

# life

Sustaining Oxygen Delivery





## About Hemosol

Hemosol is an integrated biopharmaceutical company developing innovative life sustaining therapies, used initially for the treatment of acute anemia. The Company's immediate focus is on the development and successful commercialization of Hemolink™ (hemoglobin raffimer). Hemosol also is furthering the development of its multi-product pipeline based on proprietary hemoglobin modification and cell expansion technologies.

## About HEMOLINK

HEMOLINK is a life-sustaining therapeutic, designed to deliver oxygen immediately, effectively and safely to the body's tissues and organs. HEMOLINK is a leader in an emerging new class of pharmaceuticals called oxygen therapeutics that reflect a new approach to the treatment of patients suffering from acute anemia.

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# Highlights 2001

## Amended the Company's U.S. clinical program for HEMOLINK to include:

- Two cardiac bypass grafting surgery trials (primary and "re-do") plus two additional studies (chemotherapy-induced anemia and general surgery)

## Established a global regulatory strategy, seeking approvals to market HEMOLINK in key markets:

- Canada (NDS under review)
- The United Kingdom (approval anticipated in late 2002/early 2003)
- Europe (additional approvals anticipated in 2003)
- The United States (expect to file BLA in 2003)

## Continued development of Meadowpine, the Company's state-of-the-art commercial-scale HEMOLINK production facility

- Initial annual capacity of 300,000 units
- Hemosol moved into offices and laboratories in December 2001

## Filed for regulatory approval to market HEMOLINK in the United Kingdom

## Successfully listed common shares on NASDAQ

- Funds raised: C\$109 million



JOHN W. KENNEDY  
President & Chief Executive Officer

## President's Message

**"We have made tremendous progress in our quest to be the leading company in the establishment and successful commercialization of oxygen therapeutics."**

### **Dear Shareholders,**

2001 was a challenging and ultimately rewarding year for Hemosol, thanks to the focused efforts of our dedicated employees. We successfully addressed some major challenges and moved even closer to realizing our goal to commercialize a life sustaining oxygen therapeutic that is both safe and effective. We plan to take full advantage of this position and assume our place as a leading biotechnology company. Hemosol shareholders should know that the advances we have made are the result of the energy, commitment, and passion of a very talented and skilled group of employees. Our actions are driven by our fundamental belief in the therapeutic potential of Hemolink™ (hemoglobin raffiner) and the pipeline of technologies which will follow.

Hemosol is committed to revolutionizing the treatment of acute anemia, and consequently, we have been developing oxygen therapeutics to commercialize important first-in-class products that will sustain and extend lives. We believe that widespread availability of HEMOLINK will drive change in the treatment of acute anemia. Our clinical research to-date has shown HEMOLINK to be a clinically relevant product. HEMOLINK therapy allows patients to avoid donor red blood cell transfusions and, perhaps more importantly, may also improve other outcomes such as the rate of post-operative infections and hospital readmissions. These benefits remain to be proven and are currently being studied in our robust clinical trial program. What is certain is that our manufacturing process is extremely effective at removing contagions that may be present in units of donor red cells. In addition, HEMOLINK reduces the risk of immune reactions, is universally acceptable, and is completely acellular and thus free of the degradation products of cell death and deterioration. Most importantly, HEMOLINK is exquisitely effective in immediate oxygen delivery under normal conditions, throughout its long shelf life. This key feature opens up the possibility of treating acute anemia and sustaining life more effectively, not only in the hospital but also in geographic situations where a patient is in desperate need.

In 2001, the U.S. Food and Drug Administration (FDA) required that we amend our pivotal trial protocol and registration plans. Although it is clear that the changes to our U.S. registration program have moved back our timelines for U.S. commercialization, we believe that the resulting plan has better positioned us for success. We are now pursuing a global registration strategy that aims at achieving U.K. approval late in 2002/early 2003, to be followed by other European approvals in 2003. We plan to use the new U.S. studies to further support our European registration program.

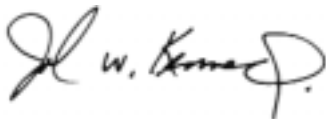
We have already begun a clinical trial in primary coronary artery bypass grafting (CABG) surgery. The study will include 180 primary CABG patients at more than 40 centres in the United States and the United Kingdom. In addition to this efficacy study in primary CABG patients, we have also initiated a similar efficacy study in "re-do" CABG surgery. This second trial will include 140 patients who have previously undergone a CABG procedure and will run concurrently with the primary CABG trial. We are working closely with our clinical trial sites to enrol patients in these trials expeditiously so that the data can be used to meet our global objectives. Once we complete these two trials, we will discuss our Phase III plan with the FDA and design and initiate a third study pivotal for U.S. registration.

