from his 26-year position as President and CEO of Wipak Ltd., a company he co-founded in 1977. Wipak Ltd. manufactures and distributes high-quality packaging materials and innovative packaging machines. Prior to co-founding Wipak, he spent 16 years working with the firm of Ernst & Ernst, now part of KPMG LLP. He continues on the board of directors of Wipak Ltd. and all its subsidiary companies, and is a director of ENSIS Growth Fund Inc., Jazz Golf Equipment Inc., Online Business Systems, and SleeveCo, Inc. Mr. Lavery is on the Advisory Council of Friesen Corporation, the Advisory Board of Brett-Young Seeds Ltd. and has served on the boards of a number of community healthcare corporations.

**R. Craig Baxter** graduated with a Bachelor of Commerce from Concordia University and is a Certified Management Accountant. He has 25 years of business experience, 20 of which have been in the pharmaceutical industry. Mr. Baxter is currently President of Apotex International, Inc. and Executive Vice President of Apotex Inc.

**Jerry Treppel** is General Partner and fund manager at Wheaten HealthCare Partners LP and Principal of Wheaten Capital Management LLC in the United States. He was Managing Director of Equity Research at Banc of America Securities, LLC from June 1999 until 2002. From 1995 until 1999 he was Managing Director of Equity Research at UBS Warburg. He is also on the board of Akorn, Inc., an American Stock Exchange-listed company.

### **Reliance on the Exemption in Subsection 3.3(2)**

The Company has relied on the exemption in *Multilateral Instrument 52-110*, Subsection 3.3(2) with respect to Controlled Companies over the course of the most recently completed financial year. The exemption was used with respect to Audit Committee member, Craig Baxter, who is an officer and director of companies within the Apotex Group, which owns the majority of the publicly traded shares of the Company. The rationale for appointing Mr. Baxter to the Audit Committee is that as a CMA, he has relevant accounting knowledge, which combines with his Bachelor of Commerce degree and 20 years of pharmaceutical industry experience to make him a valuable contributor to the committee. Also, at the time of his appointment to the committee, the Company did not have three

independent directors and the Audit Committee regulations require a minimum of three members. The board has determined in its reasonable judgment that Mr. Baxter is able to exercise the impartial judgment that is necessary to fulfill his responsibilities as an Audit Committee member and that his appointment serves the interests of the Company and its shareholders.

### **Pre-Approval Policies and Procedures**

The Audit Committee shall review and pre-approve any engagements for material, non-audit services provided by the external auditor or its affiliates. The Committee will consider any fees payable for such services and consider the impact of such payments on the independence of the external auditors. The Audit Committee has established pre-approved limits for immaterial, non-audit services within which management may engage the external auditor or its affiliates to perform such services without further pre-approval, provided that management is satisfied such services will not impair the independence of the external auditors. Immaterial, non-audit services are defined as services to provide tax planning or accounting advice for which the fees do not exceed \$5,000 for any single engagement and provided that the total fees for all such engagements do not exceed \$30,000 annually. Management must report to the Audit Committee all engagements for non-audit services where management initiates an engagement under pre-approval.

### **External Auditor Service Fees (By Category)**

The aggregate amounts billed to the Company by Ernst & Young LLP, the auditors of the Company, for audit, audit-related, tax, and other fees in the fiscal years ended July 31, 2005 and 2004 were as follows:

Category	2005	2004
Audit fees <sup>1</sup>	\$ 188,350	\$ 200,840
Audit-related fees <sup>2</sup>	76,266	—
Tax fees <sup>3</sup>	9,870	4,157
All other fees <sup>4</sup>	1,082,696	291,893
<b>Total</b>	<b>\$ 1,357,182</b>	<b>\$ 496,890</b>

Notes:

- 1 “Audit fees” includes the aggregate professional fees billed by Ernst & Young LLP for the annual audit of the consolidated financial statements, including services related to financial presentation and disclosure issues
- 2 “Audit-related fees” includes the aggregate fees billed by Ernst & Young LLP for performance of quarterly financial-statement reviews during the 2005 fiscal year
- 3 “Tax fees” includes the aggregate fees billed by Ernst & Young LLP for Canadian and U.S. income-tax-provision analysis, including process review and disclosure assistance
- 4 “All other fees” includes the aggregate professional fees billed by Ernst & Young LLP for professional services assisting the Company with the preparation of government contract proposals.

The Audit Committee has considered and agreed that the above fees are compatible with the Company’s auditors maintaining independence. Further, the Audit Committee has determined that, in order to ensure the continued independence of the auditors, only limited non-audit related services will be provided to the Company by Ernst & Young LLP and in such case, would be in accordance with the pre-approval process described in the previous section.

**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, 2005 and accompanying auditor's report, the most recently filed interim financial statements for any period following that year end, the Management Information Circular dated October 21<sup>st</sup>, 2005 issued in respect of the Company's 2005 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, and securities authorized for issuance under an equity compensation plan, as at the end of the Company's fiscal year ended July 31, 2005, is contained in Cangene's Management Information Circular dated October 21<sup>st</sup>, 2005, prepared for its 2005 Annual Meeting of Shareholders.

Additional financial information is provided in Cangene's comparative financial statements and Management's Discussion and Analysis ("MD&A") for its most recently completed financial year, which are included in Cangene's 2005 Annual Report. Information about the Company's product development pipeline is also contained in its 2005 Annual Report.

Additional information relating to Cangene, including its 2005 annual report, MD&A and Management Information Circular, may be found on the System for Electronic Document Analysis and Retrieval ("SEDAR") website at [www.sedar.com](http://www.sedar.com) or on Cangene's website at [www.cangene.com](http://www.cangene.com). Printed copies of these documents, or other 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).

***APPENDIX A – following pages***

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

October 12, 2005

*This review contains management's discussion of the Company's operating results and financial condition for the year ended July 31, 2005, and should be read in conjunction with the accompanying audited financial statements and associated notes.*

## **Disclosure controls and procedures**

*Management has established and maintained disclosure controls and procedures for the Corporation in order to provide reasonable assurance that material information relating to the Corporation is made known to it in a timely manner, particularly during the period in which the annual filings were being prepared. Management has evaluated the effectiveness of the Corporation's disclosure controls and procedures as of the date of this report, and believes them to be effective in providing such reasonable assurance.*

## **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. These risks and uncertainties include, but are not limited to, those discussed in the RISKS AND UNCERTAINTIES section within this MD&A. 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 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 performance based on two operating segments: biopharmaceutical operations, and contract R&D and manufacturing. International sales are transacted mainly in U.S. dollars.

Cangene is developing two different categories of products: hyperimmunes, 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 technologically complex and sterile injectable products, and also offers contract R&D and manufacturing services to other biopharmaceutical organizations.

In addition, Cangene has an ongoing innovative R&D program, providing further opportunities for long-term growth.

Cangene's first licensed product was WinRho<sup>®</sup>, and its development established a core competency in developing and manufacturing hyperimmunes. Two additional hyperimmune products, VariZIG<sup>™</sup> and Vaccinia immune globulin ("VIG") have also been licensed. A hepatitis B immune globulin has been filed for regulatory review.

Cangene is also developing certain recombinant biopharmaceutical products as follow-on biologics (a similar strategy to that of traditional generic drugs). The Company has filed in Canada for regulatory approval of its leading product in this category, Leucotropin<sup>®</sup> ("GM-CSF"), and expects to file an application for its second follow-on product, human growth hormone, in the U.S. in the coming months. Much of this work is supported by an R&D agreement with the Apotex Group, which includes Apotex Holdings Inc., Apotex Inc. (a leader in the Canadian drug industry), Apotex Research Inc. and other subsidiaries. The Apotex Group is indirectly controlled by Bernard Sherman and holds approximately 80% of Cangene's common stock at October 12, 2005.

