

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

*(Unless stated otherwise, dollar amounts are in Canadian dollars)*

## **October 15, 2008**

*This review contains management's discussion of Cangene's operating results and financial condition for the year ended July 31, 2008, and should be read in conjunction with the 2008 audited annual consolidated financial statements and associated notes.*

**The discussion of products in this report is intended as an information summary for investment purposes and does not contain all relevant safety information. Healthcare professionals and patients should refer to the appropriate prescribing information, drug identification or product monographs, available on our website at [www.cangene.com](http://www.cangene.com). Product names may differ in various countries.**

### **Disclosure and internal controls**

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

*Management is also responsible for the design of our internal controls over financial reporting in order to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with Canadian generally accepted accounting principles ("GAAP"). Management has evaluated the design of our internal controls and procedures over financial reporting as at the end of the period covered by the annual filings, and believes the design to be sufficient to provide such reasonable assurance.*

### **Forward-looking statements**

*Management's discussion and analysis contains certain forward-looking statements that are predictive in nature and subject to risks and uncertainties that may cause actual results or events to differ materially from the results or events predicted in this discussion. These risks and uncertainties include, but are not limited to, those discussed in the **Risks and Uncertainties** section within this MDE&A. Forward-looking statements may include words such as "expects", "plans", "will", "believes", "estimates", "intends", "may", "bodes" and other words of similar meaning (including negative and grammatical variations) and may relate to future financial performance, business strategies, or safety and efficacy of*

*unapproved products. Should known or unknown risks or uncertainties materialize, or should management's assumptions prove inaccurate, actual results could vary materially from those anticipated. Management is under no obligation to update any forward-looking statements, except as required by applicable law.*

### **Non-GAAP financial measures**

*Management's discussion and analysis contains 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.*

### **Overview**

Cangene Corporation ("Cangene", "the Company", "the Corporation" or "we") is a biopharmaceutical company in the business of developing, manufacturing, and commercializing products and technologies for global markets. We manage our business and evaluate performance based on two operating segments: biopharmaceutical operations and contract services. Revenues are generated from product sales, contract-manufacturing and contract-R&D services, and royalties. International sales are transacted mainly in U.S. dollars, as is customary in the industry.

Strategically we are focused primarily on therapeutics for infectious diseases and biodefence applications. We have particular development and manufacturing expertise with two main types of products: hyperimmunes, which are concentrated specialty antibody preparations made from plasma, and recombinant biopharmaceuticals, which are therapeutic proteins made by introducing a particular gene into a host organism, which in turn produces the protein of interest. We have expertise in manufacturing technologically complex and sterile injectable products, and also offer contract R&D and manufacturing services to other biopharmaceutical companies and government organizations. In addition, we have an ongoing innovative R&D program, providing further opportunities for long-term growth.

Our first licensed product was WinRho<sup>®</sup>, and its development established a core competency in developing and manufacturing hyperimmunes. Three additional hyperimmune products, VariZIG<sup>™</sup> (Varicella Zoster Immune Globulin), VIG (Vaccinia Immune Globulin) and HepaGam B<sup>®</sup> (Hepatitis B Immune Globulin) have also been licensed.

We are also developing certain recombinant biopharmaceutical products. Our first licensed recombinant product is Accretropin™, our human growth hormone, which was approved by the U.S. Food and Drug Administration (“FDA”) in the second quarter of 2008. Much of the work in this area is supported by an R&D agreement with Apotex Inc., a company controlled by the Apotex Group. As of October 15, 2008, to the knowledge of the directors of Cangene, the Apotex Group (“Apotex”) controlled, directly or indirectly, 42,875,787 common shares, representing 61% of the outstanding common shares of Cangene. The Apotex Group includes Apotex Holdings Inc., Apotex Inc. (a leader in the Canadian generic drug industry), Apotex Research Inc., Apotex Corp., as well as charitable foundations, Sherman Foundation and Apotex Foundation. The Apotex Group 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 is a director and President of Sherman Foundation and Apotex Foundation.

Revenues from the biopharmaceutical operations segment result largely from sales of WinRho® SDF, which are primarily through Baxter International, our distributor in the U.S. and Europe. Sales of other approved products are, however, beginning to grow. Research revenues from recombinant biopharmaceutical products we are developing in conjunction with Apotex also contribute to total revenues. We are making efforts to increase penetration in existing markets through distribution relationships, such as the agreement that our U.S. HepaGam B® distributor, Apotex Corp., signed with the group purchasing organization, Novation, LLC.

We are seeking additional geographic markets for WinRho® SDF (see **Outlook**) and our other licensed hyperimmune products. We also seek to expand the market for WinRho® SDF by investigating its use in new patient populations and by developing potential enhancements such as the liquid version. We will employ similar strategies aimed at expanding markets for our other hyperimmunes into new geographic markets, indications or patient populations.

We have leveraged our capability to develop and manufacture hyperimmunes into a contract-services business. We have been awarded several contracts to develop and manufacture certain biodefence products for the U.S. government.

The first of these was a contract with the U.S. Centers for Disease Control and Prevention (“CDC”) to develop and manufacture VIG, a product used to treat certain complications associated with smallpox vaccination. Revenue from this contract peaked in fiscal 2003 and the product was subsequently approved by the FDA in May 2005. During fiscal 2006, we were awarded significant stockpiling contracts by the U.S. Department of Health and Human Services (“HHS”) to develop and supply immune globulins aimed at botulism toxins (heptavalent Botulism Antitoxin, “BAT”) and inhalational anthrax (Anthrax Immune Globulin, “AIG”) under the U.S. Project BioShield initiative. These contracts are managed by the Biomedical Advanced Research and Development Authority (“BARDA”) within the HHS. The base contracts for BAT and AIG have a combined value of approximately US\$505 million. Early in fiscal 2008, we achieved the “usable product” milestone as defined by both the BAT and AIG contracts. Subsequent delivery and acceptance into the U.S. Strategic National Stockpile (“SNS”) of both products allowed us to invoice for these initial shipments. Revenue recognized on these contracts, including product costs and reimbursable development costs incurred to date, amounted to \$75.9 million in 2008.

Our specialized facilities in Winnipeg, Manitoba, Canada and our manufacturing experience allow us to offer contract services for a broad range of technologically complex, process-sensitive compounds in addition to hyperimmunes. Our Chesapeake Biological Laboratories, Inc. (“Chesapeake”) subsidiary in Baltimore, Maryland, United States, offers facilities for filling and finishing process-sensitive biologics.

Our contract-services segment continues to contribute significant revenues to our overall business; however, this segment is subject to large fluctuations in activity and revenue due to timing of contracts. We are pursuing new contract R&D and manufacturing opportunities, including further contract opportunities with the U.S. and other governments. We also seek contract R&D and manufacturing agreements with biopharmaceutical industry partners, particularly at the Chesapeake operation.

We anticipate using revenue from the U.S. government stockpiling contracts to increase investment in independent research and development, ranging from expanding applications of hyperimmunes to innovative research into entirely new therapies with a primary focus on infectious disease.

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

### Outlook

Our current focus is on meeting delivery commitments on the U.S. government BAT and AIG contracts. We do not anticipate further AIG deliveries until the second quarter of 2009 as we have undertaken an extended summer shutdown for maintenance and upgrades. During this period, we focused on continuing to build up an inventory of AIG plasma. Our current inventory levels are now ahead of schedule and we anticipate that we will be successful in meeting our revised delivery requirements. With AIG, we expect to complete delivery of one third of the contract doses by the end of 2009, with the remaining two thirds to be delivered fairly evenly over the course of 2010 and 2011. With BAT, we expect to deliver approximately one third of the remaining contract doses in 2009, with the remaining two thirds to be delivered evenly over the course of 2010 and 2011. We are also continuing to work on the licensing elements of the contracts for both products, and those efforts are expected to continue, with the majority of the effort occurring in the next two years.