In addition to the ongoing CABG trials, the clinical program will include a high-dose general surgery study and a study in patients experiencing chemotherapy-induced anemia. Hemosol plans to initiate these trials in the coming months.

Our global clinical and regulatory plan coincides with our efforts to lead the industry by becoming the first company with the capacity to meet large-scale commercial demand. Our Meadowpine manufacturing facility is proceeding on schedule. We expect construction to be complete this summer and the first batch of HEMOLINK produced by the end of the year. As a result, we will be in a position to complete our validation programs and begin to build inventory to support Phase III in the U.S., early commercial objectives in Europe or Canada and, most importantly, the BLA review process in 2003. This 300,000-unit per year facility will be upgraded as needed to meet demand, and as demand continues to grow, other facilities will be constructed.

As a result of the challenges we faced in 2001 we are a stronger and better company. We have made tremendous progress in our quest to be the leading company in the establishment and successful commercialization of oxygen therapeutics. While there may be more challenges ahead, I remain very confident that Hemosol has the technology and the people to deliver on the promise. Our clinical and regulatory plan is achievable. Our technology platform and manufacturing capacity are well established. Finally, the need for our product is acute.

We thank those of you for continued support and encouragement, especially the clinicians and health professionals at the numerous clinical study sites in the U.S., Europe and Canada, who are playing a pivotal role in bringing HEMOLINK to Life.

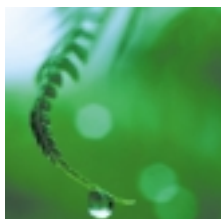


JOHN W. KENNEDY  
President & Chief Executive Officer  
March 31, 2002



# therapeutic

## ● HEMOLINK ● A Life Sustaining Oxygen Therapeutic



Our ongoing clinical development program is focused on achieving market approval for Hemolink™ (hemoglobin raffiner) in global markets and to develop medical expertise with this potentially life sustaining oxygen therapeutic.

Based on the clinical data derived to-date and including data from two ongoing coronary artery bypass grafting (CABG) trials, Hemosol anticipates receipt of approvals to market HEMOLINK in the United Kingdom in late-2002/early 2003, followed by other European markets in 2003.

To-date, Hemosol has completed eight clinical trials involving over 500 patients. Overall, these studies have demonstrated that HEMOLINK is safe and effective. In addition, HEMOLINK has been used on a compassionate basis in a number of patients in situations where the use of donor blood was not an option.

### CABG Surgery – The Lead Indication for HEMOLINK

In 2000, Hemosol successfully completed a pivotal Phase III clinical trial of HEMOLINK in Canada and the United Kingdom (U.K.). This trial involved a total of 299 patients undergoing CABG in conjunction with a blood conservation technique called intra-operative autologous donation (IAD). IAD is a technique in which the patient's own blood is withdrawn just prior to surgery. Following administration of HEMOLINK, the patient's own fresh blood is re-administered over the course of the procedure as needed, thereby avoiding the need for donor blood and the associated risks.

Results from the efficacy analysis on 288 patients in the Canada/U.K. Phase III trial showed that 83% of the HEMOLINK group completely avoided blood transfusions, a statistically significant difference relative to the control group. Furthermore, in the HEMOLINK treated group:

- the amount of donor blood used in patients requiring transfusion was significantly reduced;
- time to first transfusion of donor red blood cells (RBCs) was significantly longer; and
- a reduced amount of other blood products were used, including plasma and platelets.

Based on the strength of the aforementioned Phase III trial, Hemosol filed for regulatory approval to market HEMOLINK in Canada and the U.K.

In 2001, Hemosol revised its clinical development plan for HEMOLINK to strengthen the overall program and improve the chances for global approvals with commercially advantageous labels. Specifically, a 180-patient efficacy study in primary CABG surgery is currently being conducted in the U.S. and the U.K., alongside a 140-patient efficacy study in "re-do" CABG surgery (re-do refers to the second or subsequent time a patient under goes a CABG surgery). Both of these trials are expected to be completed in the second quarter of 2002 and are marked for inclusion in regulatory submissions to both the U.K. and U.S. authorities. A third CABG study is expected to combine elements of these two studies and be pivotal for registration. This study will be conducted to confirm efficacy and complete the safety database required for U.S. approval.

### Beyond CABG Surgery

Hemosol has completed evaluations of HEMOLINK in clinical applications beyond the series of CABG surgery trials, including a trial of HEMOLINK in combination with erythropoietin in patients undergoing renal dialysis and orthopedic surgery trials. New trials evaluating HEMOLINK in combination with erythropoietin in patients experiencing chemotherapy-induced anemia, general surgery and catastrophic blood loss are also planned for 2002.