Revenues from the biopharmaceutical operations segment are largely derived from sales of WinRho<sup>®</sup> SDF, which has been sold in more than 40 countries. Cangene continues to seek additional geographic markets for WinRho<sup>®</sup> SDF, while also making efforts to increase penetration in existing markets through new distribution relationships and investigating use of the product in new patient populations.

In December 2004, WinRho<sup>®</sup> SDF was licensed in 10 European countries through the Mutual Recognition Procedure ("MRP") based on earlier licensing in the U.K. In conjunction with its European distribution partner, Baxter Healthcare S.A., the Company is preparing additional MRP filings for several more jurisdictions where a significant market opportunity exists.

In 2005, Cangene selected Baxter Healthcare Corporation, an affiliate of the Company's European distribution partner, as its new WinRho<sup>®</sup> SDF distributor for the U.S. in order to align its international marketing efforts and potentially increase penetration in the competitive U.S. market.

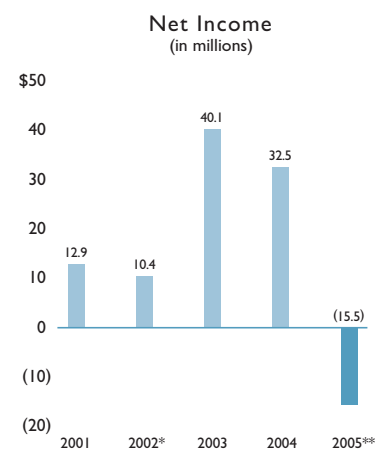
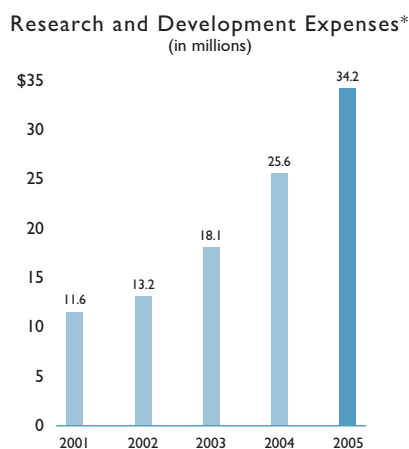
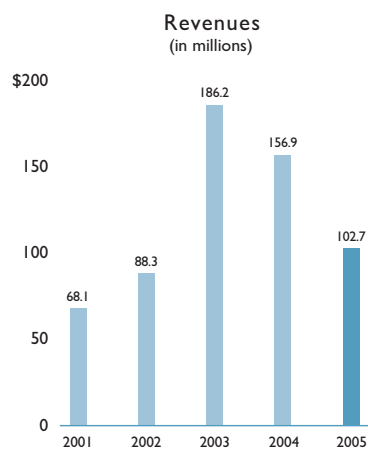
Shortly thereafter, the Company received approval to market a liquid formulation of WinRho<sup>®</sup> SDF in the U.S., which could increase market acceptance due to increased ease of use. The Company will continue to employ similar market expansion strategies for other hyperimmunes and its recombinant products as they move through the development pipeline.

Cangene has leveraged its capability to develop and manufacture hyperimmunes into a contract R&D and manufacturing business. The Company has been awarded several contracts to develop and manufacture certain biodefense and infectious-disease-related products for the U.S. government. The largest of these was a contract to develop and manufacture VIG, a product used to counteract certain side effects of smallpox vaccination. Cangene submitted a Biological License Application (“BLA”) for VIG to the United States Food and Drug Administration (“FDA”) at the end of July 2004. The application was given fast-track designation, and was subsequently approved in May 2005. Cangene has already manufactured and delivered an initial supply of VIG under the five-year supply-and-development agreement with the United States Centers for Disease Control and Prevention (“CDC”) that began two years ago. Immune globulins aimed at botulinum toxin (botulism) and anthrax are also being developed under R&D contracts with the U.S. government. These may also lead to supply contracts.

Cangene’s specialized facilities and manufacturing experience allow it to offer contract R&D and manufacturing services for a broad range of technologically complex, process-sensitive compounds in addition to hyperimmunes. The Company’s Chesapeake Biological Laboratories, Inc. (“Chesapeake”) subsidiary in Baltimore, Maryland offers facilities for filling and finishing process-sensitive biologics. One of these, a viral vaccine-filling facility, was instrumental in Chesapeake securing a portion of the U.S. government smallpox vaccine contract in a prior year.

The contract R&D and manufacturing segment continues to contribute significant revenues to the overall business; however, this segment is subject to large fluctuations in activity as contracts are completed and new contracts initiated. During fiscal 2004, contract R&D and manufacturing revenues declined 28% as the Company completed supplying the initial order for the VIG contract part way through that year and the Chesapeake operation faced weaker customer demand. Contract manufacturing revenue declined further in fiscal 2005 as Chesapeake completed, early in the year, the significant subcontract to fill/finish smallpox vaccine for the primary U.S. government supplier, and no new major contract orders were received. 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 potential contracts with the U.S. government to develop and supply products under the *Bioshield Act*. These contracts, if awarded, would provide Cangene with revenues from the development and supply of products over the next few years as biodefense stockpiles are built, and could provide potential to expand product sales to other governments. The Company is currently marketing the VIG product to other governments and has experienced early success. Cangene also seeks contract R&D and manufacturing agreements with biopharmaceutical industry partners, particularly at its Chesapeake subsidiary.

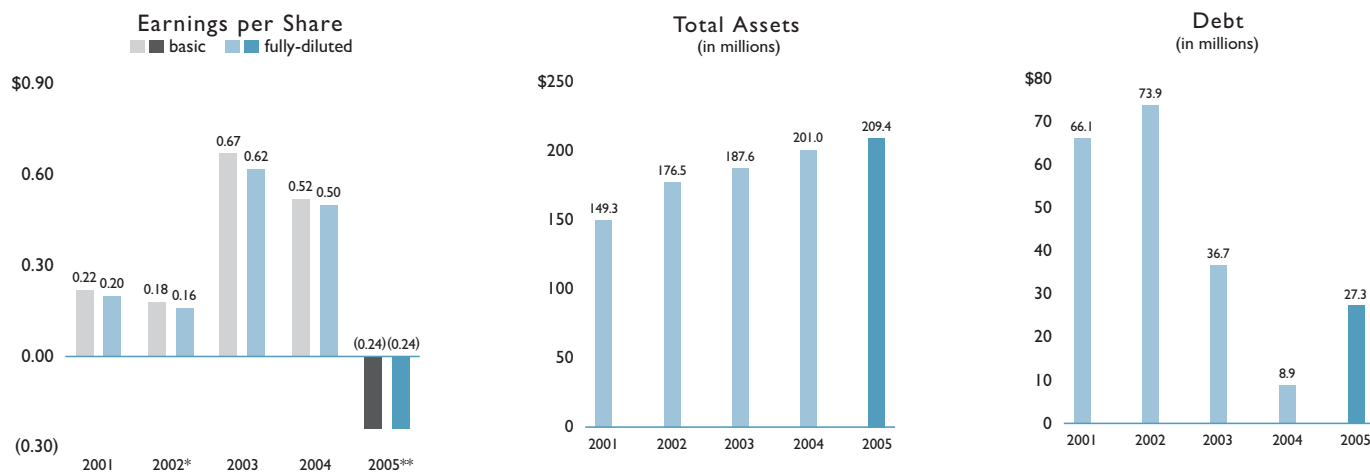
## SELECTED ANNUAL INFORMATION



\* After applying investment tax credits

\* Includes a \$5.0-million charge against goodwill  
\*\* Includes an \$18.0-million non-cash impairment loss related to the Chesapeake facility

