



**CANGENE CORPORATION**  
**2008** Annual Information Form  
October 24, 2008

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## GENERAL

This Annual Information Form ("AIF") is intended to provide material information about Cangene Corporation ("Cangene", the "Corporation", or the "Company") and its business.

Unless otherwise indicated, all information in this AIF is presented as at July 31, 2008 and all amounts are expressed in Canadian dollars.

### *Incorporation by Reference*

Cangene's 2008 Management's Discussion and Analysis, dated October 15, 2008 ("MD&A"), is hereby incorporated by reference into this AIF and is available on SEDAR at [www.sedar.com](http://www.sedar.com) or on Cangene's website at [www.cangene.com](http://www.cangene.com).

## TRADEMARKS

"Accretropin", "Cangene", "Cangenus", "HepaGam B", "Leucotropin", "VariZIG", "WinRho" and "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.

## DRUG NAMES

Cangene's proprietary names for drugs are used throughout this document for convenience; complete names are as follows (names may differ in various countries):

Accretropin™ [somatropin (rDNA origin)] Injection  
 HepaGam B® [Hepatitis B Immune Globulin (Human) Injection]  
 Leucotropin® [recombinant human GM-CSF or Granulocyte-Macrophage Colony-Stimulating Factor]  
 Vaccinia Immune Globulin Intravenous (Human) [VIGIV]; (referred to in this document as "VIG")  
 VariZIG™ [Varicella Zoster Immune Globulin (Human)]  
 WinRho® SDF [Rh<sub>0</sub> (D) Immune Globulin (Human) for Injection]

## DISCLAIMERS

### *Cautionary Note Regarding Forward-looking Information*

This AIF and the documents incorporated by reference herein contain certain forward-looking statements about the Corporation, including its business operations, strategy, and expected financial performance and condition. Forward-looking statements include statements that are predictive in nature, depend upon or refer to future events or conditions, or include words such as "expects", "anticipates", "intends", "plans", "will", "believes", "estimates", or negative versions thereof, and similar expressions. In addition, any statement that may be made concerning future financial performance (including revenues, earnings or growth rates), ongoing business strategies or prospects, future use, safety and efficacy of unapproved products or unapproved uses of products, and possible future action by the Corporation are also forward-looking statements. Forward-looking statements are based on current expectations and projections about future events and are inherently subject to, among other things, risks, uncertainties and assumptions about the Corporation, economic factors and the biopharmaceutical industry generally. They are not guarantees of future performance. Actual events and results could differ materially from those expressed or implied by forward-looking statements made by the Corporation due to, but not limited to, important factors such as sales levels; fluctuations in operating results; the Corporation'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; the availability and cost of raw materials, and in particular, the cost, availability and antibody concentration in plasma; progress and cost of clinical trials; 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 costs associated with its defence as well as general economic, political and market factors in North America and internationally; interest and foreign exchange rates; business competition; technological change; changes in government action, policies or regulations; unexpected judicial or regulatory proceedings; catastrophic events; the Corporation's ability to complete strategic transactions; and other factors beyond the control of management.

The reader is cautioned that the foregoing list of important factors is not exhaustive and there may be other factors listed in other filings with securities regulators, including factors set out under "Risk and Uncertainties" in the Corporation's MD&A, which, along with other filings, is available for review at [www.sedar.com](http://www.sedar.com). The reader is also cautioned to consider these and other factors carefully and not to place undue reliance on forward-looking statements. Other than as specifically required by applicable law, the Corporation has no intention to update any forward-looking statements, whether as a result of new information, future events or otherwise.

### ***Cautionary Note Regarding Non-GAAP Financial Measures***

This AIF and the documents incorporated by reference contain non-GAAP financial measures. Terms by which non-GAAP financial measures are identified include but are not limited to "net cash", "total assets", "sales" and other similar expressions. Non-GAAP financial measures are used to provide management and investors with additional measures of performance. However, non-GAAP financial measures do not have standard meanings prescribed by GAAP and are not directly comparable to similar measures used by other companies. Please refer to the appropriate reconciliations of these non-GAAP financial measures to measures prescribed by GAAP.

### ***Scientific and Drug Information***

Product information is included in this AIF for investor information purposes only. Scientific information that relates to unapproved products or unapproved uses of products is preliminary and investigative. No conclusions can or should be drawn regarding the safety or efficacy of such products. Only regulatory authorities can determine whether products are safe and effective for the uses being investigated. Healthcare professionals are directed to refer to approved labelling for products and not rely on information discussed in this document. Prescribing information or drug names may differ in various countries.

### **CURRENCY**

Unless specified otherwise, dollar amounts are in Canadian dollars.

### **CORPORATE STRUCTURE AND MAJORITY SHAREHOLDER**

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

Cangene Corporation ("Cangene", 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 of the Corporation ("Common Shares") on a four-for-one basis. Pursuant to Articles of Amalgamation dated November 1, 1995, Rh Pharmaceuticals Inc. was amalgamated with the Corporation. On October 24, 2008, the Articles of the Corporation were further amended to change the maximum number of directors from 10 to 15.

Cangene's registered office moved during the current fiscal year and is located at 180 Attwell Drive, Suite 360, Toronto, Ontario, M9W 6A9. At the Corporation's Annual and Special Meeting of Shareholders, to be held on December 12, 2008, the shareholders of the Corporation will be asked to pass a special resolution change the municipality of the registered office from the City of Mississauga to the City of Toronto.

Cangene's head office is located at 155 Innovation Drive, Winnipeg, Manitoba, R3T 5Y3.

### ***Inter-corporate Relationships***

Cangene 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., which is incorporated in the State of California, and Mid-Florida Biologicals, Inc., which is incorporated in the State of Florida. Cangene also owns 100% of the voting securities of Cangene Europe Limited, a company incorporated in the United Kingdom.

### ***Majority Shareholder***

As at October 24, 2008, to the knowledge of the directors and executive officers of the Corporation, the Apotex Group ("Apotex"; a group of entities under common control, which includes the entities listed below) controlled, directly or indirectly, 42,875,787 Common Shares representing 61% of the outstanding Common Shares as follows:

Apotex Inc.	57,315 Common Shares
Apotex Holdings Inc.	24,500,493 Common Shares
Sherman Foundation	17,395,822 Common Shares
Apotex Foundation	787,157 Common Shares
Bernard Sherman	135,000 Common Shares (held directly)

The Apotex Group, which also includes Apotex Research Inc. and Apotex Corp., is controlled, directly or indirectly, by Bernard Sherman and the Bernard and Honey Sherman Family Trust, of which he is the trustee. Dr. Sherman is also Chairman, Chief Executive Officer and a director of Apotex Inc., and he is a director and President of Sherman Foundation and Apotex Foundation, and as such controls the holdings in these charitable foundations indirectly.

## **GENERAL DEVELOPMENT OF THE BUSINESS**

### ***Overview***

Cangene develops, manufactures and markets biopharmaceutical products, mainly specialty plasma products (hyperimmunes) and recombinant therapeutic proteins, with a core strategic focus on infectious-disease-related therapies and medical countermeasures to bioterrorism. The markets for these products can be split into two categories: commercial and government. In addition, the Company provides contract services to organizations such as national governments or other members of the biopharmaceutical industry.

Hyperimmunes are purified antibodies that are used therapeutically, and Cangene uses its own innovative approach to manufacture these products, which results in a high yield and excellent product purity. The Company has three hyperimmune products that have been approved in the United States and Canada, and a fourth that is approved in Canada only. Several others are in various stages of development. In addition, one of Cangene's approved hyperimmunes and two others have been delivered and accepted into the United States Strategic National Stockpile ("SNS") under contract with the U.S. government.

The Company has developed recombinant protein expressions systems, which have been used to develop a number of recombinant protein products that can be manufactured in its specialized facility. The two leading recombinant products are proteins that have already demonstrated commercial utility and both have been submitted for regulatory

review. One of these, Accretropin™, was approved by the U.S. Food and Drug Administration (“FDA”) during fiscal 2008, although due to certain patent-related and marketing issues, the product has not been launched. The second, Leucotropin®, has been filed in Canada for a cancer-related indication but the Company is currently focused on developing the product for a potential biodefence use. Both of these proteins were developed under an R&D agreement with Apotex and as such, Apotex retains certain rights to the products.

An important factor in Cangene’s hyperimmune operation is its ability to obtain sufficient quantities of the type and quality of plasma needed to manufacture its hyperimmune products. Cangene collects a portion of its own plasma. It operates the Rh Plasma Center in Winnipeg and owns two medium sized U.S. subsidiaries that actively operate plasma centres—Biotherapeutic Laboratories, Inc. in Van Nuys, CA, and Mid-Florida Biologicals, Inc. in Altamonte Springs, FL and Frederick, MD. Currently, a significant portion of Cangene’s plasma supply is obtained from third-party plasma collection centres, and although Cangene believes it has adequate supplier relationships, there is increasing competition for plasma supply. Consequently, the Company is planning to expand its U.S. collection facilities with the ultimate goal of doubling internal capacity by the second half of fiscal 2009.

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”), which results in a clotting deficiency due to a drop in blood platelets. Results from a 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.

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 ITP. In addition, Baxter (through Baxter Healthcare Corporation) has exclusive marketing and distribution rights for WinRho® SDF in the U.S. Using a manufacturing process similar to that used for WinRho® SDF, Cangene has developed and manufactured several other hyperimmune products. Two of these, HepaGam B® and Vaccinia immune globulin (“VIG”; see page 15), are approved for sale in Canada and the United States. HepaGam B® is approved for two indications in the U.S. and one in Canada (see page 14). A third hyperimmune, VariZIG™, is approved for sale in Canada and is available in the United States under an expanded-access investigational new drug protocol. The U.S. FDA has granted VariZIG™ orphan drug designation for passive immunization of exposed, susceptible individuals who are at-risk of complications from chickenpox virus. The FDA has also granted HepaGam B® orphan drug exclusive approval. VIG was originally developed and supplied under a five-year agreement with the United States Centers for Disease Control and Prevention (“CDC”); it has also been sold to other governments for inclusion in national stockpiles. As a result it generates an uneven revenue flow. During fiscal 2008, this original contract was extended for a further five years. HepaGam B® is distributed in the U.S. by Apotex Corp. Sales and marketing strategies are aimed at expanding HepaGam B’s market share in in-patient and homecare market segments.

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., which is located in Baltimore, MD. Chesapeake has served a range of customers, from major international pharmaceutical firms to emerging biotechnology companies. The specialized development services it provides include: development of sterile product formulations, test-method development and validation, process design and manufacturing validations, and regulatory and compliance consulting. A facility for fill/finishing of live viral vaccines exists but is not currently active.

The nature of the contract business creates an uneven revenue flow; during fiscal 2008, contract-services revenue made up 63% of the Company’s total revenue, compared with 33% the year before. Under certain of the development and supply contracts (generally the government contracts) that it undertakes, Cangene retains ownership of the products and as such, revenue from any of these products becomes recorded under the biopharmaceutical segment once the product has been approved for sale.

Cangene has a research and development agreement with Apotex to support the development of certain recombinant biopharmaceuticals (including Leucotropin<sup>®</sup> and Accretropin<sup>™</sup>; see **Recombinant Biopharmaceuticals** page 21) through to initial regulatory filing. In return, Apotex will receive royalties on sales of certain products developed pursuant to the research and development agreement and a further right to distribute the products. No sales of biopharmaceutical products developed pursuant to this agreement have been made to date. Apotex and Cangene will share profits after deducting royalty expenses.

Resulting from an earlier licensing agreement, Cangene receives 50% of any net profits worldwide on a drug called Ferriprox<sup>®</sup> (deferiprone) that Apotex developed and markets. Apotex has its head office in Toronto and is Canada's largest domestically owned pharmaceutical company. It is a fully integrated manufacturer and distributor of over 300 generic drugs to more than 115 countries, and has more than 6,500 employees worldwide.