**STEVEN HILL M.D.**, ASSISTANT PROFESSOR OF ANESTHESIOLOGY, DUKE UNIVERSITY MEDICAL CENTER

"I've been involved with HEMOLINK studies for years and am personally excited to continue enrolling patients into further clinical trials. Through research such as this, I hope to be able to soon treat patients in need when blood transfusion is not an option.

I know all too well the challenges we face daily with blood transfusions and treating people with acute anemia, where providing oxygen immediately to tissues and organs in the body is critical to sustain life. It is important that we work hard to move oxygen therapeutic agents safely and effectively into clinical practice.

Essentially, the goal of HEMOLINK is to provide enough oxygen to the body's tissues and organs to retain normal function and sufficient oxygen delivery in the face of acute anemia. Restoring adequate oxygen delivery is essential in order to reduce any damage resulting from tissue hypoxia, a condition in which the cells are starved of oxygen."

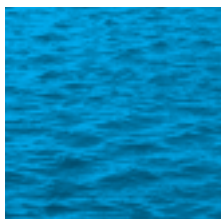


**COMPLETED CLINICAL TRIALS OF HEMOLINK TO-DATE**

Phase	Patients	Number of Patients	Results	Country
I	Healthy Volunteers	42	Safety & Pharmacokinetics	Canada
II	Hip/knee replacements	16	Safety vs saline following IAD	Canada
II	Renal failure on dialysis	29	Safety of repeated low doses in combination with EPO	Canada; US
II	CABG Surgery	60	Safety confirmed; 90% of HEMOLINK patients avoided donor red blood cells	Canada; UK
II	CABG Surgery	78	Safety confirmed; HEMOLINK patients received significantly less donor RBCs than control	US
II	Orthopedic Surgery	40	Results combined: safety confirmed; HEMOLINK patients had a clinically meaningful delay in donor RBC transfusions	UK
II	Orthopedic Surgery			UK; US
III	CABG Surgery	299	Safety confirmed; 83% of HEMOLINK patients avoided donor RBCs	Canada; UK

# delivery

## ● Manufacturing: A Competitive Edge



In conjunction with Hemosol's efforts to gain regulatory approval in key global markets, the construction of a commercial-scale manufacturing facility is a key component of the Company's commercialization strategy. Today, Hemosol leads the industry in the creation of a facility that will meet demand for safe, effective oxygen carrying therapeutics. The Company's flagship product, Hemolink™ (hemoglobin raffiner) will be the first of Hemosol's human hemoglobin-derived therapeutics to be manufactured on an industrial level.

### Safe, Effective Oxygen Delivery

HEMOLINK was purposefully designed for safe, effective and rapid oxygen delivery to sustain life. Through a series of proprietary processes, hemoglobin is extracted and purified from human donor blood. Next, a chemical cross-linker creates stable links within and between the hemoglobin molecules, allowing for longer duration of activity. All together, this specific, proprietary molecular configuration offers efficient oxygen delivery, prolonged circulation time and freedom from concern of viral contagion.

### 25,000 Units Today

Hemosol has completed validation and scale-up of its facility at Skyway, which currently has a capacity of 25,000 units per year. In addition to supplying finished product for the Company's ongoing clinical program, Skyway will be used for initial licensing purposes in both Europe and Canada. The experience gained

from building this facility has proven valuable in the construction of the Company's new state of the art facility – Meadowpine.

### 300,000 Units By 2003

Work on the \$90 million Meadowpine facility is proceeding on schedule, and the Company moved into the new offices and labs in December of 2001. The facilities are truly state-of-the-art and provide the Company with an entirely new range of capabilities. Installation of process equipment is expected to be finished by the middle of 2002 with validation of this 300,000-unit facility to take place early in 2003, in time for anticipated European regulatory approval. The facility will also be included in the Company's U.S. Biologics License Application to the FDA.

### And Much More to Come

Once finished, Hemosol will be the first company to have a fully operational, industrial-scale manufacturing facility to produce oxygen therapeutics. Furthermore, the Meadowpine site is expandable up to 600,000 units of HEMOLINK per year. And as demand continues to grow, more facilities will be built.

### Meadowpine – Quick Facts

- Capacity – 300,000 units of HEMOLINK
- 120,000 square feet
- Construction initiated in September 2000
- Expected completion date is summer 2002
- Expected validation date is early 2003



DIRK ALKEMA, VICE PRESIDENT, OPERATIONS

“There’s never been anything like Meadowpine. Located in Mississauga, Ontario, just a 20-minute drive from downtown Toronto, the 120,000 square-foot HEMOLINK manufacturing facility is both the first of its kind and a symbol of how Canadian science, technology and a sound business plan can combine to create innovative products that can effectively complete on a global basis.