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS (CONTINUED)



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

\*\* Reflects an \$18.0-million non-cash impairment loss related to the Chesapeake facility

The selected annual information presented above and on page 17 is extracted from the Company's audited 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 increased research and development activities aimed at expanding 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 charge 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/finish subcontract at Chesapeake. In fiscal 2004, the Company completed supplying the initial order for the VIG contract midway through the year. At the same time, the volume of fill/finishing activity for smallpox vaccine at Chesapeake was diminishing as that contract neared completion. Consequently, contract-manufacturing volume declined in 2004. However, the number and magnitude of contract-research and development projects, along with Cangene's own new product research and development efforts, increased, causing a rising trend in research and development expenditures and related contract revenues. These trends continued in fiscal 2005, with a continued decline in contract-manufacturing activity coupled with increasing investment in research and development, especially focused on biodefence-related R&D contracts. Earnings per share over the period reflects the fluctuations in earnings, while the number of shares outstanding has grown gradually over the period, due to the exercise of stock options.

### NEW DEVELOPMENTS

In August 2004, the Company announced that it would process plasma to be collected from anthrax-vaccinated military personnel. The U.S. Department of Defense announced it will support a Health and Human Services ("DHHS") 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. This was an expansion of an earlier contract with the CDC. The Company subsequently submitted proposals to the DHHS and the CDC for an AIG supply agreement. Subsequent to the year end, late in September 2005, Cangene was awarded a contract by the Office of Public Health Emergency Preparedness, in the office of the Secretary of the DHHS, to supply Cangene's AIG to be used for preliminary efficacy testing. Based on the outcome of this testing and several other factors, the DHHS has an option, within a year of the award date, to purchase between 10,000 and 100,000 doses of AIG over a period of three years. If the DHHS exercises this option, Cangene will be required to undertake the steps necessary for licensure by the U.S. FDA.

Also in August 2004, Cangene began recruiting patients for a clinical trial to investigate WinRho® SDF in a new patient population. This trial built on findings from a pilot study that indicated administration of WinRho® SDF may improve patient survival in cases of dengue hemorrhagic fever (“DHF”). Both trials were conducted in the Philippines where DHF creates a severe healthcare burden. DHF causes increased blood vessel permeability resulting in plasma loss, decreased levels of blood platelets, and hemorrhagic tendencies. The disease can kill through circulatory failure and shock. Cangene announced on February 15, 2005, that analysis of interim data collected from the study indicated the primary endpoint of the trial had been met. Ninety percent of patients receiving WinRho® SDF responded. These results suggest that WinRho® SDF may be an effective treatment for other infectious diseases that can cause dangerously low platelet counts, and which may have greater market potential.

In September 2004, Mr. Michael Graham joined Cangene 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 2004, continues with his responsibilities for sales, marketing and business development as Vice President of Commercial Development.

In October 2004, Chesapeake completed the fill/finishing subcontract with the supplier of smallpox vaccine to the U.S. government. Cangene and Chesapeake are currently assessing new contract manufacturing opportunities for the specialized viral fill/finishing facility, which is temporarily idle. The U.S. government announced in July 2005 that it intends to purchase an additional 80 million doses of smallpox vaccine over the next five years. Chesapeake is well positioned as a potential subcontractor to at least one of the parties that may compete for this new smallpox vaccine contract.

Also in October, the Company reported that the CDC intends to negotiate a sole-source agreement with Cangene to provide up to 200,000 doses of botulinum toxin immune globulin. Negotiations on this development and manufacturing contract are underway; however, no contract has yet been awarded. The Company expects that such a contract would follow on an earlier research contract, under which Cangene is completing initial development and testing of a botulinum toxin immune globulin.

In December 2004, the Corporation successfully completed the European Mutual Recognition Procedure (“MRP”) for the approval of WinRho® SDF in ten European countries for use in preventing hemolytic disease of the newborn and treating a clotting disorder called ITP. As a result, WinRho® SDF can be launched in Belgium, Finland, Greece, Iceland, Ireland, Italy,

Luxembourg, Norway, Portugal and the Netherlands. WinRho® SDF was approved in the United Kingdom in 1999. The newly approving European Union countries mutually recognized the U.K. licence after completion of the MRP. Cangene’s European distribution partner, Baxter Healthcare S.A., will undertake the launch and marketing in these countries. Cangene plans to follow the same process for approval in additional EU member states in the future.

In January 2005, the Company reached agreement with its senior lenders to renew its credit facilities, including increasing the operating line of credit from \$15 million to \$20 million. The renewal also included a new \$30-million, non-revolving term loan facility to be used for further development of its plasma fractionation plant capacity. The Company expects to draw on the expansion facility over the period through September 2006, after which the term loan will become repayable in monthly instalments over five years.

In early March 2005, the Company was awarded a contract by the Health Canada Centre for Emergency Preparedness and Response to supply VIG and seek its licensure for the treatment of certain complications that can result from vaccination against smallpox. The value of the contract was approximately \$3.2 million; the product was delivered during the third quarter of fiscal 2005.

Effective March 28, 2005, Baxter Healthcare Corporation (“Baxter”), an affiliate of Cangene’s European distribution partner, assumed exclusive rights to market and distribute WinRho® SDF in the United States following the expiry of Cangene’s distribution agreement with Nabi Biopharmaceuticals. The Company believes that having the same distributor in the two major markets will enhance its worldwide marketing efforts and allow better coordination of sales and inventory.

In April 2005, the FDA approved the liquid formulation of WinRho® SDF. The liquid formulation provides an important alternative to the lyophilized (freeze-dried) product, eliminating the need for reconstitution prior to administration and increasing the convenience for physicians. Baxter intends to launch the new liquid formulation in the U.S. later in 2005.

In May 2005, the FDA also approved the VIG hyperimmune product for licensure. VIG is the first of Cangene’s biodefence products to receive approval and the Company was able to reach this goal only nine months after the drug’s submission, representing a significant milestone in the Company’s biodefence strategy. The Company believes that having an FDA licence for VIG in the U.S. will enhance the product’s international marketability and, subsequent to the fiscal year end, the U.K. Department of Health awarded Cangene a contract to supply VIG. The contract has an estimated value of

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS (CONTINUED)

approximately \$17.0 million. Cangene expects to complete delivery during fiscal 2006. The U.S. Department of Defense has indicated it intends to contract with Cangene as the sole source for a supply of VIG for a period of up to five years.

In June, the Company announced the addition of Mr. John Vivash to its board of directors. Mr. Vivash has substantial experience in the investment industry, including 20 years of board experience. From 1954 to 1987 he held various investment dealer positions, up through director and vice president. Since then, he has served as president and CEO of Fidelity Investments Canada Limited (1987–1989), CIBC Securities Inc. (1990–1995) and Manulife Securities International (1995–1997). Currently, and since 1989, he has been president and CEO of Tesseract Financial Inc., a financial services consulting company he founded. In addition, Mr. Vivash has participated on committees for the Toronto, Montreal and Vancouver Stock Exchanges, and the Ontario Securities Commission. He has lectured at the Universities of Alberta, Toronto and Western Ontario (Ivey School of Business), and given more than 500 investment seminars and lectures in Canada, the United States and Europe. Mr. Vivash has participated on more than 20 boards of directors in Canada and abroad.