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.

### ***Three-Year History***

#### **Fiscal 2006 Highlights**

Cangene completed delivery on a \$16-million contract with the U.K. Department of Health to supply VIG.

Cangene was awarded contracts by the Biomedical Advanced Research and Development Authority ("BARDA") within the U.S. Department of Health and Human Services ("HHS") to develop a clinical-grade anthrax immune globulin ("AIG") and to develop a hyperimmune to treat botulism (botulism antitoxin or "BAT"). The five-year BAT contract was awarded to Cangene in May 2006. This base contract is valued at US\$362 million with additional optional task orders that could add a further US\$234 million. HHS exercised its option to purchase 10,000 doses of AIG under a modification of an earlier contract. This contract is valued at US\$143 million.

HepaGam B<sup>®</sup> was approved in the U.S. for post-exposure prophylaxis indication

Liquid WinRho<sup>®</sup> SDF was launched in the U.S.

Cangene submitted its recombinant human growth hormone product, Accretropin<sup>™</sup>, for review by the FDA.

#### **Fiscal 2007 Highlights**

Cangene announced a potential new peptide-based treatment ("PEP 35") for certain antibiotic-resistant, hospital-acquired *Staphylococcus aureus* bacterial infections.

The FDA granted orphan drug designation for VariZIG<sup>™</sup>.

Cangene completed an \$81-million offering that included 4,375,000 shares issued from treasury and a secondary offering of 5,625,000 shares that were sold by Sherman Foundation, a charitable foundation related to Apotex. The deal yielded approximately \$33.5 million in net proceeds to Cangene that was used to repay \$24.0 million in outstanding debt. The public float increased by 10 million shares as a result of this offering.

HepaGam B<sup>®</sup> was approved in Canada (Notice of Compliance with conditions) for preventing hepatitis B recurrence in liver transplant recipients.

HepaGam B<sup>®</sup> was approved in the U.S. for preventing hepatitis B recurrence in liver transplant recipients.

The Company had designed and constructed a 42,500 square foot plasma fractionation facility adjacent to its main building in Winnipeg. The new facility is now being used to manufacture the BAT product.

VIG was approved in Canada for treating certain complications that may be associated with smallpox vaccination.

### **Fiscal 2008 Highlights**

The Company delivered initial quantities of both BAT and AIG, and they were accepted into the SNS, permitting the Company to begin invoicing. During the fourth quarter of fiscal 2008, Cangene made the first substantial product deliveries under the BAT contract. Total revenues recorded for the two contracts during 2008 were \$75.9 million.

The original CDC VIG contract was extended for an additional five years; this extension supports licensing requirements, ongoing stability studies, further clinical testing and development projects, and could provide for future orders.

Cangene consolidated R&D operations and closed the small R&D operation in Mississauga, Ontario. The change was made to strengthen the links between research, product development and manufacturing, and to improve operational effectiveness by bringing all R&D activities into close proximity. The Company re-located the Ontario-based regulatory, sales and marketing, and administrative staff to an office in Toronto.

The liquid version of WinRho<sup>®</sup> SDF was approved and launched in Canada during fiscal 2008. Liquid versions of injectable drugs can offer greater convenience for physicians and healthcare providers than the freeze-dried product, which must be reconstituted before use.

The FDA approved Accretropin<sup>™</sup> for treatment of pediatric patients who have growth failure due to an inadequate secretion of normal endogenous growth hormone, or treatment of short stature associated with Turner Syndrome in certain pediatric patients. This product was developed under a research and development agreement with Apotex, Cangene's majority shareholder, and Apotex retains its marketing rights. Apotex and Cangene are assessing the current market situation and related patent issues to determine the most effective overall strategy going forward.

There were several changes to Cangene's board of directors. First, one of the independent directors, Jerry Treppel, resigned in order to devote more time to pursuing other business interests. Shortly thereafter, the Company recruited three new, independent members to the board—Drs. D. Bruce Burlington, Philip Johnson and R. Scott Lillibridge—who bring extensive experience in the U.S. regulatory environment, government biodefence and infectious disease programs, and the medical aspects of infectious disease worldwide. Their addition brings the total number of board members to 11, six of whom are independent of the Apotex Group and marking the first time that Cangene has had a majority of independent board members.

HepaGam B<sup>®</sup> was granted orphan drug exclusive approval by the FDA for a liver transplantation indication. This approval gives HepaGam B<sup>®</sup> seven years of market exclusivity in the United States and could facilitate the recovery of certain regulatory filing fees.

Canadian Blood Services and Héma-Québec, the two exclusive distributors of blood products in Canada, signed five-year agreements with Cangene under which they will continue to purchase WinRho<sup>®</sup> SDF and VariZIG<sup>™</sup>, and will now also purchase HepaGam B<sup>®</sup> for preventing recurrence of hepatitis B virus infection following liver transplantation.

Cangene instituted a normal course issuer bid (the "Bid"). The Bid was approved by the Toronto Stock Exchange and will expire one year after it commenced or earlier if the maximum number of shares has been purchased. Under the terms of the Bid, Cangene may acquire for cancellation up to 1,000,000 Common Shares, which at the date the Bid commenced represented approximately 1.4% of Cangene's total issued and outstanding Common Shares.

Cangene filed a centralized Marketing Authorization Application for HepaGam B<sup>®</sup> in Europe (subsequent to the fiscal year-end).

## **NARRATIVE DESCRIPTION OF THE BUSINESS**

### ***General***

Cangene is a Canadian biopharmaceutical company that has established expertise and technologies for developing, manufacturing specialty plasma products (hyperimmunes) and recombinant protein therapeutic products. It is largely focused on therapeutics for infectious disease and biodefence applications. Several of these products have been approved in various jurisdictions and the Company markets these products internationally.

Operations related to products within the Company's product portfolio are recorded as the biopharmaceutical segment. The Company also offers various contract-R&D and manufacturing services to other biopharmaceutical companies and government organizations and records these operations as contract services.

Cangene has been listed since 1991 on the Toronto Stock Exchange under the symbol CNJ. The Apotex Group controls 61% of the issued and outstanding Common Shares of Cangene at October 24, 2008 (see page 5).

Having two independent revenue streams from product sales and contract services 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 profitable since 1995, although the Company reported a loss in the second and fourth quarters of fiscal 2005. Following the exceptional results recorded in 2003, results have been variable, largely due to the nature of the Company's contract business. For example, revenues from two large U.S. government contracts, signed during fiscal 2006, began to be recognized during fiscal 2008 and contributed \$75.9 million in revenues during the year.

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

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 R&D in this area has been supported by an R&D agreement with Apotex Inc. Cangene's majority shareholder, the Apotex Group, includes Apotex Inc., which is the largest Canadian-owned pharmaceutical company and a world leader in the generic drug industry.

The Company's product portfolio consists of a number of products with significant commercial potential, including five products that have been approved in the U.S. and/or Canada. WinRho<sup>®</sup> SDF, which was the Company's first licensed hyperimmune product, is licensed and sold in many countries worldwide, including Canada and the United States. WinRho<sup>®</sup> SDF accounted for 85% of the Company's \$42.1 million in biopharmaceutical product sales in 2008. Its sales have been somewhat variable the last three years, reflecting the opposing impacts of reduced U.S. sales as Cangene transitioned to a new distributor and as the U.S. dollar weakened, versus increasing sales of the new liquid formulation in the U.S. and improved sales in Europe. HepaGam B<sup>®</sup> was originally approved in the U.S. during fiscal 2006, but was approved for a second, larger indication during 2007. HepaGam B<sup>®</sup> sales grew during fiscal 2008 and have begun to make a significant contribution to biopharmaceutical revenues. VIG has been sold to a number of national governments; it is generally sold for inclusion in national stockpiles and as such, tends to generate an uneven revenue flow. During fiscal 2008, the U.S. government extended the VIG contract with Cangene for a further five years.

## Product Portfolio

	PRODUCT	RESEARCH/ PRECLINICAL	PHASE I	PHASE II	PHASE III	APPROVED
Infectious Disease/ Biodefence Therapeutics	HepaGam B <sup>®</sup>	—————●				
	Vaccinia immune globulin	—————●				
	Botulism antitoxin	—————●				
	Anthrax immune globulin	—————●				
	VariZIG <sup>™</sup>	—————●				
	Leucotropin <sup>®</sup>	—————● <small>developing for new indication</small>				
	PEP 35	—————●				
	Ebola/Marburg antibodies	—————●				
	Undisclosed anti-infective	—————●				
	WinRho <sup>®</sup> SDF	—————●				
	Accretropin <sup>™</sup>	—————●				

## Business Strategy

Cangene has built its business by developing products based on platform manufacturing technologies, rather than concentrating on a single product or even a single disease area. 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 has helped Cangene build a solid product portfolio with significant growth potential. In the last few years, the Company has strategically narrowed its focus to issues related to infectious disease and medical countermeasures to bioterrorism.

With the exception of certain innovative drugs in its discovery research program, Cangene's current 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. Going forward, the Company intends to increasingly target its development efforts on products aimed at infectious disease and biodefence targets regardless of the technology involved in their manufacture.

Cangene has been marketing its services for contract R&D and manufacturing for nearly ten years. In 2001 Cangene acquired 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, and have capabilities to serve a variety of commercial customers ranging from major international pharmaceutical firms to emerging biotechnology companies. The specialized development services Chesapeake provides include: development for sterile product formulations, test-method development and validation, process design and manufacturing validations, preparation of clinical trial and toxicology materials, aseptic filling, and accelerated and ongoing stability studies. Through the combination of capabilities at Chesapeake and capacity at Cangene's head-office operations, contract services have become a significant contributor to the Company's revenue stream and in fiscal 2008 contract services accounted for 63% 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, BAT and AIG contracts (see pages 15, 17 and 18) that contributed significantly to the exceptional financial results Cangene recorded in 2003 and 2008. Such contracts, while of significant benefit to the Company, can result in uneven revenue and cash flows since they rely on payments based on certain contract deliverables and supplying a stockpile, rather than ongoing sales.

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, primarily aimed at infectious disease and biodefence applications. Among other development projects, the Company is developing products and technologies in the area of monoclonal antibodies and peptide drugs. One of the Company's goals is to introduce eight new drugs over the next eight years.

None of Cangene's business is seasonal in nature.

### ***Biopharmaceutical Operations Segment***

#### **Hyperimmunes**

##### Background

One class of Cangene's biopharmaceutical products is 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. Hyperimmunes can be used therapeutically to affect or enhance immunity in the recipient—they can confer immediate, passive immunity or block an unwanted immune response, as in the case of Cangene's lead hyperimmune, WinRho<sup>®</sup> SDF. Cangene has four approved hyperimmunes; WinRho<sup>®</sup> SDF generated most of Cangene's biopharmaceutical product sales in 2008.

With nearly thirty years of manufacturing WinRho<sup>®</sup> SDF and a number of large U.S. government development and supply contracts, Cangene is recognized as a leader in developing and manufacturing hyperimmune products. Cangene differentiates itself from its competitors by incorporating a specialized column-chromatographic method for fractionating plasma, which is ideally suited for producing high-quality, small-batch speciality products like hyperimmunes.

To support the continued growth in its hyperimmune product line-up, the Company designed and constructed a 42,500 square foot plasma fractionation facility adjacent to its main building in Winnipeg. The new facility significantly increased the plasma fractionation capacity for new product manufacturing and added 79,000 cubic feet of cleanroom space and four separate purification suites to allow maximum manufacturing flexibility for the future. Construction of the facility was completed during fiscal 2007 and the Company began amortizing the \$36.9-million expansion effective January 15, 2007. The Company is now using the new facility to manufacture the BAT product.