Strategically, we are also focused on expanding our plasma collection capabilities through expansion of four existing plasma centres. The expansions are currently underway and will result in more than double the current capacity. Current activities include design and construction, and finalizing leasing arrangements. These efforts are aimed at bringing more of our plasma supply in-house. Competition for plasma supplies is a significant risk for us with respect to most of our hyperimmune products (see **Risks and Uncertainties**) and we are looking to reduce this risk by becoming increasingly self-sufficient in plasma supply. In addition, in-house supply of plasma can be more cost-effective than commercial purchases. We anticipate that the expanded sites will be operational in the third or fourth quarter of 2009.

We are also concentrating on ongoing marketing efforts related to WinRho<sup>®</sup> SDF and HepaGam B<sup>®</sup>. For WinRho<sup>®</sup> SDF, we are working to obtain approval in additional European Union countries through their Mutual Recognition Procedure. Along with our marketing partner Baxter International, we are establishing an enhanced marketing and regulatory presence in the countries where approval has already been obtained to help grow sales, build relationships and finalize country-specific details such as pricing and labelling. Sales in European countries are beginning to show growth, while competition is intensifying in the U.S.

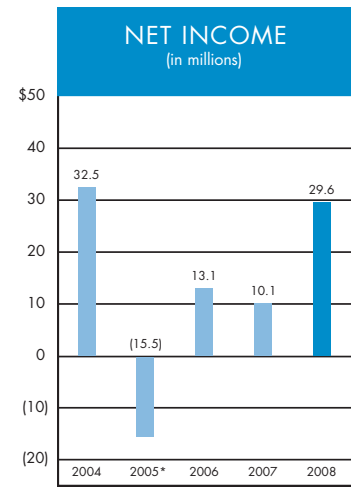
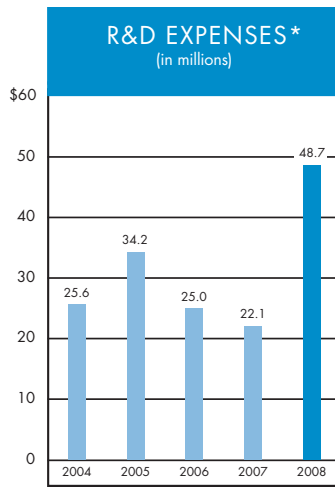
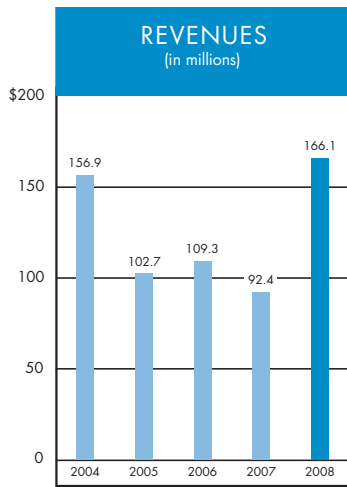
For HepaGam B<sup>®</sup>, we are primarily focused on the U.S. market, and the Apotex Corp. marketing team is targeting the largest liver transplant centres in the country as well as the long-term post-transplant (home therapy) market to introduce them to the product. The FDA granted HepaGam B<sup>®</sup> orphan drug status, which confers seven years of market exclusivity for the licensed indication to prevent hepatitis B recurrence following liver transplantation. With this market exclusivity and as the first hepatitis B immune globulin licensed by the FDA for this indication, we believe that HepaGam B<sup>®</sup> will provide strong sales in the years to come as we continue to penetrate the U.S. market. We are also hoping to introduce the product into Europe (see **New Developments**) and have submitted a centralized Marketing Authorization Application for HepaGam B<sup>®</sup> to the European Medicines Agency.

Proposing the application of our Leucotropin<sup>®</sup> product, we have responded to a U.S. government request for proposal (the "RFP") with respect to treating Acute Radiation Syndrome. The RFP calls for 100,000 treatment courses and includes an option for a further 100,000 courses. Although information issued with the RFP indicated that a decision was likely in the first quarter of our fiscal 2009, we have since been advised that an award is more likely to be made in our second quarter. If we are successful in the bid process, this would be a very significant contract for us.

In 2009, we intend to focus our efforts on a number of independent research and development initiatives that we feel have great potential, including hyperimmune process improvements, HepaGam B<sup>®</sup> studies, and development of monoclonal antibody technology and the innovative anti-infective we call PEP 35.

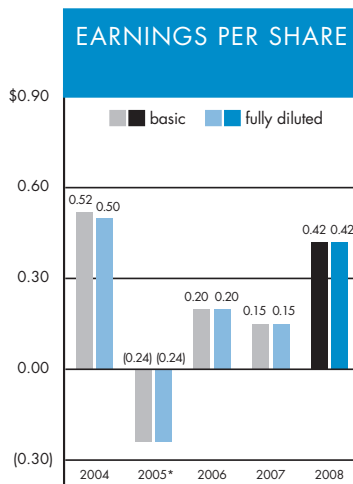
### Selected Annual Information

The summarized information in the following charts is taken from our Canadian GAAP consolidated financial statements and reported in Canadian dollars. A significant portion of our revenues are in U.S. dollars and we have significant operations in the U.S., requiring translation of these revenues and operations to Canadian dollars. Net cash is not a defined term under Canadian GAAP and it should not be construed as an alternative to using the balance sheet as a measure of our financial position. Readers are cautioned that our method of calculating net cash may not be comparable to similar measures presented by other issuers.

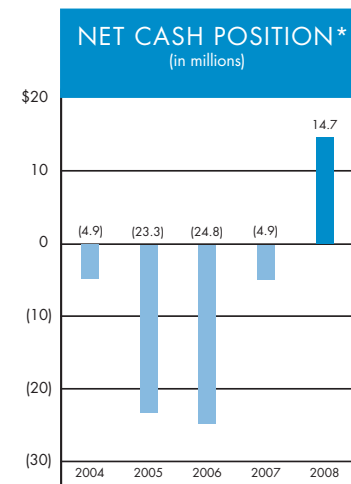
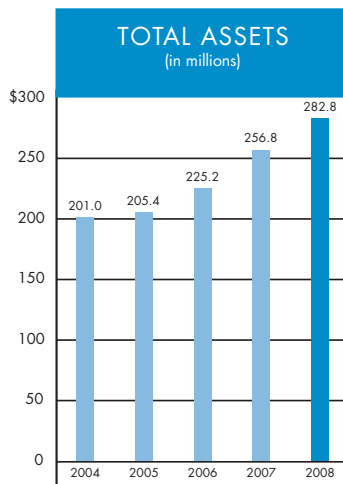


\* After applying investment tax credits

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



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



\* Net cash position = cash - debt

Revenue fluctuations within the contract-services segment, coupled with increased research and development activities aimed at expanding our product pipeline, have contributed to fluctuations in profitability over the last five years. In fiscal 2004, we completed supplying the initial order for the CDC VIG contract midway through the year. At the same time, the volume of fill/finish activity for smallpox vaccine at Chesapeake was diminishing as that contract neared

completion. Consequently, contract-manufacturing volume declined by the end of 2004. However, the number and magnitude of contract-R&D projects along with our own new product R&D efforts increased, causing a rising trend in R&D expenditures and related contract revenues. These trends continued in fiscal 2005, with a continued decline in contract-manufacturing activity coupled with increasing investment in research and development, especially focused

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

on biodefence-related research contracts. In 2006, contract-research activities in the biodefence product pipeline declined as CDC research agreements were completed and we prepared to embark on the recent supply contracts with HHS. Approved product sales in 2006 increased as a result of a significant international sale of VIG and improved WinRho<sup>®</sup> SDF sales. In 2007, our net income decreased due to the absence of a significant VIG sale and reduced revenues on earlier BAT and AIG R&D contracts, compounded by the fact that the BAT and AIG stockpiling contracts awarded in 2006 were not yet generating revenue. These factors were partially mitigated by improved WinRho<sup>®</sup> SDF sales, and improved margins and prices on the liquid formulation in the U.S. In 2008, we reached significant milestones in both the BAT and AIG stockpiling contracts. The product deliveries and ongoing licensing and development work associated with these contacts contributed \$75.9 million in revenue in 2008, resulting in a substantial improvement over recent years' revenue. The large increase in research and development expenses in 2008 is also associated with the contacts. Some of the activity took place in prior periods but was only able to be expensed when the associated contract revenues were earned in 2008 following achievement of contract milestones.