Hemosol will be the first to market oxygen therapeutics on a large commercial scale – no one in this industry today is even close to having a facility like Meadowpine. Even with its 300,000-unit start-up capacity, we foresee demand for HEMOLINK quickly outstripping our ability to manufacture the product. As we put the finishing touches on this facility, we are using this experience to plan for new, even more impressive facilities that we expect one day will be found across North America and Europe.”



### HOW HEMOLINK IS MADE



# oxygen

## Life Sustaining Oxygen Delivery



### HEMOLINK – An Oxygen Therapeutic

Hemolink™ (hemoglobin raffimer) is an oxygen therapeutic designed to sustain life through effective and immediate treatment of acute anemia. The objective of HEMOLINK therapy is to deliver oxygen through the circulatory system quickly, safely and effectively.

### Acute Anemia

Anemia is a deficiency of red blood cells (RBCs), the cells containing the hemoglobin that carries life sustaining oxygen to the body's tissues and organs. RBC deficiency (anemia) results in a deficiency in the body's oxygen supply. This serious condition requires immediate treatment.

Acute anemia is a short-term condition that can result from the loss of large amounts of blood due to injury or surgery, or from the interruption of normal RBC production or viability. Presently, donor RBC transfusion is the primary short-term therapy used to restore oxygen delivery to patients experiencing acute anemia. This therapy is associated with well-known clinical limitations and risks.

### Acute Anemia – Large and Growing Market

Approximately \$4.5 billion US is spent annually in North America to treat acute anemia. Globally, the acquisition cost alone for RBCs to manage acute anemia is estimated to be as high as \$15 billion US.

Beyond the initial applications in acute anemia therapy, oxygen therapeutics have potential application in other situations where therapeutically enhanced oxygen delivery may be beneficial, such as in cancer radiation therapy.

### Acute Anemia Due to Surgery

Roughly 60% of all donor RBC transfusions are used to manage acute anemia due to surgery. Approximately 600,000 Americans and 250,000 Europeans undergo CABG surgery each year, and nearly half of

these patients already receive acute anemia therapy under current practices.

### Chemotherapy-Induced Anemia

Chemotherapy treatment can result in acute hemoglobin deficiencies, as it suppresses the body's ability to replenish RBCs. Estimates show that more than 60% of all cancer patients experience some chemotherapy-induced anemia (CIA) at some point during therapy. The consequences of this include fatigue, weakness, and drowsiness, all of which can significantly reduce the patient's feeling of physical well being.

More than 257,000 cases of lung, ovarian and breast cancers, leukemia, and lymphoma are diagnosed annually in France, Germany, the Netherlands, and the U.K. This, combined with an estimated 170,000 patients in North America with these malignancies, represents a global patient group of well over 500,000 at risk of CIA.

The potential use of HEMOLINK to provide immediate oxygen carrying capacity during CIA represents a significant opportunity. Dependant upon the chemotherapy, 20-50% of these patients require treatment of the acute phase of their anemia with RBCs. In addition, a significant number receive erythropoietin therapy for the longer-term management of CIA, a therapy which requires at least two weeks to become effective and is ineffective in approximately 33% of patients.

Patients with CIA may benefit from HEMOLINK in two ways. First, administration of HEMOLINK during the acute phase of treatment could make patients feel better earlier, recover faster, and be better able to tolerate cancer treatment. In addition, pre-clinical data suggests a synergistic effect between HEMOLINK and erythropoietin. In the clinical setting, this effect may enhance the speed at which the body produces RBCs or induce response in erythropoietin non-responders.