Manufacture of hyperimmune products is dependent on availability of the appropriate specialty blood plasma with a sufficient concentration of the desired antibodies. Cangene collects a portion of its own plasma through four wholly owned plasma collection operations (one in Winnipeg and three in the United States). The Company also purchases a substantial portion of its plasma from commercial suppliers. The Company believes it has a good relationship with its suppliers; nevertheless, worldwide supplies can vary from year to year and competition for good quality plasma is increasing. The availability and cost of plasma can significantly impact Cangene's business. Consequently, management is focused on expanding Cangene's in-house plasma collection capabilities through expansion of its own plasma centres. The expansions are currently underway and will result in more than doubling the current capacity. Current activities include design and construction, and finalizing leasing arrangements.

Cangene has four approved hyperimmunes, two that have been developed and manufactured and a number that are in various stages of R&D and at varying levels of activity.

WinRho<sup>®</sup> SDF [Rh<sub>o</sub> (D) Immune Globulin (Human) for Injection]

**Status** Approved for both ITP and HDN (see below) in many jurisdictions including Canada and the United States.

**Description/ Background** WinRho<sup>®</sup> SDF [Rh<sub>o</sub> (D) Immune Globulin (Human) for Injection] was Cangene's first hyperimmune product and is the only one that has its primary use aimed at non-infectious disease applications. It is a purified polyclonal human immune globulin (antibody) specific for Rh<sup>+</sup> red blood cells. As an antibody that is specific for the Rh<sub>o</sub> (D) antigen on these red blood cells, WinRho<sup>®</sup> SDF can be generally referred to as an anti-D product.

WinRho<sup>®</sup> SDF was initially developed by Rh Pharmaceuticals (a company that amalgamated with Cangene in 1995) as a preventative for hemolytic disease of the newborn ("HDN"); it 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 mounts a severe immune response against them, causing HDN in subsequent pregnancies. By reacting with any fetal blood in the mother's blood stream, WinRho<sup>®</sup> SDF can prevent the immune reaction, reducing the likelihood of future complications.

In the 1980s, Cornell Medical College started studying the use of WinRho<sup>®</sup> for 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. WinRho<sup>®</sup> SDF, therefore, does have certain infectious-disease-related uses. 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<sup>®</sup> SDF was licensed by the FDA for treating ITP in the United States in 1995 and by Health Canada in 1996. It has subsequently been approved in several other jurisdictions for the ITP indication. Cangene uses solvent-detergent and special nanofiltration steps to remove viruses that may be present in the blood plasma used to make WinRho<sup>®</sup> SDF.

In 2004, Cangene initiated a clinical study to investigate the use of WinRho<sup>®</sup> 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 use of WinRho<sup>®</sup> SDF would be an expansion of its ITP indication into a new patient population. The Company plans to use these results to assess the potential for WinRho<sup>®</sup> SDF to treat other common and economically significant diseases that also cause reduced platelet levels, further linking the drug to potential infectious-disease-related applications.

**Marketing/ Sales**

WinRho<sup>®</sup> SDF is licensed and sold in many countries worldwide for one or both of its licensed indications; it generated 85% of the Company's \$42.1 million in biopharmaceutical product sales revenue in 2008. While the product is being successfully marketed internationally, Cangene continues pursuing a broadened distribution network worldwide.

WinRho<sup>®</sup> SDF currently accounts for 100% of the existing Canadian anti-D market and is distributed through Canadian Blood Services and Héma Québec. This arrangement was renewed for a further five years during fiscal 2008. The HDN market accounts for the majority of Cangene's Canadian WinRho<sup>®</sup> SDF sales.

WinRho<sup>®</sup> SDF was introduced to the U.S. market in 1995. There, it is sold almost entirely for the ITP indication and constitutes Cangene's largest market.

Cangene has a European marketing and distribution agreement with Baxter Healthcare S.A. Under the agreement, Baxter will market and distribute WinRho<sup>®</sup> SDF in Europe for treating ITP. In December 2004, European approval for WinRho<sup>®</sup> SDF was expanded to eleven countries through the European Mutual Recognition Procedure ("MRP"). Baxter has currently launched the product in Belgium, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal and the United Kingdom. Launches in Finland and Norway are expected in January 2009. A second round of MRP for 16 new countries is underway. Baxter (through Baxter Healthcare Corporation) assumed exclusive marketing and distribution rights for WinRho<sup>®</sup> SDF in the U.S. in March 2005, when a previous marketing arrangement with Nabi Biopharmaceuticals expired. This transition in U.S. distributors temporarily disrupted sales and this, along with the effect of translating the weaker U.S. dollar, caused lower U.S. WinRho<sup>®</sup> SDF sales during 2005. With the transition complete, the launch of a convenient new liquid version of the product in the U.S., as well as the launch of product in certain European countries, WinRho<sup>®</sup> SDF sales had recovered by the third quarter of fiscal 2006. U.S. and European sales continued an upward trend in 2007, and while U.S. sales decreased somewhat during 2008, European and Canadian sales have increased.

The Company has marketing and distribution arrangements with other companies in various other jurisdictions.

#### Recent

**Developments** WinRho<sup>®</sup> SDF has recently been launched in several European countries for the ITP indication. And further submissions are in progress under the Mutual Recognition Procedure for an additional 16 countries in the European Union.

Canadian Blood Services and Héma Québec recently renewed their agreement to purchase WinRho<sup>®</sup> SDF (among other hyperimmunes) for a further five years.

#### Competition

There are a number of competitors for the anti-D immune globulin market. The competition differs in various jurisdictions and for different indications, depending on the nature and stage of regulatory approval. As well, WinRho<sup>®</sup> SDF competes in the ITP market with non-anti-D therapies such as intravenous immune globulin ("IVIG"), immunosuppressants and chemotherapies.

Cangene is the only anti-D product available for prevention of HDN in the Canadian market. For the ITP indication, competition is largely from non-anti-D therapies, such as IVIG, steroids and splenectomy.

In the U.S., WinRho<sup>®</sup> SDF is not actively marketed for the HDN indication due to low prices and competition from major pharmaceutical companies including Ortho-Clinical Diagnostics (a Johnson & Johnson company), CSL Behring (a subsidiary of CSL Limited), and Talecris Biotherapeutics, Inc. WinRho<sup>®</sup> SDF sales in the U.S. are almost exclusively for the ITP indication. WinRho<sup>®</sup> 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. During 2007, CSL Behring's product, Rhophylac<sup>®</sup>, received FDA approval for treatment of ITP in chronic adult patients. While its indication is limited compared to WinRho<sup>®</sup>'s ITP indication, its approval does add a competitor in the U.S. market. In August 2008, the FDA approved Nplate<sup>™</sup> (romiplostim), which is manufactured by

Amgen Inc. Nplate™ is only licensed for patients with chronic ITP who have had an insufficient response to other therapies (including WinRho® SDF).

Elsewhere in the world, competing products are manufactured by a number of other companies. 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.

### INFECTIOUS-DISEASE AND BIODEFENCE TARGETED HYPERIMMUNES

#### HepaGam B® [Hepatitis B Immune Globulin (Human) Injection]

**Status** Approved in the U.S. by the FDA for post-exposure prophylaxis of hepatitis B and for prevention of hepatitis B recurrence following liver transplantation in patients who are positive for hepatitis B surface antigen (see below). HepaGam B® is the first hepatitis B immune globulin to be licensed in the United States for the liver transplant-related indication and it was granted orphan drug exclusive approval by the FDA for this indication. HepaGam B® was approved by Health Canada with conditions in January 2007 for the liver-transplant-related indication.

#### **Description/ Background**

Cangene's HepaGam B®, Hepatitis B Immune Globulin (Human) Injection, is a purified polyclonal human immune globulin (antibody), specific for the hepatitis B surface antigen. It is formulated for intravenous and intramuscular administration; the route of administration is determined by the indication being treated. HepaGam B® is indicated in the United States for:

- a) prevention of hepatitis B recurrence following liver transplantation in liver-transplant patients who are positive for hepatitis B surface antigen ("HBsAg");
- b) treatment of acute exposure to blood containing HBsAg, including perinatal exposure of infants born to HBsAg-positive mothers, sexual exposure to HBsAg-positive persons and household exposure to persons with active hepatitis B virus infection. These indications are commonly referred to as post-exposure prophylaxis of hepatitis B.

HepaGam B® is indicated in Canada for prevention of hepatitis B recurrence following liver transplantation in adult patients with hepatitis B who have no or low levels of hepatitis B virus replication (under a marketing authorization with conditions: a Notice of Compliance with conditions or NOC/c). It is the first hepatitis immune globulin to be licensed for this indication in Canada. Products approved under Health Canada's NOC/c policy are intended for treating, preventing or diagnosing serious, life-threatening or severely debilitating illness and have demonstrated promising benefit, are of high quality and possess an acceptable safety profile. In addition, they either respond to a serious unmet medical need in Canada or have demonstrated a significant improvement in the benefit/risk profile over existing therapies. Product approval is granted in these cases while the Company completes confirmatory trials.

#### **Market/ Sales**

Hepatitis B is a major disease worldwide and a significant public health problem. Approximately 350 million people worldwide have chronic hepatitis B infection. 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. It can also 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 lead to end-stage liver disease, a condition that necessitates liver transplantation. In the developing world, most people become infected during childhood and hepatitis B infection in young children is most likely to become chronic, leading to severe liver disease. In the U.S., it is estimated that

46,000 new cases of hepatitis B are reported annually (2006) and there are an estimated 800,000–1.4 million chronic cases. While an effective vaccine is now available and has decreased 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.

HepaGam B<sup>®</sup> is marketed and distributed in the U.S. by Apotex Corp., a member of the Apotex Group. It is estimated that the market for the liver-transplant-related indication in the U.S. is approximately US\$40–45 million annually. The liver transplantation indication constitutes the vast majority of the U.S. market, and Cangene's product is the first hepatitis immune globulin to be approved for this indication in the U.S. and its orphan drug exclusive approval provides market exclusivity for seven years. Sales and marketing strategies going forward are aimed at expanding HepaGam B's share of the in-patient and homecare market segments.

HepaGam B<sup>®</sup> has been launched in Canada and is available through Canadian Blood Services and Héma-Québec.

#### Recent

**Developments** During 2008, the FDA granted HepaGam B<sup>®</sup> orphan drug exclusive approval for the liver-transplantation-related indication. This approval gives HepaGam B<sup>®</sup> seven years of market exclusivity in the United States and could facilitate the recovery of certain regulatory filing fees. The exclusivity further solidifies the drug's position in the U.S. market as the only hepatitis B immune globulin approved for this indication.

Cangene has filed a centralized regulatory submission in Europe for both indications. This one, centralized submission is applicable to 30 European Economic Area countries (all 27 European Union members and three European Free Trade Association members – Iceland, Liechtenstein and Norway).

Canadian Blood Services and Héma Québec recently renewed their agreement to purchase WinRho<sup>®</sup> SDF and VariZIG<sup>™</sup> from Cangene for a further five years and the new agreement also includes HepaGam B<sup>®</sup>.

**Competition** Two competitive products are marketed in North America, Nabi-HB<sup>®</sup>, manufactured by Biotest Pharmaceuticals Corporation and HyperHEP B<sup>™</sup> S/D manufactured by Talecris Biotherapeutics, Inc. (recently purchased by CSL Behring). Nabi-HB<sup>®</sup> and HyperHEP B<sup>™</sup> S/D are both licensed to treat acute exposure to blood containing HBsAg and labelled for intramuscular administration. However, Cangene's is currently the only intravenous hepatitis B immune globulin licensed for the much larger liver transplantation indication in Canada and the United States.

#### *Vaccinia Immune Globulin Intravenous (Human) [VIGIV] ("VIG")*

**Status** Approved in the U.S. by the FDA and in Canada by Health Canada for counteracting certain complications that can be associated with smallpox vaccine.