Net income has fluctuated over the last five years, largely as a result of varying levels of activity on biodefence contracts. The loss in 2005 was the result of the write-down of a specialized facility at Chesapeake. Earnings per share over the five-year period primarily reflects the fluctuations in earnings due to the changing activity on biodefence contracts. To a lesser extent, the increased number of shares outstanding that resulted from the share offering in fiscal 2007 and the exercise of stock options over the last five years also lowered earnings per share. Earnings per share in 2008 is considerably improved over the previous three years.

Over the last five years, we have also added significant strength to our financial position. Our asset base has grown each year, and while our net cash position initially decreased to correspond with a major hyperimmune production-facility expansion and with the investment in inventories and contracts in progress associated with the stockpiling contracts, it increased as debt was repaid in 2007 and 2008, and as stockpiling contract revenues were received in 2008. A large portion of our debt was repaid in 2007 with the proceeds of a share offering. As at July 31, 2008 we have no debt outstanding.

### New Developments

On August 13, 2007, we reported that we had met all regulatory and manufacturing requirements that allowed us to deliver BAT and AIG products to the SNS under contracts with the U.S. government and to begin invoicing once delivery was accepted. The initial payments included reimbursable development costs incurred to date as well as payment for the initial product delivery. Subsequently, on August 29, 2007, we announced that we had completed delivery of the initial order for AIG and that the drug had been formally received into the SNS. And, on September 27, 2007, we announced that we had completed delivery of the initial order for BAT and that drug had also been formally received into the SNS.

On August 16, 2007, we announced that our contract with the CDC for the supply of VIG had been extended for five more years. The original contract was signed in 2002 and under that contract we developed and delivered VIG product to the SNS. The extended contract supports licensing requirements, ongoing stability studies, further clinical testing and development projects, and could provide for future orders.

On October 2, 2007, we announced that we were closing our R&D operation in Mississauga, Ontario and consolidating all of our research and development within the Winnipeg, Manitoba head office location. 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. This re-organization resulted in a reduction in staff of approximately 4% and an expected ongoing net operating savings of approximately \$1.5 million annually. Severance and outplacement-services costs, and other costs associated with the staff reduction, amounting to approximately \$1.4 million, were recorded in 2008 in addition to losses of \$0.5 million on disposal of capital assets from the operation.

Certain R&D activities have been wound down because they related to two products that have been submitted for regulatory review and to a contract-research project with the Apotex Group that was concluded in the first quarter of 2008. The Apotex project that was concluded contributed \$3.5 million in gross profit in fiscal 2007.

On November 28, 2007, we announced that Health Canada had approved the liquid formulation of WinRho<sup>®</sup> SDF. This formulation provides a convenient alternative to the

lyophilized (freeze-dried) version of the therapeutic. This convenient formulation has been available since 2006 in the United States. WinRho<sup>®</sup> SDF is distributed in Canada by Canadian Blood Services and Héma-Québec.

On January 24, 2008, we announced that the FDA had approved Accretropin<sup>™</sup>, our recombinant human growth hormone. The drug is indicated 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. The Apotex Group funded the development of this product under the terms of a joint development agreement and also retains marketing rights for the product. Any profits that may arise will be shared between ourselves and Apotex. Along with Apotex, we are currently assessing the market situation and related patent issues to determine the most effective strategy for this product going forward.

On February 7, 2008, we announced that Jerry Treppel had resigned from our Board of Directors, effective March 1, 2008.

Then, on March 26, 2008, we announced the appointment of three new, independent directors to our Board of Directors. The addition of Drs. Bruce Burlington, Philip Johnson and Scott Lillibridge brings our board to 11 members, six of whom are independent. The three new board members reside in the United States and have considerable experience in the fields of infectious disease, biodefence, vaccines, epidemiology and public health. For the first time, the majority of our directors are independent of the Apotex Group, our majority shareholder.

Also, on March 26, 2008, we announced that our HepaGam B<sup>®</sup> had received orphan drug exclusive approval from the FDA for the prevention of hepatitis B recurrence following liver transplantation in patients who are positive for hepatitis B surface antigen. This designation gives the product seven years of market exclusivity.

On April 10, 2008, we announced that Canadian Blood Services and Héma-Québec had signed five-year agreements to purchase three of our hyperimmune products: WinRho<sup>®</sup> SDF, HepaGam B<sup>®</sup> and VariZIG<sup>™</sup>. Under these agreements, we will continue supplying WinRho<sup>®</sup> SDF and VariZIG<sup>™</sup>, and will now supply HepaGam B<sup>®</sup> as well.

On April 17, 2008, we announced that we had initiated a voluntary product withdrawal for one lot of VIG on the basis

that a number of vials stored in our inventory failed an appearance specification that requires the product to be a clear solution. The lot had previously met appearance and all other established requirements. We will manufacture replacement product and have recorded a liability of \$1.8 million owing to customers.

On April 22 and 23, 2008, we announced application for and approval of a normal course issuer bid (the "Bid") to acquire for cancellation up to 1,000,000 of our common shares, representing approximately 1.4% of our total issued and outstanding common shares. The Bid commenced on April 25, 2008 and will expire on April 24, 2009, or earlier if the maximum number of shares has been repurchased. Other than block purchases allowable under the Toronto Stock Exchange rules, purchases will be subject to a daily restriction of 8,844 common shares, which is 25% of the average daily trading volume for the six months preceding the start of the Bid. During 2008 we purchased for cancellation 414,600 shares at a net cost of \$2.1 million.

On May 29, 2008, we announced completion of a significant delivery of BAT under the contract with BARDA. The delivery triggered invoicing, and related revenues of approximately \$20 million were recorded in our fourth fiscal quarter of 2008. This was the first significant product delivery under the stockpiling contracts as the majority of the revenue recorded in the first quarter related to development costs.

On July 11, 2008, we announced that our Vice President, Commercial Development, Mr. John McMillan, is retiring at the end of the year. We are using the services of a professional recruiting agency to identify suitable candidates as rapidly as practical for a new position of Vice President of Sales, Marketing and Business Development.

On September 18, 2008, we announced that we had submitted a centralized Marketing Authorization Application for HepaGam B<sup>®</sup> to the European Medicines Agency. The submission has been accepted for review. If marketing authorization is subsequently granted it will be valid in 30 European Economic Area countries and immediately confers licensure and permission to market the product.

On September 30, 2008, we received a contractual milestone payment of US\$3.0 million from Baxter in recognition of Baxter achieving US\$150.0 million in cumulative worldwide net sales of WinRho<sup>®</sup> SDF under our distribution agreement. This revenue will be recorded in the first quarter of 2009.

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

## Results of Operations

### Consolidated revenues

Total revenues for the year ended July 31, 2008 were \$166.1 million, compared with \$92.4 million in the prior year, an increase of 80%. Our revenues have increased dramatically in 2008, essentially due to the strength of our contract-services segment and the \$75.9 million in revenue from the BAT and AIG stockpiling contracts. In 2007 we were not yet recognizing revenue on these contracts, though work was underway.