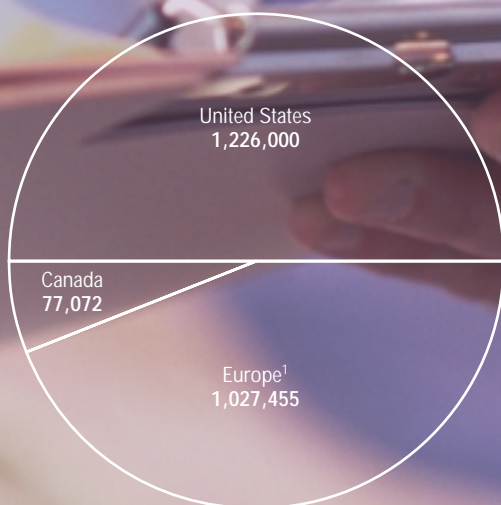


WIFE OF HEMOLINK PHASE II CLINICAL TRIAL PATIENT, DUKE UNIVERSITY

“Not having to worry about a blood transfusion during my husband’s heart surgery was a huge relief to my family and me. As a retired nurse, I know that the blood supply is safer now than ever. But, I also know that your own, fresh blood is best, and that continuous oxygen delivery during heart surgery is critical. I know from research that more than half of all heart surgeries require a blood transfusion. A doctor at Duke University suggested we consider participating in a clinical trial study that may help my husband avoid a blood transfusion during surgery. For that, we were grateful. Participating in the HEMOLINK clinical trial allowed my husband to receive his own, fresh blood back after the surgery. My husband was quickly back to walking miles a day, taking care of our farm, and playing with the grandkids.”



ESTIMATED ANNUAL CABG AND SELECTED ORTHOPEDIC SURGERIES\*



\* Based on Hemosol market research

<sup>1</sup> Belgium, Czech Republic, Denmark, Finland, France, Germany, Iceland, Ireland, Netherlands, Norway, Sweden, U.K., Austria, Greece, Hungary, Italy, Poland, Portugal, Spain, Switzerland

# natural

## ● Two Major Platform Technologies – ● A Rich Pipeline



### A Wide Range of Hemoglobin and Cell Therapeutics in Development

One of Hemosol's greatest assets is its strong research and development team. With expertise in protein chemistry, process scale engineering, cell and molecular biology, and physiology and toxicology, this effective research team has played an invaluable role in moving Hemosol's lead product, Hemolink™ (hemoglobin raffiner), from development through to its current late-phase clinical trials.

Hemosol's R&D activities are based on two platform technologies: protein bioconjugation and cell expansion.

### Protein Bioconjugation

Hemosol's expertise in protein bioconjugation chemistry is currently focused on the chemical modification of hemoglobin for the development of new hemoglobin therapeutics in order to expand the clinical indications for this class of compounds. Products in development include: a starch-hemoglobin conjugate with potential use as an oxygen therapeutic in high volume and post-surgical applications; a hemoglobin/anti-oxidant conjugate designed to prevent oxidative damage during tissue reperfusion; as well as a novel, targeted drug delivery strategy that uses hemoglobin as a drug carrier. This hemoglobin-based drug delivery strategy uses the specific uptake and processing of hemoglobin by the liver for the selective delivery of therapeutic drugs and diagnostic agents and offers a means to treat chronic liver diseases such as viral hepatitis or liver cancer.

In future research, the Hemosol bioconjugation platform may also be applicable to other blood proteins to provide novel or enhanced therapeutic functions.

### Cell Expansion

Cell expansion refers to the process by which a particular type of cell is isolated from other cell types

and then manipulated to reproduce prolifically to create a large population of the desired cell type. Hemosol is pursuing cell expansion in two areas: securing an alternative source of hemoglobin, and developing novel cell therapeutics.

### Alternative Source of Hemoglobin

The current source of hemoglobin for use in the preparation of Hemosol's hemoglobin-based oxygen carriers is human red blood cells. These cells lack the ability to grow and divide and therefore, must be constantly regenerated from stem cells in the bone marrow. Our goal is to develop a source of human hemoglobin independent of collected RBCs.

Hemosol's scientists are working with cells that have the ability to grow and divide in culture and produce human hemoglobin.

This proprietary cell expansion technology has been developed to secure this source of human hemoglobin independent of human donors. This approach may also provide a more reliable and consistent yield of hemoglobin. The development program in this area is in the research phase.

### Cell Therapy

Hemosol scientists broadened the cell expansion platform to work with cells of the immune system, notably specific types of T cells that can be selectively expanded *in vitro* for potential therapeutic reinfusion to treat cancer and possibly other diseases. Large numbers of gamma-delta (TCR $\gamma\delta$ ) T cells may be grown using proprietary methods. TCR $\gamma\delta$  T cells possess innate anti-tumour activity, permitting these cells to be broadly applied to the treatment of cancer. Cell expansion also provides opportunities in the field of cell growth factors. New cell growth factors are under investigation for their effects on T cell expansion and may have important therapeutic potential.



DAVID BELL, VICE PRESIDENT, DRUG DEVELOPMENT

“With the achievement of our immediate goal, the commercialization of HEMOLINK, drawing nearer every day, Hemosol maintains a clear focus on the accelerated development of our pipeline of products. We have achieved an early competitive edge with our commercial-scale manufacturing facility. Similarly, our pipeline of hemoglobin – and cell-based technologies strongly distinguishes us from any of our competitors and provides us with an important future advantage. That pipeline will, I believe, drive enormous growth and ensure the continued success of Hemosol in the years to come.”