#### **Description/ Background**

Vaccinia Immune Globulin Intravenous (Human) is a purified polyclonal human immune globulin (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 develop 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. There can be no guarantee, however, that development of a new treatment or vaccine would not obviate the need for VIG in the future.

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 complications that may be associated with smallpox vaccine. This five-year contract allowed for the U.S. government to order up to 100,000 doses of VIG on an as-needed basis. Cangene completed supply of the initial order under this contract during fiscal 2004 (see also page 26). As part of the contract, Cangene had agreed 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 drugs 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-related product.

#### Market/ Sales

Cangene developed and manufactured this product under contract with the U.S. government and has completed supply of 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. The order was completed with sales of \$11.2 million in the third quarter of fiscal 2004. While additional VIG product could be ordered under a five-year extension to the contract (contract extension began August 2007), additional product revenues for VIG may also 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 was to continue through the regulatory process in Canada; VIG was licensed by Health Canada in May 2007.

In September 2005, the U.K. Department of Health awarded Cangene a contract to supply VIG worth approximately \$16 million. Cangene completed delivery during fiscal 2006.

Since this product has received licensure, Cangene records sales of this product as biopharmaceutical revenue, rather than under the contract-services segment.

#### Recent Developments

In August 2007 year end, the U.S. Centers for Disease Control and Prevention extended its VIG contract with Cangene for an additional five years. The U.S. Department of Defense ("DoD") has indicated that it intends to contract with Cangene as the sole-source supplier for a one-year base period for ordering product and for optional periods for ordering product for additional years.

#### Competition

Omrix Biopharmaceuticals, Inc. has sold a VIG product to three governments. This includes a contract worth approximately US\$20 million that was awarded by the United Kingdom in December 2005.

SIGA Technologies, Inc. is developing an oral therapy that could potentially be used as a treatment for smallpox. SIGA has recently announced that they have completed a multiple dose ascending human clinical safety trial.

Botulism Antitoxin Heptavalent [Botulinum Toxin Immune Globulin] ("BAT")

Status	In development under a five-year contract with the U.S. Department of Health and Human Services ("HHS"); the contract is managed by BARDA within HHS. The product has met requirements that allowed Cangene to ship it and initial supplies were accepted into the U.S. Strategic National Stockpile ("SNS") in September 2007.
Description/ Background	Botulism Antitoxin Heptavalent ("BAT") is a purified mixture of polyclonal equine immune globulins (antibodies) with specificity for the seven toxins that can cause botulism. Botulinum toxin is a nerve toxin produced by the bacterium <i>Clostridium botulinum</i> that causes a serious paralytic illness known as botulism. Naturally occurring cases are mainly seen in infants or adults who have consumed improperly processed foods. Botulism can also be used as a bioterrorist weapon and has been identified in the U.S. as one of the highest priority bioterrorism threats. Cangene has developed this product under a five-year, US\$362-million development and supply contract from HHS (managed by BARDA) in the United States. Funding for the contract is being provided under the US\$5.6-billion <i>BioShield</i> legislation. The base contract includes a potential supplementary payment that the Company will receive if FDA licensure is obtained during the term of the contract. Optional task orders, such as ongoing testing to support long-term product shelf life, maintaining a warm-base of manufacturing or additional clinical testing in special populations, could add up to US\$234 million to the base contract amount.
Market/Sales	<p>Cangene began delivering product to the SNS in September 2007, triggering payment of \$17.3 million for initial product delivery and reimbursable development costs incurred to date. Cangene subsequently made larger product deliveries during the fourth quarter of fiscal 2008, and recorded corresponding revenues of more than \$20 million; total revenues on this contract recorded in fiscal 2008 were \$49.8 million.</p> <p>The contract also requires that the Company apply for and receive licensure from the FDA. For this, Cangene has received Fast-Track designation. Revenue received under this contract will be recorded in the Company's contract-services segment until such time as the product receives regulatory approval; if or when approved, further revenue would be recorded in the biopharmaceutical operations segment.</p>
Recent Developments	<p>As mentioned above, the Company has delivered on contractual requirements during fiscal 2008, triggering related revenues of \$49.8 million during the year. In addition, the Company has completed several of the non-clinical and clinical studies required to support licensure.</p> <p>Cangene's new fractionation facility is being used to manufacture the BAT product.</p> <p>During fiscal 2008, Cangene's heptavalent Botulism Antitoxin was used under in emergency investigational use situation to treat a newborn infant who had been hospitalized due to a case of botulism as a result of intestinal colonization by the organism that produces botulinum toxin. The infant was paralyzed and required a ventilator to breathe and had been diagnosed as having the rare Type F botulism; Cangene's heptavalent product was chosen because it has antibodies to seven botulism toxin types, including Type F. The baby subsequently recovered and was discharged from hospital.</p>

Competition Cangene is the sole-source contractor under the above agreement.

Emergent BioSolutions Inc. reports it is developing a vaccine and a botulism antitoxin aimed at two of the toxin subtypes.

Other companies may be in the early stages of developing therapies aimed at botulism; however, direct competition is limited.

Anthrax Immune Globulin ["AIG"]

Status In development under a contract with HHS; the contract is managed by BARDA within HHS. The product has met requirements and that allowed Cangene to ship it and it has been accepted into the SNS.

Description/  
Background

Anthrax Immune Globulin is a purified polyclonal human immune globulin (antibody) specific for treating inhalational anthrax. Cangene was originally contracted to develop this product by the Office of Public Health Emergency Preparedness, in the Office of the Secretary of the United States Department of Health and Human Services in September 2005. Based on successful preliminary efficacy testing, HHS (this contract is managed by BARDA) has exercised its option to purchase 10,000 doses of AIG, valued at approximately US\$143 million. The base contract includes a potential supplementary payment that the Company will receive if FDA licensure is obtained during the term of the contract. Inhalational anthrax is an acute and potentially lethal infectious disease caused by inhaling the spores produced by *Bacillus anthracis* bacteria. Anthrax has been identified in the U.S. as a Category A bioterrorism threat.

Market/  
Sales

Cangene began delivering product to the SNS in August 2007, triggering payment of \$9.7 million for initial product delivery and reimbursable development costs incurred to date. Further activity and deliveries under the contract delivered total related revenues of \$26.1 million during of fiscal 2008. Delivery on the contract is expected to be complete during 2011. Cangene has also committed to taking the product through the FDA approval process. For this, Cangene has received fast-track designation. It has also received orphan drug designation from the FDA. Revenue received under this contract will be recorded in the Company's contract-services segment until such time as the product receives regulatory approval; if or when approved, further revenue would be recorded in the biopharmaceutical operations segment.

Recent

Developments As mentioned above, Cangene made the first delivery of product to the SNS in August 2007 (first quarter, fiscal 2008), triggering the beginning of revenue from this contract. Subsequent smaller deliveries were also made during fiscal 2008. Cangene recorded \$26.1million in total revenues related to this contract in fiscal 2008.

Competition

Emergent BioSolutions Inc. has received grants from the U.S. National Institute of Allergy and Infectious Diseases ("NIAID") and development contracts from NIAID and BARDA to develop an anthrax immune globulin therapeutic product candidate.

Human Genome Sciences ("HGS") was awarded a US\$165-million contract in 2006 by HHS for the development and delivery of 20,000 treatment courses of ABthrax™, HGS' monoclonal antibody product specific for the *Bacillus anthracis* protective antigen. HGS is targeting delivery in 2008.

VariZIG™ [Varicella Zoster Immune Globulin (Human)]

**Status** Cangene's VariZIG™ received Canadian approval in January 2001 for preventing or reducing severity of maternal infections within 4 days of exposure to the Varicella zoster virus, but the product was not actively marketed. During fiscal 2006, Cangene submitted a series of notifiable changes ("NC") to Health Canada to update the VariZIG™ regulatory file. The NCs were approved by Health Canada and Cangene subsequently launched VariZIG™ in Canada during March 2006.

In addition to the Company's objective of gaining U.S. licensure for VariZIG™, Cangene initiated an expanded-access investigational new drug protocol ("EAP") in the U.S. to respond to an expected product shortage and unmet medical need due to a decision by a former competitor, Massachusetts Biological Laboratories, to discontinue production of its Varicella zoster immune globulin. The FDA approved the expanded-access protocol in January 2006 and the program was initiated in March 2006. The product subsequently received orphan drug designation from the FDA; after a drug is approved, the orphan drug designation gives it seven years of market exclusivity and allows for recovery of certain regulatory fees.

**Description/  
Background**

VariZIG™ [Varicella Zoster Immune Globulin (Human)] is a purified polyclonal human immune globulin (antibody) specific for Varicella zoster virus, the agent that causes chickenpox and that can cause shingles. VariZIG™ can be administered intramuscularly and intravenously. The following types of patients, if exposed to Varicella, are at-risk for serious infection: immune compromised pediatric or adult patients, neonates (infants less than one year old), pre-term infants, pregnant women and newborns whose mothers had Varicella zoster infection within five days before delivery or two days after delivery.

**Market/  
Sales**

As most North American adults have developed immunity to chickenpox, this product services a niche infectious disease market, evaluated at approximately \$2.0 million annually in North America. While a vaccine against chickenpox exists, certain at-risk patients would require treatment with a Varicella zoster immune globulin in the event of exposure, consequently, there is an ongoing medical need.

FFF Enterprises Inc. distributes VariZIG™ in the United States, on a cost-recovery basis, under an expanded-access protocol that was approved in 2006.

Cangene is the sole supplier of this product in Canada. Canadian Blood Services and Héma-Québec distribute VariZIG™ in Canada.

**Recent**

**Developments** Canadian Blood Services and Héma Québec recently renewed their agreement to purchase VariZIG™ (among other hyperimmunes) for a further five years.

**Competition** No currently manufactured competitive product is licensed for the North American market.

**Ebola/Marburg**

The hemorrhagic fever viruses, Ebola and Marburg, are also targets for hyperimmune technology and other antibody-based therapies (see also Monoclonal Antibodies, page 20).

### Hyperimmune Manufacturing and Supply of Raw Materials

Cangene manufactures its hyperimmune products at its facilities at 155 Innovation Drive in Winnipeg. The facility received an establishment licence from Health Canada in 1984, and was licensed by the FDA to produce WinRho<sup>®</sup> 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. The Company has built and equipped a new plasma fractionation facility that significantly increases its capacity to fractionate plasma for new products and is using the new facility for manufacturing the BAT product.

Manufacturing WinRho<sup>®</sup> SDF and other hyperimmunes depends on the availability of commercial quantities of specialty plasma (primarily human plasma) and an acceptable level of specific antibodies in that 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 increased 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 a significant portion of its plasma through supply contracts with commercial plasma collectors. Cangene believes it currently has sufficient relationships with third-party plasma collection centres to provide an adequate supply of plasma for the foreseeable future. However, competition for plasma, in terms of quality, volume and price, is increasing and there can be no assurances that shortages will not develop. 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.

Due to the importance of maintaining plasma supply, management is focused on expanding Cangene's in-house plasma collection capabilities through expansion of the four existing plasma centres. These expansions are currently underway and will result in more than doubling the current capacity; the expanded centres are expected to be operating by the second half of fiscal 2009. Current activities include design and construction, and finalizing leasing arrangements.

### **Other Antibody-based Therapies**

#### Monoclonal Antibodies

Monoclonal antibodies are made in the laboratory from a single source or clone of cells and recognize only one kind of antigen. Naturally occurring antibodies, those isolated from plasma to produce hyperimmunes, are known as polyclonal. In the 1970s, researchers began developing technologies for making monoclonal antibodies. It seemed at first that 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 government 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 has developed both polyclonal and monoclonal antibodies under this project.

All projects within Cangene's monoclonal antibody program are in the early research phase. Extensive laboratory, preclinical and clinical testing would be required to bring these to commercialization, requiring many years of development time and substantial development expense. During fiscal 2008, Cangene established a new Molecular Immunology Group to focus on development of monoclonal antibodies as infectious disease therapeutics. This group will initially choose biodefence and public-health-related targets, especially those for which funding opportunities exist.