### RESULTS OF OPERATIONS

#### Revenues

Total revenues, consisting of revenues from the biopharmaceutical, and contract R&D and manufacturing operating segments, for the year ended July 31, 2005, were \$102.7 million, compared to \$156.9 million in the prior year. Within each operating segment, revenues may include product sales and service revenues derived from the manufacture and delivery of products, R&D revenues derived from research and development activities and services, and royalties derived from intellectual property rights to products produced and sold by Apotex or other third parties.

Revenues from the biopharmaceutical operations segment were \$53.7 million in the current year compared to \$65.7 million last year. Growth in WinRho® SDF sales in international markets and an increase in research revenues related to biopharmaceutical products being developed jointly with Apotex only partly offset weaker sales in the U.S. and the impact of the weaker U.S. dollar as Cangene transitioned its U.S. distribution from Nabi Biopharmaceuticals to Baxter.

Product sales within the biopharmaceutical segment in fiscal 2005 were \$35.0 million, down from \$48.8 million in the prior year, reflecting the weaker WinRho® SDF sales in the U.S. and the weaker U.S. dollar. R&D service revenues in this segment increased to \$12.8 million in 2005, compared to \$9.3 million in the prior year, as Cangene scaled up joint research projects

with Apotex for two follow-on generic recombinant protein products, Leucotropin® and human growth hormone.

Royalty revenues declined to \$5.9 million in the current year, from \$7.6 million last year, on reduced sales of Ferriprox™ (deferiprone), a drug manufactured and marketed by Apotex for which Cangene receives 50% of net profits due to an earlier agreement.

Contract R&D and manufacturing revenues were \$49.1 million in fiscal 2005, compared to \$91.2 million in the prior year. Cangene produced and delivered \$42.3 million of VIG product under contract to the CDC last year, compared with VIG contract revenue of \$3.5 million in the current year. In addition to the effect of completion of the VIG manufacturing contract, other contract-manufacturing revenues declined from \$22.7 million last year to \$17.2 million, which includes the impact of the current year's reduced contract viral fill/finishing activities at Chesapeake.

Contract-R&D revenues for fiscal 2005 were \$28.3 million, compared to \$26.2 million in the prior year. Within the contract R&D and manufacturing segment, two significant research and development projects with the CDC contributed significantly to R&D revenue and costs during 2005. The first was an expansion of a contract awarded by the CDC in 2003 to develop a clinical-grade hyperimmune targeted at anthrax. The second relates to a contract to develop a clinical-grade hyperimmune to counteract botulinum toxin that was awarded to Cangene in 2003, also by the CDC. During the current year, in addition to working on these two contracts, the Company was completing contract-research work under the VIG contract with the CDC, and conducting ongoing contract research for the Apotex Group and other third parties relating to products that are not a part of Cangene's pipeline. The Company expects to continue to incur expenditures and record revenue in respect of the anthrax and botulinum R&D contracts with the CDC during fiscal 2006.

The Company anticipates that contract R&D and manufacturing revenues may continue to fluctuate in the future, depending on whether significant new manufacturing contracts with the U.S. or other governments are awarded.

#### Cost of sales – product sales and services

Cost of sales for the year ended July 31, 2005 decreased to \$34.3 million or 62% of product sales and service revenues compared to \$65.1 million or 57% of product sales and service revenues in the prior year, due to the reduced volume of manufacturing activity. Gross profit from product sales and services declined from \$48.7 million last year to \$21.4 million in the current year in absolute dollar terms, while the margin as a percentage of product sales and service revenues was 38%, down from 43% for the same period last year.

Gross profit earned on product sales and service revenues in the biopharmaceutical segment was \$23.5 million or 67% of revenue, compared to \$36.8 million or 75% of revenue in the prior year. It was negatively impacted by the shift in WinRho® SDF sales mix out of the U.S. and into international markets where margins are typically lower.

In the contract R&D and manufacturing segment, reduced contract production volumes of VIG in Canada and reduced viral vaccine fill/finishing activities at Chesapeake contributed to a loss of \$2.1 million at the gross profit level in fiscal 2005, compared to gross profit of \$11.9 million in the prior year, based on product service revenues from this segment.

#### **Cost of sales – R&D services**

The Company's research revenues are derived through agreements with Apotex as well as through research contracts with other parties, including the U.S. government. Research and development expenditures that relate to these sources of research revenues are classified as Cost of sales – R&D services.

Cost of sales – R&D services for fiscal 2005 increased to \$27.2 million, an increase of approximately 46% compared to \$18.6 million last year.

Cost of sales – R&D services in the biopharmaceutical segment increased to \$8.8 million in the current year, compared to \$7.3 million in 2004, as the Company continued developing the two follow-on generic products for which Cangene is receiving research revenues from Apotex. The increased research and development costs reflect increased research activity in the current year and higher per-unit overhead costs of products used for research purposes. Gross profit on research activities in the biopharmaceutical segment in fiscal 2005 was \$4.0 million or 31% of research revenue, compared to \$2.0 million or 22% of revenue last year. The improved margin in the current year is due to a greater proportion of research costs eligible for recovery through investment tax credits.

Cost of sales – R&D services in the contract R&D and manufacturing segment increased to \$18.4 million in fiscal 2005, compared to \$11.3 million in the prior year, due principally to the impact of the three contract-research agreements with the CDC. Gross profit on research activities in the contract segment totalled \$10.0 million or 35% of R&D revenues, compared to \$15.0 million or 57% of revenues in the prior year. Reduced margins in the current year reflect increased pressure on margins in more recent contract research negotiations, coupled with a greater proportion of these research expenditures ineligible for recovery through investment tax credits.

#### **Independent R&D**

Independent R&D expenditures, from which no related research revenue is derived, were \$7.0 million in fiscal 2005, unchanged from the prior year. Cangene continues to conduct independent research in several related biopharmaceutical fields, ranging from expanding applications of hyperimmunes to innovative research into entirely new therapies.

#### **Selling, general and administrative expense (“SG&A”)**

Total SG&A expense for fiscal 2005 increased to \$16.4 million, compared with \$9.7 million in the prior year. Additional general and administrative expenses, totalling \$6.7 million, include legal and accounting costs of preparing contract proposals for certain U.S. government contracts, increased consulting and regulatory filing fees, property tax increases resulting from recent reassessments charged on the Company's Canadian manufacturing facilities, separation costs arising from staff reductions at Chesapeake, and the recording of stock option expense. The Company anticipates that these types of additional expenditures, other than separation costs and stock option expense, will continue in future periods at reduced levels.

#### **Amortization**

Amortization for the year ended July 31, 2005 increased to \$9.4 million from \$7.0 million a year ago. Higher amortization costs reflect increased investment in plant and equipment for both research and manufacturing, primarily in the biopharmaceutical operations. A recent expansion of the biopharmaceutical manufacturing facility came on-stream early in the new fiscal year and the Company is now amortizing this asset.

#### **Interest**

Interest costs in fiscal 2005 were \$0.9 million, compared to \$0.8 million in the prior year. Higher interest rates were partly offset by a lower average balance of total debt outstanding under the Company's credit facilities in the current year when compared to fiscal 2004. A significant balance of long-term debt was outstanding and repaid late in fiscal 2004, while in 2005, the operating line of credit has increased in response to the slowdown in contract-manufacturing business. The Company did not employ interest rate hedging during the current year, allowing outstanding bank debt to generally float at short-term market rates of interest.