#### PRODUCT PIPELINE

PROTEIN BIOCONJUGATION			
Class	Product	Application	Status
HBOC	HRC-101	High volume blood loss	Preclinical/Scale-Up
HBOC	HRC-102	Reperfusion injury	Preclinical
Drug Delivery	HRC-201/2/3/4	Liver Cancer	<i>In Vitro</i> Proof-of-Concept
CELL EXPANSION			
Class	Product	Application	Status
Hemoglobin Production	HRC-301	Hemoglobin source	<i>In Vitro</i> Proof-of-Concept/ Scale-Up
Cell Therapy	HRC-302	Cancer	Phase I
T Cell Factor	HRC-303	Cell growth	Discovery



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# Glossary of Technical and Related Terms

## **Anemia**

Any of a number of serious medical conditions in which the number of red blood cells or the amount of hemoglobin in them is below normal. Anemia may be caused by excessive bleeding, decreased red cell production or increased red cell destruction.

## **Antigen**

Any molecule capable of stimulating an immune response.

## **Antioxidant**

A substance that prevents or slows the breakdown of another substance by oxygen.

## **Biologic License Application (BLA)**

An application to the U.S. Food and Drug Administration for authorization to market a biological product.

## **Biopharmaceutical or Biologic**

Biologics, in contrast to drugs that are chemically synthesized, are derived from living sources. Biological products often represent the cutting-edge of biomedical research and, in time, may offer the most effective means to treat a variety of medical illnesses and conditions that presently have no other treatments available.

## **Blood**

The "circulating tissue" in the body that is the means by which oxygen and nutritive materials are transported to the tissues. It consists of a pale yellow fluid (plasma) in which are suspended red blood cells (erythrocytes), white blood cells (leukocytes) and platelets.

## **Bone Marrow Transplant (BMT)**

A transplant of stem cells from the bone marrow (from another donor or from oneself) to regenerate a patient's ability to produce blood cells.

## **Cell Expansion**

A process by which a certain cell is manipulated to produce a large population of cells.

## **Cell Therapy**

The use of cells to treat disease. Examples include blood transfusion, bone marrow transplantation, skin grafting and the use of specific white blood cell populations to treat infectious disease.

## **Chemotherapy Induced Anemia (CIA)**

A form of anemia that occurs in patients undergoing chemotherapy treatments for cancer. This occurs because certain cancer fighting drugs destroy red blood cells.

## **Chronic Myelogenous Leukemia (CML)**

A form of cancer of the white cells that as it develops can become highly resistant to therapy and rapidly fatal.

## **Coronary Artery Bypass Grafting (CABG) Surgery**

A common type of cardiac surgery performed to bypass blocked vessels within the cardiovascular system, restoring blood flow to the heart.

## **Chemical Cross-linker**

A compound used to stabilize the structure of the hemoglobin molecule thereby allowing for a longer duration of activity.

## **Cross-matching**

The matching of donated whole blood to the prospective patient's blood type.

## **Drug Delivery**

The method of administering drugs to a patient that selectively targets diseased tissue, or that has increased circulation time or less systemic toxicity.

## **Erythropoietin (EPO)**

A hormone that stimulates production of red blood cells (erythrocytes) in bone marrow.

## **Ex Vivo**

Performed within a controlled laboratory environment outside the body for subsequent re-infusion.

## **Food and Drug Administration (FDA)**

The U.S. government agency which regulates the production, quality, safety, and efficacy of biological and pharmaceutical products in the United States.

## **Gamma-delta T Cell**

A type of white blood cell that plays a crucial role as part of the body's immune system. T cells protect against viral infection and can detect and destroy some cancer cells.

## **Hemodilution**

A process whereby one or more units of blood are removed prior to surgery, with the volume replaced by a plasma expander. The patient's own blood can then be re-infused during or following surgery.

## **Hemoglobin**

The protein in the red blood cell that carries oxygen.

## **Hemoglobin Based Oxygen Carrier (HBOC)**

A modified form of hemoglobin, designed to act as an oxygen carrier.

## **Hepatitis**

A viral infection that causes inflammation and damage to the liver. Examples include hepatitis A, B, and C.

## **Human Immunodeficiency Virus (HIV)**

A viral infection that progressively destroys white blood cells and results in impaired immunity.

## **Immunotherapy**

Use of the components of the immune system to treat disease.

## **Intraoperative Autologous Donation (IAD)**

See page 12.

## **Investigational New Drug (IND)**

An active IND is required in order to conduct clinical research in Canada and the U.S. Separate IND submissions must be approved by each national authority (FDA in the USA, and TPP in Canada).