## Recombinant Biopharmaceuticals

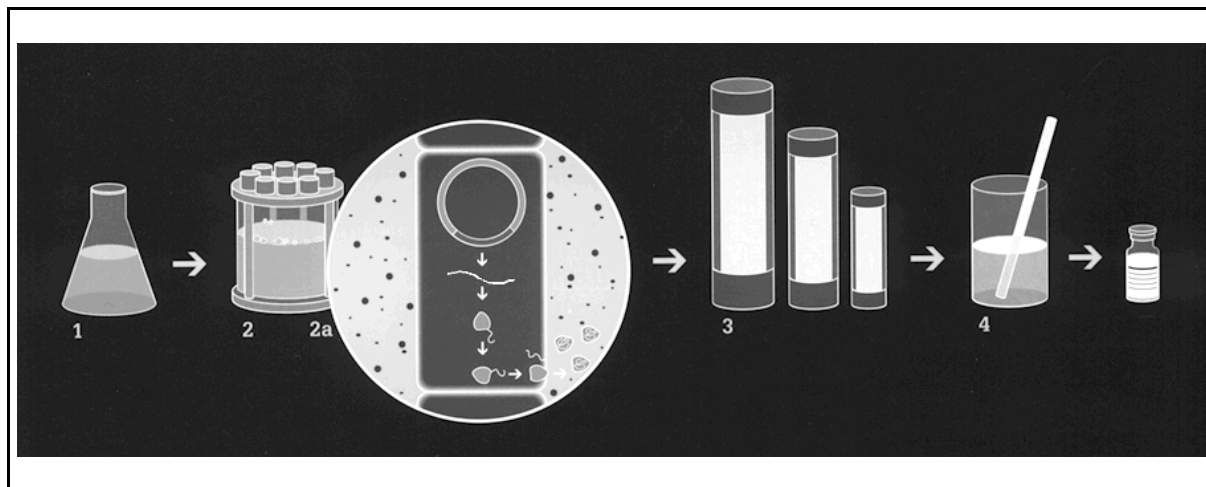
### Background

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.

### Production Technologies—Cangenus™

Cangene has developed and patented a novel gene expression system based on the soil bacterium, *Streptomyces*. The resulting technology, Cangenus™, allows economically feasible production of commercial amounts of many therapeutic proteins. Cangenus™ offers benefits that may not be shared by other bacterial, yeast or animal cell expression technologies. In particular, for certain proteins, Cangenus™ produces the precise biological shape required for activity. It also exports the product into the surrounding fermentation media, eliminating the need to break open the cells for harvest. Finally, it readily yields a product of high purity. Like other expression systems, Cangenus™ suffers from certain limitations, and some commercially valuable proteins cannot be produced using it. Nevertheless, Cangene has cost-effectively produced certain proteins using Cangenus™, including Leucotropin®, which is Cangene's version of the protein granulocyte-macrophage colony-stimulating factor.

### Schematic diagram of protein expression using Cangenus™



culture growth

desired protein is expressed by host cell

protein purification

formulation & packaging

### Production Technologies—Other Expression Systems

Cangene also has an *E. coli*-based bacterial expression system that provides an easily manipulated, cost-effective system with which to produce certain products. Cangene's human growth hormone, Accretropin™, 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; not to be confused with SARS, the acronym for severe acute respiratory syndrome) 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 mammalian cells. In 1999, Cangene received two U.S. patents with respect to this technology and a Canadian patent was issued in 2003.

### Products

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 aimed at 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 generally may not occur until regulatory approval is obtained (see GOVERNMENT REGULATION, page 30). Cangene is developing certain recombinant biopharmaceutical products, including Accretropin™ and Leucotropin®, under an R&D agreement with Apotex.

#### Accretropin™ [somatotropin (rDNA origin)] Injection

**Status** Approved by the U.S. FDA during 2008 for treatment of pediatric patients who have growth failure due to an inadequate secretion of normal endogenous growth hormone, or for treatment of short stature associated with Turner Syndrome in certain pediatric patients.

**Description/Background** The most advanced product made in Cangene's *E. coli* expression system is human growth hormone, a protein normally produced by the human pituitary gland. 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 therapeutically to combat short stature in children with hGH deficiency and girls with 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 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 provided data used to assess the drug's ability to combat short stature in children with growth hormone deficiency and in girls with Turner Syndrome.

Market/  
Sales

Accretropin™ is one of the products developed under an agreement with the Apotex Group and Apotex retains its marketing rights. The market conditions for this type of product are constantly changing, and Apotex and Cangene are assessing the current situation and related patent issues to determine the most effective overall strategy going forward. The product has not been launched.

Cangene has entered an exclusive marketing and distribution agreement with BioGeneriX AG of Mannheim, Germany, a subsidiary of Ratiopharm, for Accretropin™ in the European market.

Current marketers of the drug claim a world market of approximately \$2.5 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. However, it is a complex marketplace.

Recent

Developments The FDA approved Accretropin™ during fiscal 2008.

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 challenges over the patent rights; nonetheless, many different pharmaceutical manufacturers continue commercializing human growth hormone. The leading products include those 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.

Leucotropin® (recombinant human Granulocyte-Macrophage Colony-Stimulating Factor; "rhGM-CSF")

Status

New Drug Submission filed with Health Canada in 2003 and subject of a development proposal submitted to the U.S. government (submitted to the BARDA office within HHS) in response to a request for proposal ("RFP") during fiscal 2008.

Description/  
Background

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. These white blood cells are an important component of the immune system.

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 GM-CSF is called Leucotropin®.

Cangene believes that the use of Leucotropin® will stimulate granulocyte and macrophage development in patients whose white cells have been depleted, such as those undergoing certain anti-cancer treatments or those exposed to radiation (acute radiation syndrome). In either case, the Company expects that the use of its Leucotropin® could control or reduce the risk of contracting an infection that a loss of white blood cells might otherwise elevate.

In August 1999, Cangene began a 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 Company filed a Canadian New Drug Submission for Leucotropin<sup>®</sup> in October 2003 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 received funding from CRTI to develop a modified version of Leucotropin<sup>®</sup> as a treatment for white-blood-cell damage resulting from acute 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 investigating a second-generation, longer-acting version of Leucotropin<sup>®</sup> that has been modified by coupling it with polyethylene glycol ("PEG"). Longer-lasting action and enhanced stability could increase the drug's utility in military or emergency settings.

Market/  
Sales

Cangene developed this product under an agreement with Apotex. Under the agreement, Apotex will be entitled to receive a 12% royalty on net commercial sales, after which Cangene and Apotex will share profits equally.

For certain uses, Cangene expects to compete with other GM-CSFs as well as the related Granulocyte Colony-Stimulating Factor ("G-CSF"). G-CSF was the first colony-stimulating factor licensed and dominates this market. In 2006, the combined global market for G-CSF and GM-CSF was nearly US\$4.4 billion with G-CSF accounting for approximately 98% of this.

Recent  
Developments

Cangene has begun to investigate the potential for using the original form of Leucotropin<sup>®</sup> to treat acute radiation syndrome and during 2008 submitted a response to a request for proposal ("RFP") issued by the U.S. government (BARDA). A decision on the RFP responses is expected during Cangene's fiscal 2009. If Cangene is successful in the bid process, this could result in a significant contract.

Competition

For commercial uses, Leucotropin's market is dominated by the functionally similar product, G-CSF. The prominent G-CSFs, Neupogen<sup>®</sup> (Granulokine<sup>®</sup> in certain markets) and Neulasta<sup>®</sup> (a chemically modified, second-generation product), are owned by Amgen Inc. and generated sales in 2007 of US\$1.3 billion and US\$3.0 billion, respectively. Amgen's G-CSF products are two of the top selling biopharmaceuticals in the world and command more than 90% of the world G-CSF market.

Two versions of GM-CSF, owned by large multinational companies, have been approved for marketing—Leukine<sup>®</sup>, marketed by Bayer HealthCare Pharmaceuticals Inc., and Leucomax<sup>®</sup>, 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.

Patents with claims to GM-CSF exist in the U.S. and could prevent Cangene from selling GM-CSF in that market.

The exact status of potential competitors in the biodefence application is not yet known.

### 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. One area of particular interest is the development of peptide drugs with applications in infectious disease. A relatively new technology area for Cangene, peptides are small chains of the amino acids that make up proteins. Peptides can be designed that interact specifically with an active protein or cellular component so they block an unwanted action or promote a desirable one. Thus, they may be used therapeutically. Cangene has seen some exciting early results in a number of these collaborative research projects.

These innovative 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.

One such project is a technology that Cangene calls PEP 35. This project results from a collaborative effort conducted at Channing Laboratories, a research division of Brigham and Women's Hospital (a teaching affiliate of Harvard Medical School). The research is assessing the ability of certain peptides identified at Cangene to inhibit surgical wound infections by *Staphylococcus aureus* bacteria. These bacteria have become a serious problem in healthcare settings where increasing resistance to the antibiotic methicillin has made these infections intractable. The peptides appear to function by enhancing the patient's own immune system so that it can clear the infection. Treatment with the peptides was highly effective in reducing both the number of *S. aureus* cells found at the wound site and the associated inflammation. These data suggest a novel approach for treating and possibly preventing staphylococcal wound infections in the clinical setting. Methicillin resistance in *S. aureus* infections in healthcare settings has increased from 2% in 1974 to 63% in 2004, making the development of treatments with new mechanisms of action critical. Based on positive results from a research program, Cangene is working toward filing an investigational new drug application.

### **Contract-services Segment**

#### Background

Cangene began marketing its manufacturing capability early in fiscal 1998. Cangene offers one of the few FDA-licensed manufacturing facilities in Canada and the Company boasts several successful contracts using varied technologies. In recent years, Cangene's expertise in developing and manufacturing hyperimmune products and its focus on biodefence-related products has attracted large contracts from the U.S. government. Cangene's contract-services segment generated 63% of the Company's revenue in fiscal 2008.

Cangene receives revenue and records expenses for certain R&D projects with third parties or with Apotex; one such project was concluded during the first quarter of fiscal 2008. Depending on the project, Cangene may hold the product licence or the licence may remain the property of the contracting party. For those contracts where the product licence remains Cangene property (such as the government contracts), the Company records revenue from that product as contract-services revenue until such time as the product is licensed, and then revenue would be switched to biopharmaceutical revenue.

#### Chesapeake Biological Laboratories, Inc.

In 2001, Cangene acquired Chesapeake Biological Laboratories, Inc. ("Chesapeake") for a consideration of \$52.8 million. Chesapeake is an established commercial, 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 has served a range of customers, from major international pharmaceutical firms to emerging biotechnology companies. 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: development of sterile product formulations, test-method development and validation, process design and manufacturing validations, preparation of clinical trial and toxicology materials, aseptic filling, 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 attempted to find other contracts or customers that needed this specialized manufacturing capability; however, certain utilities and components have now been decommissioned. 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 five-year contract by the CDC to develop and supply VIG for use in treating and preventing complications that may be associated with administration of the smallpox vaccine (see also page 15). Cangene has completed supply of an initial order under this contract. In August 2007, this contract was extended for a further five years.

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. In March 2005, the Canadian government purchased \$3.2 million worth of VIG from Cangene. And, in September 2005, Cangene was awarded an approximately \$16.0-million contract by the U.K. government to supply VIG. This was followed by a U.S. Department of Defense announcement that it also intended to purchase VIG from Cangene. As VIG has now been approved for sale in the U.S. (May 2005), future revenue from VIG sales would be recorded as biopharmaceutical revenue; however, there can be no guarantees that future contracts will be awarded, whether they would be significant in scope or whether further product sales would be recorded even if such contracts are awarded.