### Biopharmaceutical operations

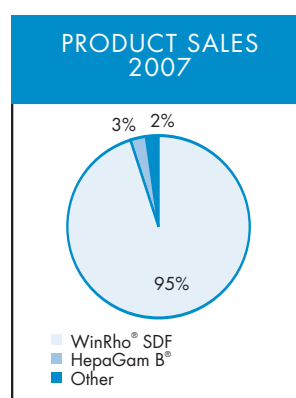
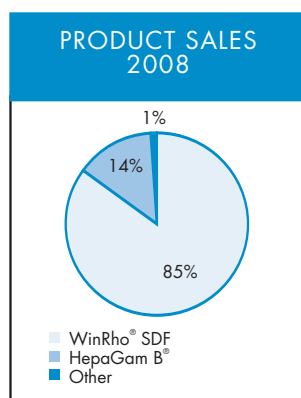
Product-sales revenues in the biopharmaceutical operations segment consist of sales of approved products. R&D-services revenues in this segment include revenue from joint development agreements with Apotex. Royalty revenues are received from Apotex based on its sales of a drug called Ferriprox<sup>®</sup> (deferiprone) that it manufactures and markets.

*in thousands of Canadian dollars*

	2008				2007			
	Product sales	R&D services	Royalties	Total	Product sales	R&D services	Royalties	Total
Revenues	\$ 42,084	\$ 11,632	\$ 7,891	\$ 61,607	\$ 41,749	\$ 11,594	\$ 8,271	\$ 61,614
Gross profit	24,870	4,210	7,891	36,971	27,131	4,196	8,271	39,598
Gross margin	% 59	% 36	% 100	% 60	% 65	% 36	% 100	% 64

In the current year, our sales of WinRho<sup>®</sup> SDF in the U.S. have declined by approximately 21%, while sales in Canada have increased by 11% and European sales have grown by 43%. The decreased WinRho<sup>®</sup> SDF sales in the U.S. result from a combination of lower sales volumes and lower net prices, both due to increased competition. Despite the decline in sales, the United States market continues to account for more than half of our WinRho<sup>®</sup> SDF sales.

HepaGam B<sup>®</sup> sales have grown in each quarter of 2008 and were a combined \$5.8 million for the year in Canada and the U.S. Our HepaGam B<sup>®</sup> product has received orphan drug exclusive approval from the FDA for the prevention of hepatitis B recurrence following liver transplantation (see **New Developments**). This designation gives the product seven years of market exclusivity.



Gross margin on product sales decreased by 6% in 2008, primarily due to the greater percentage of HepaGam B<sup>®</sup> sales. While overall product sales have remained relatively stable, the increased proportion of HepaGam B<sup>®</sup> sales has resulted in a lower gross profit because it produces lower margins than WinRho<sup>®</sup> SDF. Margins on both products have declined due to the increasing cost of plasma caused by tightening supply, while margins on WinRho<sup>®</sup> SDF itself have declined slightly in 2008 due to competitive price pressure.

Our R&D-services revenues in 2008 are consistent with 2007 as work continued on joint development agreements with Apotex, including Accretropin™ and Leucotropin®. Gross profit on R&D-services activities in this segment has remained consistent, although it varies with the level of development activities on joint research projects with Apotex and with the eligibility of research expenditures to generate investment tax credits.

The decrease in royalty revenue in the current year is due to lower sales of Ferriprox®, the drug manufactured and marketed by Apotex, for which Cangene receives 50% of net profits.

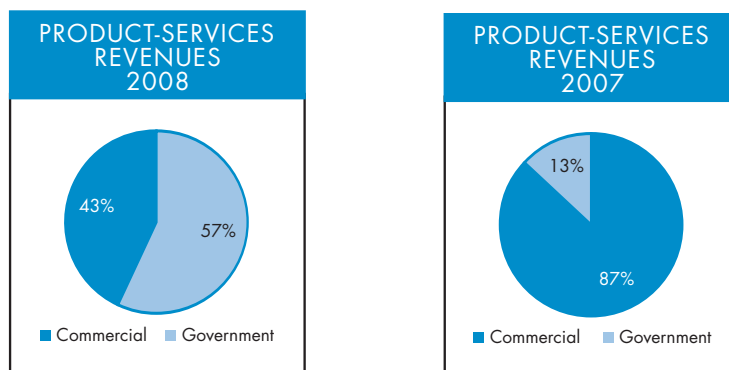
### Contract services

Product-services revenue in the contract-services segment comprises third-party contract-manufacturing revenues at Cangene's Winnipeg facilities as well as at Chesapeake. R&D-services revenues in this segment are derived from contract R&D activities for third parties including government contracts and non-government third-party customers.

*in thousands of Canadian dollars*

	2008			2007		
	Product services	R&D services	Total	Product services	R&D services	Total
Revenues	\$ 44,302	\$ 60,147	\$ 104,449	\$ 17,095	\$ 13,687	\$ 30,782
Gross profit	15,845	24,897	40,742	4,692	5,715	10,407
Gross margin	% 36	% 41	% 39	% 27	% 42	% 34

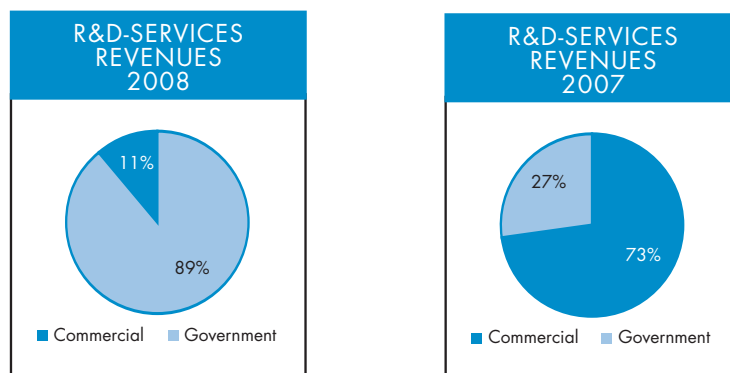
Our much higher product-services revenues in 2008 result from deliveries of product on the BAT and AIG stockpiling contracts, compounded by improved revenues at our Chesapeake subsidiary. We reached significant contract milestones and delivered quantities of product to the SNS during the year, while the prior year had very little biodefence-related revenues. Chesapeake increased its third-party contract manufacturing revenues by 27% and also contributed significantly to our efforts on the BAT and AIG stockpiling contracts in a subcontracting capacity.



The gross profit on product-services revenues increased in absolute dollars due to the substantial growth in revenues. On a percentage basis our gross margin has improved due in large part to improved performance at our Chesapeake subsidiary.

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

In R&D services, the significant increase in revenues in 2008 is due to the development and licensure components of the BAT and AIG stockpiling contracts with HHS. A previous U.S. government AIG R&D contract contributed to both revenues and costs in the prior year. Contract R&D-services revenues related to a product for which Apotex holds the licence declined by 56% compared with the prior year. This contract was concluded early in 2008 (see **New Developments**). We also continue to conduct other third-party contract-R&D work in our Canadian operations.



Gross profit on R&D-services revenues in this segment improved significantly over the prior year. On a percentage basis our gross margin has declined slightly, although we have performed well on fixed price elements of the BAT and AIG biodefence stockpiling contracts, and some components of the early-stage work are eligible for scientific research and experimental development tax credits ("SR&ED"), which improves margins.

In addition to revenues and expenses recognized to date, we have also recorded costs in raw materials and work in process inventories related to the BAT and AIG stockpiling contracts. These costs can be expensed and the related revenue recognized when revenue recognition criteria are met. At July 31, 2008, we had recorded costs of \$45.8 million related to these two contracts as follows:

- Raw materials of \$19.6 million, Work in process – product costs of \$12.6 million, Work in process – manufacturing process development costs of \$6.9 million, Work in process – development costs of \$3.8 million and Finished goods of \$0.1 million recorded in Inventories and contracts in progress;
- Insurance of \$0.9 million recorded in Prepaid expenses; and
- Insurance of \$1.9 million recorded in Other assets.