#### **Foreign exchange**

Foreign exchange gains in fiscal 2005 were \$0.7 million compared to \$2.5 million in the prior year. Foreign exchange gains arise on translation of the integrated foreign subsidiaries' operations, as well as translation of foreign-currency-denominated loans and other balances in the accounts of the Canadian company. Higher foreign exchange gains in the prior year reflect the greater degree of strengthening of the Canadian dollar during the prior year, when compared to fiscal 2005.

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS (CONTINUED)

### Facility impairment loss

In 2002, Chesapeake, the Company's U.S. subsidiary, completed the design and construction of a specialized facility to fill and finish live viral vaccines after being named as a subcontractor to a significant contract between the primary contractor and the U.S. government for the supply of smallpox vaccine. Chesapeake completed the fill/finish contract in October 2004 and has been actively pursuing other potential contracts and customers that may have a need for this specialized manufacturing capability. In efforts to minimize the financial impact of maintaining this facility during fiscal 2005, certain utilities and components were decommissioned in late 2004. Although negotiations are continuing with at least one viral vaccine manufacturer for the potential future use of this facility, there can be no assurance that Chesapeake will be successful in securing future business for this specialized manufacturing capability, or that such future business, if secured, will be sufficient to operate this facility profitably. Accordingly, the Company has recorded an impairment loss relating to this facility of \$18.0 million, excluding equipment that the Company has determined could be used within its other manufacturing operations.

### Income taxes

Income tax expense for the year ended July 31, 2005 decreased to \$5.6 million from \$18.7 million in the prior year. Lower income tax expense results from lower taxable income for the year. The effective rate of tax increased due to the Company's decision to record an impairment loss relating to viral vaccine fill/finish facility, for which no future tax benefit was recorded,

and the Company's decision to defer any further recognition of future recoveries of U.S. tax losses, beyond such losses incurred through January 2005.

### Net income (loss)

Net loss for the year ended July 31, 2005 was \$15.5 million, compared to net income of \$32.5 million recorded for the prior year. Net loss in the current year was primarily due to lower WinRho® SDF revenue in the U.S. and reduced contract-manufacturing activity, including the impact of the impairment loss recorded relating to the viral vaccine facility. Increases in research and development expenditures, SG&A costs and amortization, partially offset by lower tax expense, also contributed to lower earnings.

### Basic and diluted earnings (loss) per share

Basic loss per share for the year ended July 31, 2005 was \$0.24 per share compared to earnings of \$0.52 per share last year, reflecting the effect of reduced net earnings and an increase in the number of common shares outstanding. Diluted loss per share was \$0.24 per share for the current year, compared to earnings of \$0.50 per share in the prior year. Diluted earnings (loss) per share is calculated under the treasury stock method, which assumes that all outstanding stock options, where the exercise price is less than current market price, are exercised and the proceeds of such exercises are used to repurchase shares at the current market price. For the current year, the calculation of loss per common share on a fully-diluted basis excluded all potential common shares because the effect of including these shares would be to reduce the loss per share.

## SUMMARY OF QUARTERLY RESULTS

Quarters ended <i>in thousands of Canadian dollars except per-share data</i>	July 31, 2005 (Q4 2005)	April 30, 2005 (Q3 2005)	January 31, 2005 (Q2 2005)	October 31, 2004 (Q1 2005)	July 31, 2004 (Q4 2004)	April 30, 2004 (Q3 2004)	January 31, 2004 (Q2 2004)	October 31, 2003 (Q1 2004)
Revenues	\$ 22,205	\$ 26,628	\$ 28,519	\$ 25,373	\$ 32,988	\$ 39,193	\$ 45,524	\$ 39,198
R&D expense <sup>1</sup>	7,461	9,900	10,709	6,142	8,477	7,429	5,743	3,962
Net income (loss)	(17,383)	1,890	(2,291)	2,321	7,753	6,247	8,707	9,835
Earnings (loss) per share								
Basic	\$ (0.27)	\$ 0.03	\$ (0.04)	\$ 0.04	\$ 0.12	\$ 0.10	\$ 0.14	\$ 0.16
Diluted	\$ (0.27)	\$ 0.03	\$ (0.04)	\$ 0.04	\$ 0.12	\$ 0.10	\$ 0.13	\$ 0.15

<sup>1</sup> Includes R&D expenditures, net of investment tax credits, classified as either Cost of sales – R&D or Independent R&D.

Variations in quarterly revenues over the past eight quarters illustrate the impact of the VIG contract and the Chesapeake smallpox vaccine subcontract on total revenues over the end of 2003 and through the first half of 2005. VIG sales to the U.S. government began in the second quarter of 2003, with final deliveries of \$11.2 million completed in the third quarter of fiscal 2004.

As a subcontractor on a U.S. government contract, Chesapeake commenced filling smallpox vaccine at its viral fill/finish facility in the second quarter of 2003 and completed this contract during the second quarter of 2005. The fourth quarter of 2004, and the first and second quarters of 2005 reflect both the impact of reduced contract-manufacturing activity and the effect of the weakened U.S. dollar on foreign currency translation. Research and development expenditures continued trending upward throughout fiscal 2004 due to a greater number of revenue-generating contract research and development projects, and from internal research and development of biopharmaceutical products.

In the first quarter of 2005, research and development expenditures and related revenues for the anthrax and botulinum contracts decreased from the prior quarter, due to the timing of specific project activities and milestones. During the second quarter of 2005, research revenues and costs from these contracts rose as the projects entered more active phases. In the third and fourth quarters, research revenues and costs declined, due mainly to lower research activity on the anthrax and VIG contracts. In the third and fourth quarters of 2005, the Company ceased recognizing the tax benefit of net operating losses generated in its U.S. operations and during the fourth quarter, recorded an impairment loss in the Chesapeake subsidiary relating to the viral vaccine facility. Net income and earnings per share over the eight quarters directly reflect the impact of fluctuations in revenues and earnings from the contract R&D and manufacturing activities.

## LIQUIDITY & CAPITAL RESOURCES

### Operating activities

Cash at July 31, 2005 was \$4.0 million, unchanged from the end of the 2004 fiscal year. Cash used in operating activities of \$9.3 million during fiscal 2005 compares to cash generated from operating activities of \$39.1 million in the prior year. The use of cash in the current year reflects \$8.1 million generated from operations, offset by an increase of \$24.1 million in working capital balances, compared to \$31.6 million generated from operations coupled with a \$5.6 million decrease in working capital balances in the prior year.

Net non-cash working capital, excluding bank debt, increased to \$46.3 million at July 31, 2005 from \$20.1 million at July 31, 2004. Higher working capital levels in 2005 resulted from increases in accounts receivable and inventory, partly offset by an increase in trade accounts payable, compared to July 31, 2004. The increase in accounts receivable is due to billing certain research contracts late in the quarter and higher balances due from international customers, while the increase in inventory is due to work-in-process inventories of VIG plasma and finished WinRho<sup>®</sup> SDF product, which the

Company anticipates will be used to meet future U.S. and international orders. Final tax payments for the 2004 fiscal year and tax instalment payments for the first quarter of 2005 reduced accrued taxes payable and increased the use of cash in the period.