During 2002, Cangene was also awarded a contract by the CDC to develop a clinical-grade anthrax immune globulin ("AIG"). Under this initial program, the hyperimmune was used for preclinical studies, and human compassionate use and safety testing. In September 2005, HHS awarded a contract to Cangene for the supply of AIG to be used in preliminary comparative testing. Following the successful completion of this early phase, HHS exercised its option to extend the contract and purchase 10,000 doses of AIG. This contract is valued at approximately US\$143 million. Cangene met requirements for this product that allowed it to deliver an initial quantity to the U.S. Strategic National Stockpile in August 2007. This delivery and its acceptance into the SNS triggered the initial payment on the contract. Cangene recorded \$26.1 million in revenue related to this contract in fiscal 2008. The Company anticipates completing delivery on the contract in 2011 (see discussion under Anthrax Immune Globulin on page 18).

During 2003, the CDC awarded Cangene a contract similar to the initial AIG one to develop an antitoxin for botulism. In October 2004, the CDC announced that it intended to negotiate a sole-source agreement with Cangene to provide up to 200,000 doses of botulism antitoxin. Cangene was identified as the only prospective contractor with the necessary experience, capability and capacity to fulfil these requirements. This delivery and supply contract was awarded by HHS to Cangene in May 2006. The value of the base contract is estimated at US\$362 million; with the possibility of additional task orders worth up to US\$234 million (see discussion under Botulism Antitoxin on page 17).

Cangene met requirements for this contract that allowed it to deliver an initial quantity of product to the U.S. Strategic National Stockpile in September 2007. Also similar to the AIG contract, this delivery triggered initial payment on the contract. Cangene recorded \$49.8 million in revenue related to this contract in fiscal 2008. 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-services business with several pharmaceutical-product-development organizations, contract manufacturers of biopharmaceutical products and university research laboratories. Although many of these competitors do not offer the same range of services offered by the Company, they can and do compete effectively against certain areas of the Company's business, including its biopharmaceutical 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 is growing. Cangene has been chosen as the supplier for three products in the U.S. Strategic National Stockpile; the Company believes this helps validate its capabilities.

Cangene's contract-services 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, or to replace outdated supplies. Accordingly, demand for these products should be expected to fluctuate significantly.

### **Segment Revenues**

The Corporation manages its business and evaluates performance based on two operating segments: biopharmaceutical operations, and contract services. 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-services provides products and services to third-party clients. There are no significant inter-segment transactions. The following presents segment revenues for the years ended July 31, 2008 and July 31, 2007:

<i>in thousands of Canadian dollars</i>	2008			2007		
	Biopharm- aceutical operations	Contract Services	Total	Biopharm- aceutical operations	Contract Services	Total
<b>Revenues</b>						
Product sales and services	\$ 42,084	\$ 44,302	\$ 86,386	\$ 41,749	\$ 17,095	\$ 58,844
R&D services	11,632	60,147	71,779	11,594	13,687	25,281
Royalties	7,891	—	7,891	8,271	—	8,271
	<b>61,607</b>	<b>104,449</b>	<b>166,056</b>	61,614	30,782	92,396

## Major Customers and Geographic Segments

For the fiscal year ended July 31, 2008, sales to two customers represent 76% [2007 – two customers, 77%] of the revenue of the biopharmaceutical operating segment. And sales to two customers represent 79% [2007 – one customer, 21%] of the revenue from the contract-services segment.

Geographic information about the Corporation's revenue is based on the product shipment destination or the location of the contracting organization:

<i>in thousands of Canadian dollars</i>	<b>2008</b>	2007
	<b>Revenues</b>	Revenues
Canada	<b>\$ 30,916</b>	\$ 33,379
United States	<b>124,018</b>	47,470
Eurasia	<b>11,122</b>	11,547
	<b>\$ 166,056</b>	\$ 92,396

## PATENTS AND TRADE SECRETS

Cangene actively seeks to protect the intellectual property arising from its research and development. In general and where possible, 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. Competitors or potential competitors may claim that their existing or pending patents prevent Cangene from commercializing its products or product candidates.

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, the United States and Europe (designating major European countries). These patents specifically claim a number of biopharmaceuticals, including GM-CSF (Leucotropin®), 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 owns and has licensed patents and patent applications related to the PEP 35 technology and specifically patents covering several active peptides. Cangene has also recently filed patent applications in the U.S., Europe, Canada and Japan for the use of PEP 35 technology to treat bacterial infections.

Cangene has filed patent applications in the U.S., Europe and the Philippines for the use of any anti-D hyperimmune, such as WinRho® SDF, to treat dengue hemorrhagic fever.

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, Health Canada and European Medicines Agency-licensed manufacturing facilities comprise approximately 160,000 square feet and is located at 155 Innovation Drive in Winnipeg, Manitoba, Canada. This facility received an establishment licence from the FDA to produce WinRho<sup>®</sup> SDF for distribution in the United States in March 1995. The Company has completed construction of 42,500 square feet of additional fractionation capacity adjacent to the original building. The new facility significantly increases the plasma fractionation capacity for new products; the building incorporates four separate purification suites and other design features that allow maximum process flexibility. The new facility is now being used to manufacture the BAT product.

The Company also operates a 65,000-square-foot facility in Winnipeg, located at 26 Henlow Bay. This location includes research and development laboratories and 30,000 square feet of manufacturing space, which houses the fermentation and down-stream processing stages of manufacturing for its biopharmaceutical products, and provides capacity for the contract research and manufacturing commitments.

Cangene currently leases office space at 180 Attwell Drive, Suite 360, Toronto, Ontario, Canada, where it undertakes certain commercial and regulatory activities.

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. This cGMP facility provides contract-manufacturing services to the biopharmaceutical industry. The Company's adjacent live-viral-vaccine-filling facility has been decommissioned and is currently inactive.

The Company owns two subsidiaries involved in 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. Recently, the Company has undertaken expansion of all its U.S. plasma centre locations. The expansions will potentially double the Company's plasma-collection capacity. The Company also operates the Rh Plasma Center in Winnipeg, MB, Canada.

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, 2008, Cangene and its subsidiaries employed 699 persons in full-time positions. All of Cangene's operations are non-unionized; the Company believes its use of employee-relations best practices fosters a positive work environment.

Of Cangene's 699 full-time employees, approximately 40% work in the contract-services segment and 40% in the biopharmaceutical segment. Approximately 20% fill administrative and support roles that are shared between the segments. These percentages are approximations only as the level of staffing varies throughout the year depending on the activity in various projects.

The nature of Cangene's business demands a highly educated and skilled workforce. Typically a high proportion of its employees have a Bachelor's degree or higher. Personnel working in certain units receive significant on-the-job training. Generally, the Company has found no difficulty in recruiting qualified individuals, although it uses the services of professional recruiting firms specialized in R&D and pharmaceutical areas when necessary. As well, the Company places a high priority on retaining skilled employees. The Company provides leadership training and promotes from within wherever possible.

## FOREIGN OPERATIONS

Cangene's wholly owned subsidiary, Chesapeake Biological Laboratories, Inc., operates in Baltimore, Maryland, and comprises a significant portion of Cangene's contract-services business. And, as previously mentioned, Cangene operates active plasma centres in the U.S. Cangene also maintains an office in the U.K., through its U.K. subsidiary, Cangene Europe Limited. The Company is not aware of any risks associated with these foreign operations and believes that its U.S. operations establish a presence and add visibility in a key market. However, the majority of Cangene's international sales are transacted in U.S. dollars and the strengthening Canadian dollar in past 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 other countries.

In Canada, these activities are regulated by Health Canada. 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, 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 could 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 a pharmaceutical product 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 Health Canada in which the Company requests 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 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 Health Canada 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 Health Canada 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 involving the filing of a New Drug Application ("NDA") is regulated by the Food and Drug Administration ("FDA"), an agency within the Department of Health and Human Services.

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.

Cangene has designed and implemented quality systems to mitigate the regulatory risks and maintain compliance with regulatory requirements.

## **BUSINESS RISK FACTORS**

The Corporation is subject to certain risks and uncertainties inherent in the operation of its business. These risks are many and varied, and are influenced by factors both internal and external to the operation of the business. For a detailed description of risk factors, see pages 35–37 of the MD&A.

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

Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") for the year ended July 31, 2008 is available on SEDAR at [www.sedar.com](http://www.sedar.com) and on Cangene's website at [www.cangene.com](http://www.cangene.com). The MD&A should be read in conjunction with the Company's audited financial statements for the year ended July 31, 2008, which are included in Cangene's complete 2008 annual report (available on the SEDAR website at [www.sedar.com](http://www.sedar.com), Cangene's website at [www.cangene.com](http://www.cangene.com) or by request from Cangene Corporation).

## **DIVIDEND POLICY AND RESTRICTIONS**

Cangene has no current intention to pay dividends on its Common Shares as earnings are expected to be retained to finance the growth of Cangene's business and to expand its research and product development activities. Any future determination to declare and pay dividends will be at the discretion of the board of directors from time to time and will be dependent on the Corporation's earnings, financial condition, capital requirements and other considerations.

## **DESCRIPTION OF CAPITAL STRUCTURE**

The Corporation's authorized share capital comprises an unlimited number of preferred shares with a 4% non-cumulative dividend entitlement; an unlimited number of Class A preferred shares and an unlimited number of Common Shares. As at the end of the Corporation's most recent financial year, there were 70,090,570 Common Shares issued and outstanding and no preferred shares or Class A preferred shares issued and outstanding.

### ***Common Shares***

Subject to the prior rights, privileges, restrictions and conditions attaching to preferred shares and Class A preferred shares of the Corporation, and any other class or series of shares of the Corporation outstanding from time to time ranking prior to the Common Shares, the holders of Common Shares are entitled: (a) to receive notice of, attend and vote at all meetings of shareholders of the Corporation, except meetings at which only the holders of another specified class or series of shares are entitled to attend and vote; and (b) to receive dividends, if, as, and when declared by the board of directors of the Corporation (no dividends have been declared to date); and (c) upon liquidation, dissolution or winding up of the Corporation, to share rateably in the remaining assets of the Corporation available for distribution after payment of liabilities.

### **Preferred Shares**

The holders of preferred shares do not have any voting rights, nor are they entitled to attend meetings of shareholders of the Corporation except as may be provided by law or as specifically provided in the provisions attaching to the preferred shares. The holders of preferred shares are entitled, in the discretion of the directors of the Corporation, to non-cumulative dividends at a rate of 4% per annum of the amount paid thereon. With respect to the payment of dividends and the distribution of assets in the event of the liquidation, dissolution or winding-up of the Corporation, whether voluntary or involuntary, the preferred shares shall rank in priority to all other shares of the Corporation. The Corporation has the right to redeem the whole or any part of the preferred shares on payment for each share to be redeemed of the amount paid up thereon, together with all dividends declared thereon and unpaid.

### **Class A Preferred Shares**

The holders of Class A preferred shares are not entitled to receive notice of, to attend or to vote at any meeting of the shareholders of the Corporation except as may be provided by law or as specifically provided in the provisions attaching to the Class A preferred shares. The Class A preferred shares may be issued in one or more series with such rights, privileges, restrictions and conditions as the board of directors of the Corporation may designate from time to time. With respect to the payment of dividends and the distribution of assets in the event of the liquidation, dissolution or winding-up of the Corporation, whether voluntary or involuntary, or any other distribution of the assets of the Corporation among its shareholders for the purpose of winding-up its affairs, the Class A preferred shares of each series shall rank on a parity with the Class A preferred shares of every other series, and shall be entitled to priority over the Common Shares of the Corporation and over any other shares of any other class of the Corporation ranking junior to the Class A preferred shares.