We anticipate that contract-services revenues will continue to fluctuate in the future, depending on varying levels of activity related to existing contracts and whether significant new R&D or manufacturing contracts with the U.S. government or other parties are awarded.

### Independent R&D

Independent R&D expenses, from which no related revenue is derived, were \$6.0 million in fiscal 2008, compared with \$6.7 million in the prior year. Expenses decreased marginally as significant efforts were dedicated to development and licensure efforts on the BAT and AIG stockpiling contracts. Significant independent R&D expenditures in 2008 were related to hyperimmune process improvements, HepaGam B<sup>®</sup> studies and the PEP 35 project. In 2007, we had significant activity related to HepaGam B<sup>®</sup> approvals. We continue to conduct independent research in several related biopharmaceutical fields, ranging from expanding applications of hyperimmunes to innovative research into entirely new therapies. In 2009, we intend to continue focusing our efforts on hyperimmune process improvements, HepaGam B<sup>®</sup> studies and the PEP 35 project, and in addition, on monoclonal antibody development.

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

Total SG&A expense in 2008 increased to \$17.8 million from \$13.0 million in the prior year. Increased SG&A expense includes higher compensation costs, as well as increased legal and consulting costs associated primarily with contract bid and proposal activity, and product licensure efforts. Regulatory filing fees also increased during the year. Increased compensation costs are largely a result of increased staffing to support work on the BAT and AIG stockpiling contracts.

### Amortization

For the year ended July 31, 2008, amortization increased to \$12.4 million from \$10.3 million in the prior year, primarily because this was the first full year of amortization expense on the fractionation-plant expansion.

### Income taxes

Income tax expense of \$12.0 million for the year ended July 31, 2008 increased from \$8.7 million in the prior year due to the significant increase in taxable income. However, the effective tax rate in 2008 is lower than in 2007, primarily due to the recording in 2008 of previously unrecognized tax losses and timing differences relating to U.S. operations. The recognition of these tax losses and timing differences also contributed to the recovery of future tax.

In 2007, Cangene’s future tax expense was much larger than its current tax expense. The principal reason for this was the significant deferral of development costs in inventories and contracts in progress related to the U.S. government stockpiling contracts. Although deferred for financial statement purposes, these costs were deductible for tax purposes when incurred, resulting in a large timing difference and future tax liability.

### Net income

Net income for the year ended July 31, 2008 was \$29.6 million, compared with \$10.1 million for the prior year, an increase of 194%. Net income for 2008 is much higher than 2007, primarily due to the addition of \$75.9 million in revenue on the BAT and AIG stockpiling contracts. In 2008 we reached significant milestones and delivered quantities of product to the SNS. By comparison, in 2007 we were not yet invoicing or recognizing revenue for the stockpiling contracts, as discussed earlier in **Contract Services**. A lower effective tax rate also contributed to our higher net income in 2008.

### Basic and diluted earnings per share

For the current year, our higher basic and diluted earnings per share reflect the effect of increased net income, as discussed above.

## Summary of Quarterly Results

Quarters ended in thousands of Canadian dollars except per-share data	July 31, 2008 (Q4 2008)	April 30, 2008 (Q3 2008)	January 31, 2008 (Q2 2008)	October 31, 2007 (Q1 2008)	July 31, 2007 (Q4 2007)	April 30, 2007 (Q3 2007)	January 31, 2007 (Q2 2007)	October 31, 2006 (Q1 2007)
Revenues	\$ 63,114	\$ 29,650	\$ 23,467	\$ 49,825	\$ 24,241	\$ 22,730	\$ 20,641	\$ 24,784
R&D expense <sup>1</sup>	15,943	7,002	6,184	19,571	4,589	5,710	6,110	5,670
Net income	18,658	3,144	3,537	4,286	1,948	1,761	1,927	4,448
Earnings per share								
Basic	\$ 0.27	\$ 0.04	\$ 0.05	\$ 0.06	\$ 0.03	\$ 0.03	\$ 0.03	\$ 0.07
Diluted	\$ 0.27	\$ 0.04	\$ 0.05	\$ 0.06	\$ 0.03	\$ 0.02	\$ 0.03	\$ 0.07

1. Includes R&D expenditures, net of investment tax credits, classified as either cost of sales – R&D services or independent R&D.

Revenues over the past eight quarters have fluctuated in response to the timing and number of manufacturing and R&D contracts. Fiscal 2007 saw lower revenues and net income due to the fact that we were not yet recognizing revenue on the BAT and AIG stockpiling contracts awarded in 2006. We had recorded \$38.0 million in inventories and contracts in progress, prepaid expenses and other assets related to these contracts in 2007, including \$12.3 million in the fourth quarter. The lack of revenues associated with the stockpiling contracts was partially offset by improved WinRho<sup>®</sup> SDF sales in the U.S. and the introduction of the more profitable liquid formulation. Net income for the first quarter of 2007 was higher than the subsequent three quarters due to the inclusion of a reversal of incentive plan expense and a revised estimate of rebates and discounts on previous WinRho<sup>®</sup> SDF sales. The increase in revenues and net income from the third to fourth quarter in 2007 was primarily due to revenue received in the fourth quarter under the U.S.VIG contract as product in the stockpile was re-labelled to reflect its licensure.

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

The significant increase in revenues in the first quarter of 2008 was due to the achievement of milestones on the BAT and AIG stockpiling contracts, which permitted Cangene to both invoice and recognize revenue. In comparison with the first quarter, lower revenues in the second quarter of 2008 reflect the fact that there were no product deliveries made on the BAT and AIG stockpiling contracts. Higher revenues in the third quarter of 2008, compared with the second quarter, reflect a small AIG delivery and further development-related revenues on these stockpiling contracts, although these were partially offset by lower WinRho® SDF sales in the U.S. Net income in the third quarter of 2008 was adversely affected by a \$2.8-million expense associated with the withdrawal of one lot of VIG. Of this expense, \$1.8 million remains as a liability owing to customers (see **New Developments**). Our revenues increased dramatically in the fourth quarter of 2008 compared with the first three quarters, due to delivery of a significant number of doses of BAT, a smaller AIG delivery, and ongoing licensure and development activities on the stockpiling contracts.

R&D expense has fluctuated over the last two years with varying levels of activity on independent R&D, Apotex joint-development agreements and other third-party R&D contracts. Certain manufacturing process development costs, incurred in 2007 and 2008 on the BAT and AIG contracts, are capitalized in inventories and contracts in progress and will be expensed as product is delivered. As discussed earlier, acceptance of these products into the SNS occurred in the first quarter of 2008, triggering significant recognition of licensure and development costs that had previously been recorded in inventories and contracts in progress. Similar to the first quarter, our fourth quarter included significant R&D expense associated with the stockpiling contracts.

Earnings per share over the two-year period reflects the fluctuations in net income as well as an increase in the number of shares outstanding due to the share offering in the second quarter of 2007.

### Liquidity & Capital Resources

#### Operating activities

Cash at July 31, 2008 was \$14.7 million, compared with \$Nil at the end of the 2007 fiscal year. Cash was provided by operating activities during 2008, compared with cash used in operating activities during the prior year. The change was primarily due to the significant increase in net income combined with a smaller increase in non-cash working

capital related to operations. Net non-cash working capital from operations, excluding bank debt, has increased by \$13.3 million since July 31, 2007. Higher working capital levels at July 31, 2008 resulted from increased accounts receivable, which reflects deliveries on the stockpiling contracts, as well as increased inventories and contracts in progress, which reflects plasma collection activities and capitalized development costs for the stockpiling contracts. Offsetting the impact of these increases, income and other taxes recoverable has decreased as Cangene received income tax refunds during 2008 that related to prior years. Accounts payable and accrued liabilities has increased due to activity on the stockpiling contracts for BAT and AIG.