### Financing activities

Cash provided by financing activities totalled \$22.7 million in fiscal 2005 compared to cash used in financing activities of \$17.0 million in the same period of the prior year. The use of cash to repay \$25.7 million of long-term debt and finance \$24.4 million of capital expenditures in fiscal 2004 was largely generated from operations, with the remainder of \$8.7 million coming from proceeds of stock options exercised during the year. For the year ended July 31, 2005, although the Company repaid \$3.8 million of long-term debt and received proceeds of \$4.3 million on the exercise of stock options, it borrowed \$16.2 million on its operating facility and drew \$6.0 million on the facility-expansion term loan to fund \$13.4 million of capital expenditures and meet short-term cash requirements.

### 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 table provides 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, 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
Stock options exercised	1,037,750	4,321
Share capital as at July 31, 2005	65,020,970	\$ 29,037

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, 2005, 1.1 million [July 31, 2004 – 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 the options are granted. These options expire no later than five and eight years after the date they are granted for non-employee directors and employees, respectively, and vest over four fiscal years.

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS (CONTINUED)

A summary of the status of the Corporation's stock option plan as of July 31, 2005 and 2004 and changes during the years ending on those dates is presented below:

Stock Options	2005		2004	
	Number of shares	Weighted-average exercise price	Number of shares	Weighted-average exercise price
Outstanding at beginning of year	4,436,150	\$ 6.04	5,085,000	\$ 6.23
Granted	7,500	9.33	50,000	11.11
Exercised	(1,037,750)	4.16	(625,650)	4.15
Cancelled	(297,050)	9.67	(73,200)	9.72
Outstanding at end of year	3,108,850	\$ 7.02	4,436,150	\$ 6.52
Exercisable at end of year	3,098,225	\$ 7.01	3,928,563	\$ 6.04

The following table illustrates the expected and maximum number of common shares outstanding as at October 12, 2005, assuming exercise of all exercisable outstanding stock options:

	Exercise price	Number of securities outstanding	Weighted-average remaining contractual life	Number of securities outstanding and exercisable	Number of common shares upon conversion or exercise <sup>1</sup>
Common shares		65,020,970			65,020,970
Stock options	\$ 3.55	353,625	0.6 years	353,625	353,625
	3.50	309,000	1.2	309,000	309,000
	4.65	286,375	2.2	286,375	286,375
	8.03	404,300	2.9	404,300	404,300
	6.25	657,100	3.2	657,100	657,100
	7.04	56,300	3.8	56,300	56,300
	9.31	489,950	4.3	489,950	489,950
	10.60	534,700	5.0	534,700	534,700
	9.33	10,000	7.0	5,000	5,000
	\$ 9.33	7,500	7.0 years	1,875	1,875
Subtotal – Stock options		3,108,850		3,098,225	3,098,225
<b>Total</b>		<b>68,129,820</b>			<b>68,119,195</b>

<sup>1</sup> Assuming exercise of all exercisable options whether currently in the money or not. Closing price for Cangene's common shares on the Toronto Stock Exchange on October 12, 2005 was \$8.18.

During the year ended July 31, 2005, the Company recorded total stock-based compensation of \$0.7 million related to stock options granted after July 1, 2002 in accordance with the change in accounting policy detailed under the subheading Stock-based compensation in the Notes to the consolidated financial statements.

The table below presents pro forma net income and earnings per share for fiscal 2004 as if compensation expense related to stock options granted to employees had been determined based on the fair-value method. The table includes only stock options granted by the Corporation after August 1, 2002, the date of adoption of Section 3870, of the *CICA handbook*.

<i>in thousands of Canadian dollars except per-share data</i>		2004
Net income for the year as reported		\$ 32,542
Pro forma compensation expense		921
<b>Pro forma net income for the year</b>		<b>\$ 31,621</b>
<b>Pro forma basic earnings per share</b>		<b>\$ 0.50</b>
<b>Pro forma diluted earnings per share</b>		<b>\$ 0.49</b>

The estimated fair values of stock options issued during the years ended July 31, 2005 and 2004 were determined using the Black-Scholes options pricing model using the following weighted average assumptions: annualized volatility of 45%, risk-free interest rate of 4%, expected life of 5 years and a dividend yield of 0%. The resulting weighted-average fair value per option issued during the year ended July 31, 2005 was \$4.95 [2004 – \$4.95].

The Corporation anticipates that present and former 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.

The Corporation anticipates that it could raise new equity where new capital is required to fund growth, and where and when a market opportunity exists.

#### Debt

Effective January 1, 2005, the Corporation renewed its senior credit facilities, consisting of a \$20-million revolving operating line of credit, a new \$30-million term-loan facility to fund plant expansion, and \$2.8 million U.S. of non-revolving term loans, representing the remaining outstanding balance of a loan originally used to fund capital expenditures in 2002.

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, 2005 unless otherwise renewed at the option of the bank. As at July 31, 2005, the Corporation had \$16.2 million in advances [July 31, 2004 – \$Nil] outstanding under the revolving operating facility.

As at July 31, 2005, \$1.3 million U.S. [\$1.6 million Cdn] of the term loan used to fund capital expenditures remained outstanding [July 31, 2004 – \$3.3 million U.S. or \$4.3 million Cdn]. 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. [\$203,000 Cdn], with final repayment of any outstanding principal amount due on April 30, 2007.

As at July 31, 2005, \$6.0 million of the new non-revolving term-loan facility used to fund plant expansion was outstanding [July 31, 2004 – \$Nil]. The non-revolving term loan is collateralized by a general security agreement and bears interest at Banker's Acceptance rates plus 1.5%. The Company may draw up to \$30.0 million of this loan facility to fund plant expansion on or before September 30, 2006, after which the loan becomes repayable in equal monthly instalments over a period of five years.

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, 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] that has 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. [\$184,000 Cdn]. As at July 31, 2005 there was a balance of \$2.9 million U.S. or \$3.5 million Cdn [2004 – \$3.5 million U.S. or \$4.6 million Cdn] outstanding under the bond.

Chesapeake also has a \$1.0-million U.S. revolving line of credit with a regional U.S. bank, which is 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, 2005. As at July 31, 2005, there was no balance [2004 – \$0.4 million U.S. or \$0.5 million Cdn] 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 2006. As at July 31, 2005, no balance [July 31, 2004 – \$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 July 31, 2005</b>	Payments due by period			
		Less than 1 year	1–3 years	4–5 years	After 5 years
Long-term debt	\$ 11,107	\$ 2,343	\$ 7,530	\$ 552	\$ 682
Capital lease obligations	–	–	–	–	–
Operating leases	4,453	1,875	1,480	154	944
Purchase obligations <sup>1</sup>	–	–	–	–	–
Other long-term obligations <sup>2</sup>	–	–	–	–	–
<b>Total contractual obligations</b>	<b>\$ 15,560</b>	<b>\$ 4,218</b>	<b>\$ 9,010</b>	<b>\$ 706</b>	<b>\$ 1,626</b>

<sup>1</sup> "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.

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

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS (CONTINUED)

### Investing activities

Cash used in investing activities decreased to \$13.4 million for fiscal 2005, compared with \$24.4 million in the same period last year. The decrease in investing activity reflects reduced capital expenditures on plant and equipment during the current year following significant capital expenditures on information systems and expansion of the biopharmaceutical manufacturing facility in fiscal 2004. The Corporation is, however, further expanding its facilities to address new business opportunities and has commenced a capital expansion project that will expand its plasma fractionation capacity to meet future demand for hyperimmune production. At July 31, 2005, \$8.6 million [July 31, 2004 – \$Nil] has been spent on the fractionation expansion, and the Company has entered into agreements to spend a further \$3.5 million related to this project.