### **MARKET FOR SECURITIES**

The Common Shares are listed and posted for trading on the Toronto Stock Exchange under the symbol CNJ. The following table provides trading price and volume statistics regarding activity during the Corporation's 2008 financial year:

<b>Month</b>	<b>High</b>	<b>Low</b>	<b>Volume</b>
August 2007	8.10	7.01	1,224,606
September 2007	8.00	7.10	194,711
October 2007	8.51	7.66	1,342,594
November 2007	8.00	7.27	517,921
December 2007	7.76	6.80	530,219
January 2008	7.40	5.57	871,556
February 2008	6.25	5.75	651,102
March 2008	5.99	5.28	508,654
April 2008	5.95	5.00	1,180,414
May 2008	5.50	4.75	648,241
June 2008	5.59	4.85	1,581,950
July 2008	5.02	4.56	1,078,197

**DIRECTORS AND OFFICERS****Directors**

<b>Name and Place of Residence</b>	<b>Office</b>	<b>Director Since</b>	<b>Principal Occupation</b>
R. Craig Baxter <sup>1</sup> Ontario, Canada	Director	November 1, 1995	President of Apotex Holdings, Inc. (officer). Prior to that, he was President of Apotex International, Inc. and Executive Vice President of Apotex Inc. for more than five years. Mr. Baxter has been employed with Apotex since May 1985. Apotex has its head office in Toronto and is Canada's largest domestically owned pharmaceutical company; it is a member of the Apotex Group.
D. Bruce Burlington <sup>3</sup> Pennsylvania, United States	Director	March 11, 2008	Consultant in pharmaceutical development and regulatory affairs. Recently retired from previous position as Executive Vice President, Business Practices and Compliance at Wyeth Pharmaceuticals, a position he had held since 2005. Prior to that, from 2002 until 2005, he was Executive Vice President, Quality, Regulatory, Safety, Compliance and Audit at Wyeth.
Jeremy Desai <sup>3</sup> Ontario, Canada	Director	December 6, 2006	Executive Vice President R&D, Apotex Inc. since April 2006. Prior to that Dr. Desai had been Senior Vice President R&D since joining Apotex in January 2003. Prior to that he was Vice President R&D at IVAX Pharmaceuticals U.K. since June 2001. Apotex has its head office in Toronto and is Canada's largest domestically owned pharmaceutical company; it is a member of the Apotex Group.
Brenda Drinkwalter <sup>1,3</sup> Ontario, Canada	Director	December 6, 2006	Principal, Brenda Drinkwalter & Associates (officer), a consulting firm that advises clients on business strategy, including communications and stakeholder relations. From 1999 to 2004 Ms. Drinkwalter was Senior Vice President Corporate Affairs, Canada and Latin America Region, and Global Privacy Coordinator at IMS Health Limited, a leading provider of health business intelligence and strategic consulting services.
Philip Johnson <sup>1</sup> Pennsylvania, United States	Director	March 11, 2008	Chief Scientific Officer and Executive Vice President at The Children's Hospital of Philadelphia, and Professor of Pediatrics at the University of Pennsylvania School of Medicine, positions he has held since 2005. From 2002 through the end of 2004, he was President of the Columbus Children's Research Institute at Children's Hospital, Inc. in Columbus, Ohio
Jack Kay Ontario, Canada	Director and Board Chair	November 1, 1995	President and Chief Operating Officer of Apotex Inc. (officer). Prior thereto, he was Executive Vice President of Apotex Inc. Mr. Kay joined Apotex in 1982. Apotex has its head office in Toronto and is Canada's largest domestically owned pharmaceutical company; it is a member of the Apotex Group.

John Langstaff Manitoba, Canada	President, Chief Executive Officer, and Director	November 1, 1995	President and Chief Executive Officer of Cangene since November 1, 1995.
J. Robert Lavery <sup>1,2</sup> Manitoba, Canada	Director	June 1, 2004	President of Shaunnara ULC (officer), an investment management company he has owned since forming the company in 1977. In December 2003, Mr. Lavery retired from his 26-year position as President and CEO of Winpak Ltd., a company he co-founded in 1977. Winpak Ltd. manufactures and distributes high-quality packaging materials and innovative packaging machines.
R. Scott Lillibridge <sup>2</sup> Texas, United States	Director	March 11, 2008	Assistant Dean, School of Rural Public Health at Texas A&M Health Sciences Center, a position he has held since 2007. Prior to that, from 2002 until 2007, he was Director, Center for Biosecurity and Public Health Preparedness at the University of Texas Health Science Center Houston.
Michael Spino <sup>2</sup> Ontario, Canada	Director	November 1, 1995	President (officer), ApoPharma Inc. since January 2004. Prior thereto, he was Senior Vice President – Scientific Affairs of Apotex Inc. for more than five years. Dr. Spino joined Apotex in 1991.  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 Canada's largest domestically owned pharmaceutical company.
John Vivash <sup>2,3</sup> Ontario, Canada	Director	June 8, 2005	President and Chief Executive Officer (officer) of Tesseract Financial Inc. since 1989.  Tesseract is a financial services consultancy founded by Mr. Vivash in 1989.

- 1 Member of Audit Committee  
2 Member of Governance and Nominating Committee  
3 Member of Human Resources and Compensation Committee

For a more detailed discussion of board committees please refer to the Management Information Circular dated October 21, 2008 available on SEDAR at [www.sedar.com](http://www.sedar.com)

The term of office of each director will expire at the close of the next annual meeting of shareholders. Brenda Drinkwater and Michael Spino will not be standing for re-election at the annual and special meeting of shareholders to be held on December 12, 2008.

**Officers**

<b>Name and Place of Residence</b>	<b>Office</b>	<b>Principal Occupation</b>
John Langstaff Manitoba, Canada	President, Chief Executive Officer and Director	President and Chief Executive Officer of Cangene since November 1, 1995.
William Bees Manitoba, Canada	Senior Vice President, Operations	Senior Vice President, Operations at Cangene since November 1, 2005. Prior thereto, he had been Vice President Operations of Cangene since 1995.
Michael Graham Manitoba, Canada	Chief Financial Officer	Chief Financial Officer of Cangene since September 20, 2004. Prior thereto, since January 2000, he had been Vice President and Chief Financial Officer of The Boyd Group Inc. The Boyd Group is an operator of collision-repair centres.
Grant McClarty Manitoba, Canada	Vice President Research & Development	Vice President, R&D of Cangene since January 24, 2007. Prior thereto, Dr. McClarty was Director of Biomedical Research at the National Microbiology Laboratory ("NML"), a division of the Public Health Agency of Canada, for six years. The NML is Canada's leading public health infectious disease laboratory.
John McMillan Manitoba, Canada	Vice President, Commercial Development and Corporate Secretary (until June 30, 2008 when he resigned this position in preparation for retirement)	Mr. McMillan is retiring at the end of the calendar year and resigned his positions as Vice President, Commercial Development and Corporate Secretary, effective June 30, 2008. He had held these positions since September 20, 2004. Prior thereto he had been General Manager since 1998 and Corporate Secretary. Mr. McMillan also served as interim CFO from March 1, 2004 until September 20, 2004.
Andrew Storey Manitoba, Canada	Vice President, Quality Assurance/Clinical & Regulatory Affairs	Vice President, Quality Assurance/Clinical & Regulatory Affairs of Cangene since 1999.

**Shareholdings of Directors and Officers**

At October 24, 2008, the directors and senior officers of Cangene, as a group, beneficially own, directly or indirectly, or exercise control or direction over, 822,044 Common Shares, representing approximately 1.2% of Cangene's outstanding Common Shares.

### **Corporate Cease Trade Orders or Bankruptcies**

Jerry Treppel (a director on Cangene's board until he resigned effective March 1, 2008) 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 has not been a member of Able's board of directors for more than one year. The assets of Able were subsequently acquired by Sun Pharmaceutical Inc. (a wholly owned subsidiary of Sun Pharmaceutical Industries Ltd.).

J. Robert Lavery is a director and chairman of 2980304 Canada Inc. (formerly Jazz Golf Equipment Inc.). In October 2006, the company made a proposal under the *Bankruptcy and Insolvency Act* (Canada), which involved the sale of all the company's assets to a newly formed company that was wholly owned by its main shareholder, ENSIS Growth Fund Inc. The proposal received court approval and was subsequently approved by the creditors of the company.

### **Penalties or Sanctions**

Not applicable

### **Personal bankruptcies**

Not applicable

### **Conflicts of interest**

R. Craig Baxter, Jeremy Desai, Jack Kay and Michael Spino are officers of certain Apotex Group companies. R. Craig Baxter and Jack Kay are also directors of certain Apotex Group companies. The Apotex Group controls 61% of Cangene's outstanding Common Shares. Further discussion of Cangene's Board and its Corporate Governance practices is contained within the Company's Management Information Circular dated October 21, 2008, available from the SEDAR website at [www.sedar.com](http://www.sedar.com).

## **INTERESTS OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS**

Cangene has agreements with companies controlled by the Apotex Group. A discussion of the agreements is contained in the MD&A and in the notes to the financial statements for the most recently completed financial year. As outlined above, several members of Cangene's board of directors are also directors and/or officers of certain Apotex Group companies.

## **TRANSFER AGENT AND SHARE REGISTRAR**

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

## **MATERIAL CONTRACTS**

The Company has not entered into any material contracts other than in the normal course of business.

## **INTERESTS OF EXPERTS**

Ernst & Young LLP is the external auditor of the Corporation which prepared the Auditors' Report to Shareholders included with the consolidated financial statements of the Corporation for the most recently completed financial year. To the knowledge of the Corporation, Ernst & Young LLP is independent within the meaning of the Rules of Professional Conduct of the Institute of Chartered Accountants of Manitoba.

## AUDIT COMMITTEE INFORMATION

### ***Audit Committee Charter***

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

### ***Composition of the Audit Committee***

The Audit Committee of the Company is chaired by J. Robert Lavery and also includes R. Craig Baxter, Brenda Drinkwalter and Philip Johnson. J. Robert Lavery, Brenda Drinkwalter and Philip Johnson are independent directors as defined under *Multilateral Instrument 52-110 – Audit Committees* (“MI 52-110”). R. Craig 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 ULC, an investment management company he has owned since founding the company in 1977. In December 2003, he retired from his 26-year position as President and CEO of Winpak Ltd., a company he co-founded in 1977. Winpak Ltd. manufactures and distributes high-quality packaging materials and innovative packaging machines. Prior to co-founding Winpak, he spent 16 years working with the firm of Ernst & Ernst, now part of KPMG LLP. He continues on the board of directors of Winpak Ltd. and all its subsidiary companies, and is a director of ENSIS Growth Fund Inc., Online Business Systems, and SleeveCo, Inc. Mr. Lavery is on the Advisory Council of Friesen Corporation 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, more than 20 of which have been in the pharmaceutical industry. Mr. Baxter is currently President of Apotex Holdings Inc. He serves on the board of the Humber River Regional Hospital.

**Brenda Drinkwalter** is a senior consultant in the areas of business strategy, communications, and community, government and regulatory relations. She has an MBA from York University and an Honours BSc in Biochemistry from Queen’s University. She is accredited by the ICD/Rotman School of Management Directors Education Program. She is principal of Brenda Drinkwalter & Associates, a past Senior Vice President of Corporate Affairs, Canada and Latin America Region and Global Privacy Coordinator with IMS Health Limited, and Past President of the Canadian Drug Manufacturers Association.

**Philip Johnson** is a physician executive with 12 years of hands-on, senior administrative and operating experience within two large, independent pediatric academic medical centres. In his current role as Chief Scientific Officer and Executive Vice President of The Children’s Hospital of Philadelphia, he is directly responsible for a US\$250 million annual budget that supports over 1600 faculty and staff. He is accountable for federal, state and local regulatory compliance, facilities oversight and development, strategic planning, training and education and information systems. He received his medical degree from the University of North Carolina at Chapel Hill. His extensive medical background, largely in pediatrics and vaccine technology, also includes work at the U.S. National Institutes of Health and the University of Pennsylvania School of Medicine.