#### Financing activities

In 2008, cash of \$6.5 million was used in financing activities as we repaid long-term debt and bank indebtedness in the amount of \$4.9 million, and also spent \$2.1 million on the repurchase of shares for cancellation under a normal course issuer bid. In the prior year, financing cash flow was positive as the proceeds on issuance of common shares exceeded the repayment of long-term debt associated with the fractionation-facility expansion.

#### Equity

The following table provides a continuity of the common shares issued and outstanding:

<i>in thousands of Canadian dollars except share-related data</i>	Number of shares	Share capital
As at July 31, 2006	65,775,670	\$ 32,250
Stock options exercised	258,800	1,143
Issuance of shares	4,375,000	33,501
As at July 31, 2007	70,409,470	66,894
Stock options exercised	95,700	450
Repurchase of shares for cancellation	(414,600)	(396)
As at July 31, 2008	70,090,570	\$ 66,948

At July 31, 2008, 1.8 million [July 31, 2007 – 1.2 million] options remained available to be granted under a stock option plan. Although we have not recently granted any stock options under the plan, it remains in effect until all outstanding options expire, or are exercised, forfeited or cancelled.

We anticipate that employees and directors will continue to exercise options in the future if exercise prices are less than the market price of the common shares.

A summary of the status of our stock option plan as at July 31, 2008 and 2007, and changes during the years ended on those dates is presented below:

	2008		2007	
	Number of shares	Weighted-average exercise price	Number of shares	Weighted-average exercise price
Stock options				
Outstanding at beginning of year	1,939,300	\$ 8.28	2,307,750	\$ 7.91
Exercised	(95,700)	4.70	(258,800)	4.42
Forfeited, expired and cancelled	(547,500)	8.48	(109,650)	9.62
Outstanding at end of year	1,296,100	\$ 8.46	1,939,300	\$ 8.28
Exercisable at end of year	1,295,475	\$ 8.46	1,937,425	\$ 8.28

The following table illustrates the number of common shares that would be outstanding, as at October 15, 2008, if all outstanding stock options were exercised.

	Exercise price	Number of securities outstanding	Weighted-average remaining contractual life	Number of options outstanding and exercisable	Number of common shares upon conversion or exercise <sup>1</sup>
Common shares		69,763,370			69,763,370
Stock options	\$ 6.25	485,300	0.5 years	485,300	485,300
	7.04	46,600	0.6	46,600	46,600
	9.31	369,000	1.5	369,000	369,000
	10.60	385,200	2.3	385,200	385,200
	9.33	5,000	3.8	5,000	5,000
	9.33	2,500	3.8	2,500	2,500
	\$ 8.68	2,500	4.8	2,500	2,500
Subtotal – Stock options		1,296,100	1.4 years	1,296,100	1,296,100
<b>Total</b>		71,059,470			71,059,470

1. Assuming exercise of all exercisable options whether in the money or not. Closing price for Cangene's common shares on the Toronto Stock Exchange on October 15, 2008 was \$3.30.

## Debt

The Corporation has available a \$20.0-million operating line of credit with a bank. As at July 31, 2008, there was \$Nil [2007 – \$2.1 million] outstanding on the operating line.

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

<i>in thousands of Canadian dollars</i>	Payments due by period				
	Total at July 31, 2008	Less than 1 year	1–3 years	4–5 years	After 5 years
Long-term debt	\$ —	\$ —	\$ —	\$ —	\$ —
Operating leases	4,648	875	1,491	1,066	1,216
Purchase obligations <sup>1</sup>	9,342	5,763	2,637	942	—
<b>Total contractual obligations</b>	<b>\$ 13,990</b>	<b>\$ 6,638</b>	<b>\$ 4,128</b>	<b>\$ 2,008</b>	<b>\$ 1,216</b>

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

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

### Investing activities

Cash used in investing activities decreased in 2008, reflecting a slowdown in expenditures on plant and equipment from \$8.5 million to \$7.5 million.

### Liquidity & capital resources summary

Our ability to generate cash from operating activities, including product sales and contract services, as well as our ability to obtain debt financing from our bank, are expected to provide sufficient liquidity to meet anticipated needs of existing projects including the U.S. government stockpiling contracts for BAT and AIG, absent the occurrence of any unforeseen events. We also anticipate that we could raise further new equity or obtain debt financing if and when new capital is required to fund growth and when a market opportunity exists.

### Related-party Transactions

We have agreements with Apotex to support the development of certain biopharmaceutical products. An agreement to conduct contract research and contract manufacturing of a biopharmaceutical product for which Apotex retains proprietary rights was concluded this year (see **New Developments**). In addition, we receive royalties on sales of Ferriprox<sup>®</sup> from Apotex.

During fiscal 2006, we entered into a distribution agreement with Apotex Corp. for it to market and distribute HepaGam B<sup>®</sup> in the U.S.; we will manufacture and continue to hold the licence for the product.

Pursuant to the above agreements, in the year ended July 31, 2008, we earned revenues from Apotex of \$27.4 million, a slight decrease from the \$27.5 million earned during the prior year. At July 31, 2008, \$6.7 million was included in accounts receivable from these related-party transactions, compared with \$5.0 million at July 31, 2007. Related-party transactions are recorded at their exchange amount.

### Critical Accounting Estimates

The preparation of financial statements that present fairly the financial position, financial condition and results of operations in accordance with Canadian generally accepted accounting principles requires that we make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the balance sheet date, and reported amounts of revenues and expenses during the reporting period. Actual results could

differ materially from these estimates. The following is a summary of critical accounting estimates and assumptions that we believe could materially impact our reported financial position, financial condition or results of operations.

### Future benefit of tax-loss carryforwards

In accordance with *Canadian Institute of Chartered Accountants* ("CICA") *Handbook Section 3465 – Income Taxes*, we should only recognize the future benefit of tax-loss carryforwards where it is more likely than not that sufficient future taxable income can be generated in order to fully utilize such losses and deductions. We are required to make significant estimates and assumptions regarding future revenues and earnings, and our ability to implement certain tax planning strategies in order to assess the likelihood of utilizing such losses and deductions. These estimates and assumptions are subject to significant uncertainty and if changed could materially affect our assessment of the ability to fully realize the benefit of the future income tax assets. Future tax asset balances would be reduced and additional income tax expense recorded in the applicable accounting period in the event that circumstances change and we, based on revised estimates and assumptions, determined that it was no longer more likely than not that those future tax assets would be fully realized.

As at July 31, 2008, after utilizing tax-loss carryforwards to offset current year taxable income and revaluing the tax asset at current exchange rates, we have recorded a future tax asset of \$8.6 million to recognize the future benefit of tax-loss carryforwards and deductible temporary differences arising from our U.S. operations, principally the Chesapeake subsidiary. We believe that tax losses currently recorded will be utilized. Unrecognized temporary differences total \$13.4 million and have a potential future tax value of approximately \$4.6 million. Existing accumulated operating losses can be carried forward to offset future taxable income for periods of 12–17 years.

### Goodwill valuation and impairment

In accordance with *CICA Handbook Section 3062 – Goodwill and Other Intangible Assets*, we have established a process for testing the valuation of goodwill on an annual basis for the purposes of determining any potential impairment. In order to establish that the carrying value of net assets, including goodwill, for a particular business reporting unit exceeds the fair value, we are required to make significant estimates and assumptions regarding the timing and magnitude of future cash flows.

We acquired Chesapeake Biological Laboratories, Inc., a U.S.-based contract-manufacturing business, on January 31, 2001. At July 31, 2008, the book value of goodwill related to this acquisition was \$37.3 million. Chesapeake is an integral part of our contract-services segment.