### Summary

The Company's ability to generate funds from operating activities, including product sales, and contract R&D and manufacturing, as well as the ability to obtain debt financing from its bank and Apotex, 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 to support the development of certain biopharmaceutical products. Research revenues received pursuant to this contract are based on the direct research costs plus a contribution to overhead. Under this agreement, Cangene will hold the licence to the products developed, and Apotex will be entitled to receive a 12% royalty on net sales and the right to distribute these products. Apotex 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, 2005.

The Corporation also has agreements with Apotex to conduct contract research and contract manufacturing of two biopharmaceutical products for which Apotex intends to retain proprietary rights. The terms for 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.

On November 5, 1996, Cangene acquired the rights to a drug called Ferriprox™ (deferiprone) from Apotex in exchange for warrants to purchase 5.3 million common shares of the Corporation. A total of 2.65 million warrants subsequently expired during the year ended July 31, 2002 and the remaining

2.65 million warrants were exercised by Apotex on October 30, 2003. The Corporation receives 50% of any net profits from the sales of Ferriprox™ worldwide.

Pursuant to the above agreements, in the year ended July 31, 2005, Cangene earned revenues from Apotex of \$12.8 million [2004 – \$9.3 million] for developing biopharmaceutical products, \$5.9 million [2004 – \$7.6 million] from Ferriprox™ sales, and \$6.7 million [2004 – \$4.7 million] for other contract R&D activities.

As at July 31, 2005, accounts receivable included \$3.8 million [July 31, 2004 – \$4.6 million] from these related-party transactions. Related-party transactions are recorded at the exchange amount, which the Company believes to be the fair market value.

Cangene has entered into a rental agreement with Apotex 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 \$0.4 million during fiscal 2005 [2004 – \$0.5 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, which are discounted using an estimated discount rate that 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 and will work closely in tandem on certain future contract opportunities; consequently, the goodwill was evaluated in the context of an aggregated contract R&D and manufacturing segment.

Goodwill impairment 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 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 or 2004, and, based upon the recent evaluation, no goodwill impairment was recorded for the year ended July 31, 2005. 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**

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/finish facility to process live viral vaccines. The decision to construct this facility was made in large part due to 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/finish services existed to support the decision to invest.

During the second quarter of fiscal 2005, the existing subcontract to supply fill/finish services to the smallpox vaccine manufacture was concluded and the Corporation has subsequently been evaluating a number of opportunities to generate revenues and cash flow from this facility. In July 2005, Chesapeake entered into a non-binding letter of intent with a

different smallpox vaccine manufacturer to examine the feasibility and establish the necessary capital investment plans to prepare the facility for lease, on the basis that the vaccine manufacturer may be awarded all or part of a new major contract to supply smallpox vaccine to the U.S. government. Under the terms of the letter of intent, the parties will mutually examine the feasibility of using the facility and reach agreement on a capital investment plan within a period of 90 days. Prior to the expiry of the letter of intent, the viral manufacturer may decide to exercise its option to lease the facility or enter into a reservation agreement to reserve the facility for a limited period of time. There can be no assurance, however, that this party will enter into a lease or enter into any agreement to reserve the facility for any particular period of time.

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 and discounted 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. The Corporation has concluded, based on the same approach and methodology used in prior periods, but with recent estimates and assumptions, that an impairment loss of \$18.0 million is required with respect to the Chesapeake viral facility.

Impairment relating to long-lived assets reduces the carrying value of the asset recorded on the balance sheet and results in a separate charge to income. The impairment relating to the viral facility is a non-cash charge since the investment was made in prior accounting periods.

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

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

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS (CONTINUED)

accounting period in the event that circumstances change and the Corporation, based on revised estimates and assumptions, determined that it was no longer more likely than not that future tax assets would be fully realized.

As at July 31, 2004, the Corporation had recorded a future tax asset of \$10.0 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 the third and fourth quarters of fiscal 2005, the Company did not recognize the future tax benefit of additional tax losses originating from U.S. operations in the quarters and does not expect to record the future benefit of any additional tax losses that may originate in future quarters, unless circumstances change to suggest that additional future taxable income can be generated to utilize such losses. The Company believes that tax losses currently recorded will be utilized. As at July 31, 2005, and after revaluing the tax asset at current exchange rates, the recorded future tax asset totalled \$10.9 million. Unrecorded tax losses and temporary differences, including the impairment loss, total \$22.8 million with a potential future tax value of \$9.1 million. Existing accumulated operating losses can be carried forward to offset future taxable income for periods of 15–20 years.

### 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 ("GAAP") requires that the Corporation adopt, select, and apply the appropriate accounting policies and principles, particularly where alternatives exist, within GAAP. During the first quarter of 2005, the Corporation initially adopted the following new accounting recommendation:

#### Stock-based compensation

In November 2003, the Canadian Institute of Chartered Accountants amended *Section 3870 – Stock-Based Compensation and Other Stock-Based Payments* to require that all stock-based compensation be measured and expensed using a fair-value-based methodology. The Corporation adopted the new recommendations effective August 1, 2004 on a retroactive basis, without restatement of prior periods. The effect of this change is to record a charge to net income in the current year equal to the fair value of all stock options granted since August 1, 2002 that vested during the current year. In addition, a cumulative adjustment to reduce retained earnings and increase contributed surplus was recorded at the beginning of the year, equal to the fair value of all stock options granted since August 1, 2002 that had become vested up to and including July 31, 2004.

The Corporation did not adopt any new accounting policies, nor did it change any existing accounting policies, other than noted above during fiscal 2005.

#### Recent accounting pronouncements

The following new handbook sections will be effective for fiscal years beginning on or after October 1, 2006.

Cangene is currently evaluating the effect that adoption of these standards will have on results of operations and financial positions.

#### *CICA 3855 – Financial Instruments – Recognition and Measurement:*

This section prescribes when a financial instrument is to be recognized on the balance sheet and at what amount, either a fair-value or a cost-based measure. The section also provides standards for reporting gains and losses on financial instruments.

#### *CICA 3865 – Hedges:*

This is an optional application that provides alternative treatments to Section 3855 (discussed above) for entities that choose to designate qualifying transactions as hedges for accounting purposes. It builds on existing *Accounting Guideline AcG-13 – Hedging Relationships*, and *Section 1650 – Foreign Currency Translation*, by specifying how hedge accounting is applied and what disclosures are necessary when it is applied.

#### *CICA 1530 – Comprehensive Income:*

This section provides a new requirement that certain gains and losses are to be temporarily presented outside of Net earnings and recognized as 'Other Comprehensive Income'. Comprehensive income is the change in equity of an enterprise during a period from transactions and other events, and circumstances from non-owner sources. Other comprehensive income comprises revenues, expenses, gains and losses that are recognized in comprehensive income, but excluded from net earnings.

### 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.

**Foreign currency risk**

Cangene operates internationally, and a majority of its revenue and a significant amount of its expenditures 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 is 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 long-term debt balances during the 2004 fiscal year significantly reduced the exposure to 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.

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 manufactured successfully 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 other hyperimmune products is dependent on a supply of plasma and other specialty products. 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 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 revenue generation, 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 continuous and stringent quality assurance, quality control and regulatory review processes internally to minimize this risk.

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS (CONTINUED)

### **Reliance on distribution relationships**

A significant portion of Cangene's revenues from its principal product, WinRho® SDF, are derived from sales through exclusive distributors in the U.S. and international markets. During 2005, the Corporation changed its U.S. distributor so that a sole distributor has 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 supporting 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 the 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 would be able to successfully defend such claims.