## **Ischemia**

Inadequate blood flow to a tissue or organ, often caused by vessel blockage (occlusion), leading to oxygen deprivation.

## **Leukemia**

A cancer resulting in overproduction of white or red blood cells.

## **Medicines Control Agency (MCA)**

The MCA is the government agency that regulates production, quality, safety, and efficacy of biological and pharmaceutical products in the United Kingdom.

## **Oxygen Therapeutic**

Drugs that were designed to provide the oxygen delivery function, normally provided by the hemoglobin of the RBCs in situations when the body is unable to adequately perform this function either due to loss of blood or a disease state.

## **Plasma**

The fluid component of blood.

## **Platelets**

Cell-like particles that clot blood.

## **Precursors**

Blood-forming cells which give rise to more mature cells.

## **Preoperative Autologous Donation (PAD)**

A procedure in which one's own blood is predeposited up to 4 weeks prior to surgery.

## **Protein Bioconjugate**

A biologic product that is chemically modified to provide novel or enhanced therapeutic functions.

## **Red Blood Cells (RBCs)**

Cells which carry oxygen from the lungs to the tissues. Oxygen delivery is carried out by hemoglobin molecules packed inside each red cell. Packed red cells are suspended in a small amount of plasma. They need to be stored refrigerated and must be transfused within 42 days, depending upon country of use.

## **RBC Salvage**

A procedure in which the patient's own RBCs are saved and recycled (given back to the patient) during surgery.

## **Reperfusion**

To re-establish blood flow after blockage of a vessel.

## **Stem Cell**

The source of all blood cells; an immature cell found in bone marrow that produces mature blood cells.

## **Transfusion**

A medical procedure of administering blood products to a patient. In an allogeneic transfusion the blood transfused is from an anonymous donor. In an autologous donation the patient donates blood for their own later use.

## **Therapeutic Products Programme (TPP)**

The national authority that evaluates and monitors the safety, effectiveness, and quality of drugs, medical devices and other therapeutic products available to Canadians.

## **Unit**

A volume of whole blood (typically 450 mL) or its equivalent in derived blood products.

## **White blood cells**

The cells in the blood that fight infection.

## Shareholder Information

### **Annual Meeting**

The Annual General Meeting of Shareholders will be held May 2, 2002 at 10:00 a.m. The Toronto Stock Exchange Auditorium  
2 First Canadian Place, 130 King Street West  
Toronto, Ontario

### **Stock Listing**

Toronto Stock Exchange Symbol HML  
Nasdaq National Market Symbol HMSL

### **Transfer Agent**

Computershare Trust Company of Canada  
Stock & Bond Transfer Department  
100 University Avenue, 9th Floor  
Toronto, Ontario M5J 2Y1

For change of address, lost stock certificates and other related inquiries, please write to the above address or [caregistryinfo@computershare.com](mailto:caregistryinfo@computershare.com)

### **Auditors**

Ernst & Young, LLP, Toronto, Ontario

### **Shareholder Information**

For annual and quarterly reports, news releases and other investor information, please contact:

### **Hemosol Investor Relations**

Telephone: 416-361-1331  
Toll Free: 800-789-3419  
Fax: 416-815-0080  
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[www.hemosol.com](http://www.hemosol.com)

Certain statements in this Annual Report concerning Hemosol's future prospects constitute "forward-looking statements" under the United States Private Securities Litigation Reform Act of 1995. There can be no assurances that future results will be achieved, and actual results could differ materially from forecasts and estimates. Important factors that could cause actual results to differ materially from forecasts and estimates include, but are not limited to: Hemosol's ability to obtain regulatory approvals for its products; Hemosol's ability to successfully complete clinical trials for its products; technical or manufacturing or distribution issues; the competitive environment for Hemosol's products; the degree of market penetration of Hemosol's products; and other factors set forth in filings with Canadian securities regulatory authorities and the U.S. Securities and Exchange Commission. These risks and uncertainties, as well as others, are discussed in greater detail in the filings of Hemosol with Canadian securities regulatory authorities and the U.S. Securities and Exchange Commission. Hemosol makes no commitment to revise or update any forward-looking statements in order to reflect events or circumstances after the date any such statement is made.

HEMOSOL INC.

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# financial review

Annual Report 2001





## About Hemosol

Hemosol is an integrated biopharmaceutical company developing innovative life sustaining therapies, used initially for the treatment of acute anemia. The Company's immediate focus is on the development and successful commercialization of Hemolink™ (hemoglobin raffiner). Hemosol also is furthering the development of its multi-product pipeline based on proprietary hemoglobin modification and cell expansion technologies.