We also acquired two U.S.-based plasma collection centres: Biotherapeutic Laboratories, Inc., on July 15, 1996 and Mid-Florida Biologicals, Inc., on July 11, 1997. At July 31, 2008, the book value of goodwill related to these acquisitions was \$3.2 million. The plasma centres are an integral part of our biopharmaceutical-operations segment.

When evaluating goodwill, we use estimates or forecasts of future cash flows for the next five years, plus estimates of residual cash flows beyond that time, which are discounted using an estimated discount rate that reflects our assumptions regarding the weighted-average cost of capital. Qualitative factors, including market presence and trends, strength of customer relationships, strength of local management, strength of debt and capital markets, and degree of variability in cash flows, as well as other factors, are considered when making assumptions with regard to future cash flows and the appropriate discount rate. We have not changed our approach or method of evaluating goodwill since we adopted this methodology. When evaluating the goodwill relating to the Chesapeake acquisition, we believe that our contract-manufacturing operations in Canada and the U.S. are essentially identical, and will work closely in tandem on certain current contracts and future contract opportunities; consequently, the goodwill is evaluated in the context of an aggregated contract-services segment. Similarly, the goodwill relating to the U.S. plasma centres is evaluated in the context of the aggregated biopharmaceuticals segment since these centres are integral to the supply of high-quality plasma for the manufacture and sale of hyperimmunes, which is currently the main source of revenue in this segment.

Goodwill impairment reduces the carrying value of goodwill on the balance sheet and is recorded as an expense. Goodwill impairment would typically be a non-cash expense since the valuation is performed on assets acquired and the related cash outflows from prior investments. Based on the evaluations, no goodwill impairment was recorded in 2008 or 2007. A change in any of the significant assumptions or estimates used to evaluate goodwill could result in a material change to the results of operations.

#### **Impairment of long-lived assets**

In accordance with *Section 3063* of the *CICA Handbook*, we evaluate our long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of a long-lived asset may not be recoverable.

We have considered whether or not any events or changes in circumstances have occurred in fiscal 2008 that would indicate that the carrying value of any of our remaining long-lived assets may not be recoverable, and have concluded that there is no indication of potential impairment to such assets.

Impairment relating to long-lived assets reduces the carrying value of the asset recorded on the balance sheets and results in an expense. A further change in any of the critical assumptions or estimates used to value the remaining long-lived assets could result in a material change to the results of operations.

#### **Revenue recognition – biopharmaceutical product sales**

In accordance with our revenue recognition policy, revenue from biopharmaceutical product sales, net of trade discounts and allowances, is recognized upon shipment, when all significant contractual obligations have been satisfied and collection is reasonably assured.

We have agreements with distributors for marketing and distributing our WinRho<sup>®</sup> SDF, HepaGam B<sup>®</sup> and VariZIG<sup>™</sup> products. We recognize our share of the revenue from sales of these products by distributors upon shipment by the distributors from their warehouses to wholesalers or customers.

Our distributors estimate allowances for revenue dilution items using a combination of information received from third parties, including market data, inventory reports from major wholesalers, historical information and analyses that they perform. Their estimates are subject to the inherent limitations of estimates that rely on third-party data, as certain third-party information may itself rely on estimates and reflect other limitations. Provisions for estimated rebates, and other allowances such as discounts, and promotional and other credits are estimated based on historical payment experience, historical relationship to revenues, estimated customer inventory levels and contract terms, and actual discounts offered. We believe that such provisions are determinable due to the limited number of assumptions involved and the consistency of historical experience.

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

The provision for chargebacks is a significant and complex estimate used in the recognition of revenue and is calculated by the distributors. Our distributors market products directly to wholesalers and indirectly to group purchasing organizations, physician practice-management groups and hospitals, collectively referred to as "indirect customers". The distributors enter into agreements with indirect customers to establish contract pricing for products. The indirect customers then purchase the products from wholesalers at these contracted prices. Under this arrangement, our distributors provide credit to the wholesaler for any difference between the contracted price with the indirect party and the wholesaler's invoice price. Such credit is called a chargeback. The distributors estimate the provision for chargebacks based upon historical chargeback experience and estimated wholesaler inventory levels, as well as expected sell-through levels by their wholesale customers to indirect customers. Their estimates of inventory at wholesale customers and in the distribution channels are subject to the inherent limitations of estimates that rely on third-party data. We receive regular reports from distributors, and continually assess the reasonability of chargebacks and evaluate the estimates as new information becomes available. Adjustments to these provisions are made periodically to reflect new facts and circumstances that may indicate that historical experience may not be indicative of current and/or future results. In consultation with our distributors, we make subjective judgments based primarily on our evaluation of current market conditions and trade inventory levels related to the products. This evaluation may result in an increase or decrease in the experience rate that is applied to current and future sales, or as an adjustment to past sales, or both.

### Accounting Changes, Including Initial Adoption of Accounting Policies

The preparation of financial statements that are fairly presented in accordance with Canadian generally accepted accounting principles requires that we adopt, select and apply appropriate accounting policies and principles, particularly where alternatives exist within GAAP.

During fiscal 2008 we initially adopted the following new *CICA Handbook* standards:

#### *CICA 1506 – Accounting Changes:*

This revised Section adopts relevant parts of International Financial Reporting Standards IAS 8, "Accounting Policies, Changes in Accounting Estimates and Errors".

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

This Section provides a new requirement that certain gains and losses are to be temporarily presented outside of Net earnings and recognized as "Other comprehensive income". Comprehensive income is the change in equity (net assets) of an enterprise, during a period, from transactions and other events, and circumstances from non-owner sources.

#### *CICA 3251 – Equity:*

This section replaces *CICA 3250* and establishes new standards for the presentation of equity and changes in equity during the period.

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

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

#### *CICA 3861 – Financial Instruments – Disclosure and Presentation:*

This Section prescribes the required disclosure and presentation of financial instruments in financial statements.

#### *CICA 3865 – Hedges:*

This is an optional application that provides alternative treatments to *CICA 3855* (discussed above) for entities that choose to designate qualifying transactions as hedges for accounting purposes.

### Recent accounting pronouncements

The following new *CICA Handbook* sections are effective for interim and annual financial statements relating to fiscal years beginning on or after the dates noted below, and will be adopted by Cangene in fiscal 2009 or later.

#### *CICA 1535 – Capital Disclosures:*

This Section addresses disclosure of a company's capital and how it is managed. (October 1, 2007)

#### *CICA 3031 – Inventories:*

This Section replaces the current *CICA 3030* and prescribes the accounting treatment for inventory. (January 1, 2008)

#### *CICA 3862 – Financial Instruments – Disclosures:*

This Section prescribes the required disclosure of financial instruments in financial statements. (October 1, 2007)

*CICA 3863 – Financial Instruments – Presentation:*

This Section prescribes the required presentation of financial instruments in financial statements. (October 1, 2007)

*CICA 1400 – General Standards of Financial Statement Presentation:*

This Section has been amended to include requirements to assess and disclose an entity's ability to continue as a going concern. (January 1, 2008)

*CICA 3064 – Goodwill and Intangible Assets:*

This section provides guidance on the recognition, measurement, presentation and disclosure for goodwill and intangible assets, other than the initial recognition of goodwill or intangible assets acquired in a business combination. (October 1, 2008)

We have not yet fully evaluated the impact of these standards on our financial statements.

*CICA 3031* will impact our standard costing and valuation of inventory, most significantly through the determination of normal capacity in the creation of standards. The precise financial statement impact is yet to be determined.

*CICA 1400, 1535, 3064, 3862 and 3863* are anticipated to have minimal impact on our results and will primarily result in increased disclosures in the financial statements.