### ***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, R. Craig Baxter, who is an officer and director of companies within the Apotex

Group, which owns a 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 greater than 20 years of pharmaceutical industry experience to make him a valuable contributor to the Committee. 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 reviews and pre-approves 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 Corporation by Ernst & Young LLP, the auditors of the Corporation, for audit, audit-related, tax and other fees in the fiscal years ended July 31, 2008 and 2007 were as follows:

Category	2008	2007
Audit fees <sup>1</sup>	\$ 222,000	\$ 240,000
Audit-related fees <sup>2</sup>	80,300	66,000
Tax fees <sup>3</sup>	nil	4,200
All other fees <sup>4</sup>	63,125	113,600
<b>Total</b>	<b>\$ 365,425</b>	<b>\$ 423,800</b>

- 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 professional fees billed by Ernst & Young LLP for performance of quarterly financial-statement reviews during the fiscal year
- 3 "Tax fees" includes the aggregate professional 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 a short-form prospectus and assessment of internal control over financial reporting.

### **ADDITIONAL INFORMATION**

Additional information relating to Cangene may be found on SEDAR at [www.sedar.com](http://www.sedar.com).

Additional information, including the directors' and officers' remuneration and indebtedness, principal holders of Cangene's securities, and securities authorized for issuance under an equity compensation plan, is contained in Cangene's Management Information Circular for its most recent annual meeting of shareholders that involved the election of directors.

Additional financial information is provided in Cangene's consolidated financial statements and MD&A for its most recently completed financial year.

## **APPENDIX A – AUDIT COMMITTEE CHARTER**

The committee of the board of directors (the “Board”) of Cangene Corporation (the “Company” or the “Corporation”) known as the Audit Committee (the “Committee”) is established with a role of assisting the Board in overseeing disclosure of financial statements and related information, reviewing disclosure and accounting internal controls and principles, and interacting with and overseeing the work of the external auditor. The Committee also establishes procedures for confidential, anonymous submission of complaints (“whistleblower procedures”) regarding financial or accounting matters and reviews Canadian audit committee regulations and best practices to ensure alignment of the Corporation’s financial statements with their spirit and intent. In carrying out its responsibilities, the Committee does not provide audit functions or certification of financial and related information.

### **TERMS OF REFERENCE**

The Board recognizes that the business environment may change, and accordingly, the responsibilities and procedures noted here are intended as a guideline only, and the Board or the Committee may make changes from time to time.

#### **Authority**

The Committee has unrestricted access to all the Company’s personnel, its documents and the external auditors as necessary to carry out its responsibilities.

In the event that not all the Committee members are independent, the Chair of the Committee has the authority to convene a separate meeting of the independent directors on the Committee if deemed necessary.

The Committee has the authority to retain and set the pay for special legal advisors, or accounting or other consultants to attend its meetings and/or take part in discussions and consideration of the affairs of the Committee, as the Committee deems necessary. Notwithstanding this authority, the Committee shall advise members of the senior management team of its intention to retain such advisors and of the ensuing financial obligations.

Within established, pre-approved limits, management may engage the external auditor or affiliates to perform non-material, non-audit services without further pre-approval from the Board. Non-material, non-audit services are defined as tax planning or accounting advice for which the fees do not exceed \$5,000 for any single engagement and do not exceed \$30,000 annually.

#### **Responsibilities**

The Committee shall make regular reports regarding its activities to the Board.

##### **1 Publicly Disclosed Financial Information**

Before public release, the Committee shall review:

- audited annual financial statements and related annual management’s discussion and analysis of financial condition and results of operations (“MD&A”), in conjunction with the report of the external auditors, and based on its review, make recommendations to the Board as to whether it should approve the audited annual financial statements and related materials
- interim unaudited financial statements and related MD&A, and if deemed advisable approve them
- all public disclosure documents containing audited or unaudited financial information, such as annual reports and quarterly reports, and including any related news release, prospectus, information circular, or annual information form
- 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 for any significant variances between comparative reporting periods and for items that vary from expected or budgeted amounts.

## **2 Accounting Policies, Financial Reporting and Reporting Trends**

The Committee shall:

- review and assess the effectiveness of policies and practices concerning financial reporting
- 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
- question management and the external auditors regarding significant financial reporting issues discussed and the method of resolution
- review general accounting trends and issues of accounting policy, standards and practices that affect or may affect the Company.

## **3 Internal Controls**

The Committee shall:

- assess the adequacy and effectiveness of internal controls over the accounting and financial reporting system, with particular emphasis on controls over computerized systems and ensure that adequate procedures are in place for reviewing the Corporation's public disclosure of financial information extracted or derived from the Corporation's financial statements
- review the evaluation of internal controls by the external auditors along with management's responses to the auditor's evaluation

## **4 External Auditors**

The Committee shall:

- recommend to the Board the appointment of the external auditors
- review the terms of the external auditors' engagement and the appropriateness and reasonableness of the proposed audit fees
- oversee the work of the external auditors
- obtain and review, at least annually, reports from the external auditors regarding relationships or services that may affect their independence, discuss such reports with the external auditors, and if deemed necessary, recommend that the Board take appropriate action to satisfy itself as to the independence of the external auditors
- review and pre-approve any engagements for non-audit services provided by the external auditor or their affiliates, together with the fees for such services, and consider the impact of this on the independence of the external auditors.
- review all issues related to any proposed change in external auditors, including the information to be incorporated within the Notice of Change of Auditors called for under the applicable securities laws and the planned steps for an orderly transition

- review all reportable events, including disagreements, unresolved issues and consultations, as defined in the applicable securities law, on a routine basis whether or not there is to be a change of auditors.
- periodically consider requesting a proposal from audit firms

## **5 Audit Procedures**

The Committee shall:

- review the external auditors' audit plans with management and the external auditors, and consider the degree of co-ordination in those plans and whether the planned scope of the audit can be relied upon to detect weaknesses in internal control, or fraud or other illegal acts
- recommend to the Board the scope of the external audit based on the Committee's review of the stated in the audit plans
- 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
- 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
- prepare, if necessary, an Audit Committee Report to be included in the Corporation's Management Information Circular as required by any applicable disclosure regulations

## **6 Other Responsibilities**

The Committee shall:

- review the appointment of the Chief Financial Officer and any key financial executives involved in the financial reporting process
- review any litigation, claims, transactions or other contingencies that the external auditors or any officer of the Company brings to its attention
- periodically review the Company's risk management programs and comprehensive computer disaster recovery plans
- review the policy on use of derivatives and monitor the associated risk
- consider other matters of a financial nature as directed by the Board
- review any related-party transactions
- set policies regarding the hiring by the Corporation of partners and employees, or former partners and employees of the present or former external auditors
- establish procedures for the confidential, anonymous submission and treatment of complaints received by the Audit Committee from employees and others regarding accounting or internal auditing matters

## **Membership, Procedures and Meetings**

### **1 Composition and Number of Members**

The Committee shall consist of at least three members (the “Members”) who are all directors of the Corporation and not members of management. All members of the Committee shall meet any financial literacy, independence and other requirements as stipulated by relevant securities legislation or stock exchange rules.

### **2 Appointment of Members, Chair and Secretary**

Following each annual general meeting of the shareholders, the Board shall appoint the Members who will serve until the close of the next annual meeting of the shareholders of the Company, or until the Member ceases to be a director, resigns from the Committee or is replaced, whichever occurs first. Any Member can be removed from office or replaced at any time by the Board.

In the event that membership on the Committee falls below the minimum, the Board shall appoint a new, temporary or permanent Member prior to the next meeting of the Committee.

The Board shall appoint one of the Members as Chair of the Committee. If the Chair is absent from a meeting, the Members present shall select a representative to act as Chair of that meeting.

The Committee shall appoint a Secretary who need not be a director of the Corporation.

### **3 Quorum**

A quorum shall not be less than the majority of Members. Subject to the foregoing and unless otherwise determined by the Board, the Committee shall have the power to fix its quorum.

### **4 Notice of Meeting**

Notice of each meeting shall be given to each Member, the external auditors, the Secretary, the Chair of the Board, the President and the Chief Financial Officer. The notice need not state the purpose or purposes for which the meeting is being held.

Notice of the meeting may be given orally, or by letter, facsimile transmission or e-mail, and shall be delivered not less than 24 hours before the time fixed for the meeting. Members may waive notice of any meeting provided they do so in a manner that produces a written or printed copy.

### **5 Meetings**

Regular meetings of the Committee shall be held quarterly. Special meetings may be called by the Chair of the Committee, the external auditors, the Chair of the Board, the President or 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.

The powers of the Committee shall be exercisable only at a meeting at which a quorum is present and any decisions made by the Committee shall require an affirmative vote by a majority of Members present at the meeting. Notwithstanding the foregoing, any decision prepared in writing and signed by all the Members shall be fully effective as if it had been made at a meeting duly called and held.

The Committee shall meet periodically with the external auditors and senior management. Members will meet in camera periodically.

Subject to any relevant by-laws of the Corporation, the Committee shall fix its own procedures at meetings, keep records of its proceedings and report to the Board as it deems appropriate. The minutes of any meeting of the Committee shall be tabled at the next meeting of the Board.

**Compensation**

Members of the Committee shall not receive compensation from the Company or its affiliates other than fees to which the Member is entitled as a director of the Corporation or a member of a committee of the Board.

**Evaluation**

The Committee shall review this Charter at least annually and, if necessary, recommend changes to the Board. The Committee shall also evaluate its own performance.

## APPENDIX B – 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>AIG</b>	Anthrax immune globulin
<b>antibody</b>	a specialized protein produced by white blood cells that binds specifically to a foreign substance (antigen) as part of the immune response; autoimmune disorders occur when the body inappropriately produces antibodies against its own tissues
<b>antigen</b>	see antibody
<b>BARDA</b>	U.S. Biomedical Advanced Research and Development Authority; a department within HHS
<b>BAT</b>	Botulism antitoxin heptavalent (also known as botulinum toxin immune globulin)
<b>Cangenus™</b>	a proprietary gene expression system developed by Cangen that uses a type of bacteria known as <i>Streptomyces</i> as a production vehicle; it is capable of expressing or producing selected proteins in commercially relevant amounts
<b>CBRN</b>	Chemical, biological, radiological or nuclear incidents
<b>CDC</b>	United States 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>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>Heptavalent</b>	describes the fact that there are antibodies specific for seven different toxins in the BAT product
<b>HHS</b>	United States Department of Health and Human Services
<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>immune globulin or immunoglobulin</b>	class of proteins that function as antibodies. Hyperimmunes are preparations of immune globulins.
<b>IND</b>	Investigational New Drug application: a submission to regulatory authorities that outlines a planned clinical trial program for a new drug

<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; they 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>	National Institute of Allergy and Infectious Diseases (in the United States)
<b>orphan drug</b>	FDA designation for drugs approved to treat limited patient populations (<200,000 people); guarantees U.S. market exclusivity for seven years and allows for recovery of certain regulatory filing fees
<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>PEP 35</b>	Cangene's novel peptide product that may help to treat certain antibiotic-resistant <i>Staphylococcus aureus</i> infections
<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>phantom stock</b>	A unit granted to an employee or director under an incentive plan; the unit's value is tied to the Company's stock price on a public market. Any increase in value from the grant date to the maturity date is paid to the grantee in the form of a cash bonus. No actual stock is issued under the plan.
<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>SNS</b>	United States Strategic National Stockpile
<b>solvent-detergent (SD)</b>	a process designed to inactivate certain potentially harmful 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>thrombocytopenia</b>	A disorder in which there are reduced numbers of platelets; may be associated with abnormal bleeding
<b>Turner Syndrome</b>	An X-chromosome-linked genetic disorder in girls that results in short stature and infertility
<b>VIG</b>	vaccinia immune globulin; used to treat certain complications associated with smallpox vaccination