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

Cangene is party to contracts with Canadian and U.S. government agencies, a small number of other third parties, and Apotex, 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 for development and manufacturing of products for use in biodefence programs. By their nature, these contracts call for Cangene to supply such products to a national stockpile, to be used 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 their use. There is no way to predict the level of future demand for such products.

### **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 international 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 R&D 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 for 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 compete 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 achieve or maintain its desired market share in any particular industry segment or market.

### **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).

## ***APPENDIX B***

### **AUDIT COMMITTEE CHARTER**

The Board of Directors (the “Board”) of Cangene Corporation (the “Company”) has established an Audit Committee (the “Committee”), with the following terms of reference (the “Terms”).

#### **MEMBERSHIP AND CHAIR**

Following each Annual Meeting of the Shareholders, the Board shall elect three or more directors (the “Members”), who shall meet the independence and financial literacy requirements of relevant securities legislation, specifically *Multilateral Instrument 52-110*, to serve on the Committee until the close of the Company’s next Annual Meeting of the Shareholders, or until the member ceases to be a director, resigns or is replaced, whichever occurs first. Any Member can be removed from office or replaced at any time by the Board. While the Committee has the responsibilities and powers set forth below, it is not the duty of the Committee to plan or conduct audits or to determine that the Company’s financial statements are complete and accurate. This is the responsibility of management and the external auditor. It is the duty of the Committee to conduct investigations, to resolve disagreements, if any, between management and the external auditors and to assure compliance with laws and regulations.

The Board shall appoint one of the Members as Chair of the Committee. If the Chair is absent from a Committee meeting, the Members shall select one of those in attendance to act as Chair of the meeting.

The Committee will make regular reports to the Board.

#### **RESPONSIBILITIES**

##### **Publicly disclosed financial information**

Prior to any public release, the Committee shall:

- (a) review, in conjunction with the report of the external auditors, and recommend for Board approval:
  - (i) the audited annual financial statements and the related annual management’s discussion and analysis of financial condition and results of operations
  - (ii) all public disclosure documents containing audited or unaudited financial information, including any prospectus, information circular, annual information form, or related news releases, unless otherwise specified in these Terms.
- (b) review and approve the interim unaudited financial statements, related management’s discussion and analysis of financial condition and results of operations, and related news releases.
- (c) review any report that accompanies published financial statements (to the extent such a report discusses financial condition or operating results) for consistency of disclosure with the financial statements themselves.

In its review of financial statements, the Committee should obtain an explanation from management of all significant variances between comparative reporting periods and an explanation from management for items that vary from expected or budgeted amounts as well as from previous reporting periods.

## **Financial Reporting and Accounting Trends**

The Committee shall:

- (a) review and assess the effectiveness of policies and practices concerning financial reporting
- (b) review with management and the external auditors any proposed changes in major accounting policies, the presentation and impact of significant risks and uncertainties, and key estimates and judgments of management that may be material to the financial reporting
- (c) question management and the external auditors regarding significant financial reporting issues discussed and the method of resolution
- (d) review general accounting trends and issues of accounting policy, standards and practices that affect or may affect the Company.

## **Internal Controls**

The Committee shall:

- (a) assess the adequacy and effectiveness of internal controls over the accounting and financial reporting system, with particular emphasis on controls over computerized systems.
- (b) review:
  - (i) the evaluation of internal controls by the external auditors, together with management's responses;
  - (ii) the appointment of the Chief Financial Officer and any key financial executives involved in the financial reporting process.

## **External Auditors**

The Committee shall:

- (a) recommend to the Board the appointment of the external auditor, which then reports to the Committee and the Board, but is ultimately accountable to the Shareholders.
- (b) receive periodic reports from the external auditors regarding the auditors' independence, discuss such reports with the auditor, and if determined by the Committee to be necessary, recommend that the Board take appropriate action to satisfy itself as to the external auditors' independence
- (c) review the terms of the external auditors' engagement and the appropriateness and reasonableness of the proposed audit fees
- (d) review and pre-approve any engagements for material, non-audit services provided by the external auditor or its affiliates, together with the fees for such services, and consider the impact of this on the independence of the external auditors. The Committee has established pre-approved limits for immaterial, non-audit services within which management may engage the external auditor or its affiliates to perform such services without further pre-approval, provided that management is satisfied that such services will not impair the independence of the external auditors. Immaterial, non-audit services are defined as services to provide tax planning or accounting advice for which the fees do not exceed \$5,000 for any single engagement and provided that the total fees for all such engagements do not exceed \$30,000 annually.

- (e) when a change of auditors is proposed, review all issues related to the change, including the information to be incorporated with the Notice of change of auditors called for under the applicable securities laws, and the planned steps for an orderly transition
- (f) review all reportable events, including disagreements, unresolved issues and consultations, as defined in the applicable securities laws, on a routine basis, whether or not there is to be a change of auditors

### **Audit Procedures**

The Committee shall:

- (a) review the audit plans of the external auditors, including the degree of coordination in those plans, and shall enquire as to the extent to which the planned audit scope can be relied upon to detect weaknesses in internal control, or fraud and other illegal acts. The Committee will then review these plans with the external auditors and management, and recommend to the Board the scope of the external audit as stated in the audit plan.
- (b) review any problems experienced by the external auditors in performing the audit, including any restrictions imposed by management or significant accounting issues about which there was a disagreement with management.
- (c) review the post-audit or management letter containing the recommendations of the external auditors, and management's response and subsequent follow-up to any identified weakness.

### **Other Responsibilities**

The Committee shall:

- (a) review such litigation, claims, transactions or other contingencies as the external auditors or any officer of the Company bring to its attention, and shall periodically review the Company's risk management programs and comprehensive computer disaster recovery plans.
- (b) review the policy on use of derivatives and monitor the risk.
- (c) consider other matters of a financial nature as directed by the Board
- (d) review any related party transactions in line with the applicable securities law.

### **Meetings**

- (a) regular meetings of the Committee shall be held quarterly.
- (b) Special meetings of the Committee may be called by the Chair of the Committee, the external auditors, the Chairman of the Board of the Company, the President or the Chief Financial Officer.
- (c) the powers of the Committee shall be exercisable by a meeting at which a quorum is present. A quorum shall be not less than a majority of the Members. Subject to the foregoing requirement, unless otherwise determined by the Board, the Committee shall have the power to fix its quorum and to regulate its procedures.
- (d) notice of each meeting shall be given to each Member, the external auditors, the Chairman of the Board of the Company, the President and the Chief Financial Officer, any or all of whom shall be entitled to attend and each of whom shall attend whenever requested to do so by the Chair of the Committee or the Secretary. Notice of the meeting may be given orally, in person or by telephone, or by letter, telegram, or facsimile, not less than 24 hours before the time fixed for the meeting
- (e) the Committee will periodically meet with the external auditors and senior management..

- (f) members may waive notice of any meeting. The notice need not state the purpose or purposes for which the meeting is being held.
- (g) matters decided by the Committee shall be decided by majority vote.
- (h) the Committee shall have the authority to retain special legal advisors, accounting or other consultants as it sees fit to attend its meetings and to take part in discussions and consideration of the affairs of the Committee, at the expense of the Company.
- (i) the Secretary of the Company or designate of the Secretary, or failing that the designate of the Chair of the Committee, shall be the Secretary of meetings of the Committee and shall maintain minutes of all meetings and deliberations of the Committee.
- (j) the Committee shall report to the Board on its proceedings, reviews undertaken and any associated recommendations.