### **International Financial Reporting Standards**

On February 22, 2008, Canada's Accounting Standards Board confirmed the date that will result in Canadian GAAP as used by public companies being converged with International Financial Reporting Standards. The change will be applicable to fiscal years beginning on or after January 1, 2011, which, for the Corporation, will be the fiscal year beginning August 1, 2011. The Corporation has prepared a draft changeover timeline and has begun assessing the impact of the transition. The Corporation is currently considering early adoption as an alternative.

### **Financial Instruments**

Our current assets and liabilities, which are subject to normal trade terms, are financial instruments for which the recorded carrying values approximate the fair value. We are, however, exposed to financial market risks, including foreign currency exchange rates and interest rates on operating line of credit obligations.

### **Foreign currency risk**

We operate internationally, and the majority of our revenue and a significant amount of our expenditures are denominated in U.S. dollars. We do not currently use any derivative financial instruments to manage foreign exchange risk.

### **Interest rate risk**

We are exposed to interest rate risk on borrowings under our revolving operating line of credit, which is subject to a variable interest rate. On May 1, 2008, we entered into a U.S.–Canadian dollar currency swap for purposes of lowering the interest expense associated with the Canadian dollar utilization of our operating line of credit. The principal amount of the swap is US\$10.0 million and it expires on November 6, 2008. On July 25, 2008, we entered into a second U.S.–Canadian dollar currency swap of US\$7.0 million for the same purpose. This swap expires on July 30, 2009. Both of the swaps are marked to market at July 31, 2008. If held to maturity we will pay fixed-fee swap costs of \$0.1 million for each swap.

Subsequent to year-end, we entered into an additional U.S.–Canadian dollar currency swap for US\$7.0 million that matures September 18, 2009. If it is held to maturity we will pay fixed-fee swap costs of \$0.2 million.

### **Risks and Uncertainties**

We are subject to certain risks and uncertainties inherent in the operation of our business. We attempt to mitigate these risks through a combination of sound risk-management practices, insurance and systems of internal control. Some of the principal risks and uncertainties, although not all inclusive, are:

#### **Risks associated with new product development**

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

There can be no assurance during any given research or development stage that any viable new products will be developed for which a market demand exists. The costs of conducting basic and clinical research to identify potential new product opportunities can be significant. There can be no assurance during any development stage that any new products developed will receive regulatory approval.

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

If approved, some of these products will compete with established products of proven safety and efficacy, the manufacturers of which can be expected to employ intellectual property challenges against our commercialization of these products. There can be no assurance that our products will be commercialized or, if commercialized, that medical centres, hospitals, physicians or patients will accept them in lieu of established treatments. Accordingly, there can be no assurance that these products can be manufactured successfully and/or marketed profitably.

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

Our profitable manufacture of hyperimmune products is dependent on a supply of specialty plasma. We collect plasma from donors through both our own and third-party collection centres, and accordingly are subject to donor participation. Furthermore, the level of antibodies in the plasma of donors is variable and, unless concentrations are sufficient, the cost of processing plasma to the end product may not be economically viable. We believe that we currently have 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. We are taking steps to increase our own collection capacity, but there is no guarantee of the level of donor participation.

### **Compliance with regulatory requirements**

Our ability to manufacture and ship our products is subject to numerous regulatory requirements and conditions, which are complex and evolving. The supply of product, and hence revenue generation, could be interrupted should compliance become an issue. There can be no assurance that we will remain in compliance at all times, although we undertake continuous and stringent quality assurance, quality control and regulatory review processes internally to minimize this risk.

### **Reliance on distribution relationships**

A significant portion of our revenues from product sales is derived from sales through exclusive distributors in the U.S. and international markets. A sole distributor has the rights to distribute WinRho<sup>®</sup> SDF throughout the U.S. and Europe.

In 2006, we entered into an exclusive distribution arrangement with a second distributor to market our HepaGam B<sup>®</sup> product in the U.S. As a result, we are relying on the sales and marketing strength, and distribution channels through which these distributors operate for a significant portion of our revenues. There can be no assurance that we will be able to retain these distribution relationships indefinitely and that we will be able to rely upon the sales, marketing and distribution efforts of these distributors to support sales of these products in these significant markets.

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

Certain of our biopharmaceutical products may compete with existing products in the marketplace, and due to the nature of the products being developed and the complexity of the law governing intellectual property rights, we may face increasing exposure to intellectual property claims. Defending intellectual property claims, whether or not such claims have merit, may result in us incurring significant legal costs. An inability to defend such claims could lead to loss of rights to manufacture and sell a product, even after significant costs have been incurred for development and licensing. There can be no assurances that we will not become subject to intellectual property claims, nor can there be any assurance that we would be able to successfully defend such claims.

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

We are party to contracts with Canadian and U.S. government agencies, a small number of other third parties, and Apotex, a related party. A significant portion of our revenue comes from a small number of contract customers; there can be no assurance that these customers will continue to purchase products or services from us at current levels or at all.

### **Fluctuations in demand**

We have entered into contracts and submitted proposals to develop and manufacture products for use in biodefence programs. By their nature, these contracts call for us to supply such products to a national stockpile to be used in the event of an actual incident or attack. Accordingly, demand for these products should be expected to fluctuate significantly, both at the time of establishing initial stockpiles and in the event of their use or replacement in the stockpile.

There is no way to precisely predict the level of future demand for such products. In the event of a crisis, we may be called upon by governments to dedicate capacity to the manufacture of certain biodefence products, which would impact our ability to meet customer demand for other products.

### **Expansion into foreign markets**

WinRho<sup>®</sup> SDF is licensed and sold in many countries worldwide. We view international markets as having significant potential for market expansion of several of our products. Although we believe that the international political and regulatory environment has not presented a sustained barrier to our ability to ship product in the past, each country has its own regulatory requirements, and introduction of products into new markets can take substantial time. There can also be no assurance that future political or regulatory events will not impede distribution of products to international markets in the future. In addition, we may incur significant up-front costs in efforts to gain entry to these markets. There can be no assurance that these markets will yield sufficient revenues to recover the costs of entry.

### **Competition**

We compete in a number of segments within the biopharmaceutical industry, some of which are highly competitive. Traditional pharmaceutical companies are increasingly entering biologics markets. And competition in the contract-services segment in North America appears to be intensifying, with a small number of well-positioned organizations attempting to provide a complete suite of services. We anticipate we will compete with a number of larger manufacturers for the production of certain biopharmaceutical products. In addition, we anticipate facing increasing competition as we attempt to further penetrate existing markets and expand our products into new markets. Given these industry characteristics, existing or new competitors may be significantly larger and have greater financial, research, manufacturing or marketing resources than ours. These competitors may compete with us in providing both products and services in markets in which we currently operate, as well as competing to enter new markets where we desire to expand. Further, competitors may employ tactics such as intellectual property challenges or government lobbying to prevent or impede our progress in expanding our markets. There can be no assurances that we will be able to achieve or maintain our desired market share in any particular industry segment or market.

### **Foreign currency risk**

As noted previously, the majority of our revenues are generated from non-Canadian customers and accordingly are typically transacted in foreign currencies, primarily in U.S. dollars. Although we also incur significant U.S.-dollar-denominated expenses, there has historically been a net inflow of U.S. dollars. In addition, our net income can be materially affected directly by exchange rate fluctuations as net income from U.S. operations are translated into Canadian dollars for reporting purposes.

*The preceding cautionary statements should be considered in connection with all written or oral statements, especially forward-looking statements, that are made by Cangene or by persons acting on its behalf and in conjunction with its periodic disclosure and related filings with the securities commissions. We undertake no obligation to publicly make or update any forward-looking statements, except as required by applicable law.*

*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. The discussion in this document is intended as an investor summary and does not contain all relevant safety information. Healthcare professionals are directed to refer to approved labelling and appropriate prescribing information for products and not to rely on information discussed in investor documents. Prescribing information or drug names may differ in various countries.*

### **Additional Information**

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