## About HEMOLINK

HEMOLINK is a life-sustaining therapeutic, designed to deliver oxygen immediately, effectively and safely to the body's tissues and organs. HEMOLINK is a leader in an emerging new class of pharmaceuticals called oxygen therapeutics that reflect a new approach to the treatment of patients suffering from acute anemia.

### SHARE PRICE DATA

	2001			2000		
	High	Low	Close	High	Low	Close
First Quarter	19.95	10.75	14.00	27.00	6.25	18.80
Second Quarter	16.54	12.85	14.00	25.60	14.00	14.55
Third Quarter	14.29	3.98	5.05	18.95	10.25	16.00
Fourth Quarter	8.70	4.45	7.35	17.35	11.25	13.15
Common Shares Outstanding at Year-End	40,993,861			32,269,901		
<b>Common Shares</b> Outstanding at March 1, 2002	<b>41,002,862</b>					

### Financial Review

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# management's discussion and analysis of financial condition and results of operations

*The following information should be read in conjunction with the Company's 2001 consolidated financial statements and notes therein, which are prepared in accordance with Canadian generally accepted accounting principles (Canadian GAAP). These principles differ in certain material respects from United States generally accepted accounting principles (U.S. GAAP). The differences as they affect the consolidated financial statements of the Company are described in Note 13 to the Company's 2001 consolidated financial statements.*

**Note: All figures discussed in this section are stated in Canadian dollars.**

## OVERVIEW

Since the Company's inception, we have devoted substantially all of our resources to research and development programs, clinical trials, regulatory approvals and the development of our manufacturing capabilities and capacity. We have completed a Phase III clinical trial of Hemolink™ (hemoglobin raffiner) in Canada and the U.K. and are currently seeking regulatory approval to launch HEMOLINK in those two markets. Assuming U.K. approval is received in the time period anticipated, the Company will use the Mutual Recognition Procedure to seek further European approvals in 2003. In addition, we are conducting a clinical development program of HEMOLINK in the U.S. with the intention of obtaining regulatory approval to launch there as well. To ensure that the supply of our product will be available to meet projected long-term demand, we are constructing a 300,000-unit production facility and corporate headquarters in Mississauga, Ontario. Until our new manufacturing facility is completed and validated in early 2003, production capacity at our existing pilot facility will be limited to approximately 25,000 units per year.

As a company in its pre-commercial stage of development, to-date we have been dependent primarily upon equity financing to fund our operations. We do not anticipate generating revenue until we introduce HEMOLINK into the Canadian and/or the U.K. markets and subsequently other key European countries. Assuming we obtain necessary regulatory approvals for HEMOLINK, we anticipate we will generate limited revenue in the second half of 2002 from the sale of HEMOLINK. Revenues in 2003 will be dependent on the timing of regulatory approvals for HEMOLINK and for our new manufacturing facility.

We have not yet determined the price at which we intend to sell a unit of HEMOLINK. The price will depend on a variety of factors largely dependent on the data derived from our ongoing and completed clinical trials and, among other things, market practices of governmental health care programs, private health insurers and other third-party medical reimbursers that may impact pricing.

We have not been profitable since inception, and as at December 31, 2001 we had an accumulated deficit of \$183.9 million. We expect that our operating expenses will

increase significantly in the near-term as we incur higher costs to finance our research and development and clinical trials as well as to fund the growth of our business. We also expect to incur interest expenses on funds drawn under our credit facilities in connection with the construction of our new manufacturing facility.

Our operating expenses to-date have consisted of research and development expenses, administration expenses, and marketing and business development expenses. Our research and development expenses are comprised of scientific and process development expenses and regulatory and clinical expenses. Scientific and process development expenses include expenses incurred in connection with our basic and applied research, including all pre-clinical trial activity, the optimizing of our manufacturing process and the costs of producing HEMOLINK for clinical trials. We expense research costs in the year we incur them. We also expense development costs in the year we incur them, unless a development project meets generally accepted accounting criteria for deferral and amortization. To-date, we have not deferred any development costs. Regulatory and clinical expenses include the external costs directly associated with conducting clinical trials and the in-house support required to establish, monitor and report on these trials. Administration expenses include executive and financial management, human resources, and general office expenses. Marketing and business development expenses include market development activities, including the fees of consultants used in support of market research, and expenses relating to investor relations.

We anticipate that once we begin to sell HEMOLINK commercially, our operating costs will increase to include production costs associated with the manufacture of HEMOLINK. These production costs will include the cost of procuring human red blood cells, expenses associated with the manufacture of HEMOLINK (including salary and other costs associated with an expanded manufacturing workforce), ongoing regulatory compliance costs, royalties based on the net sales of our products which are payable under our license agreement with the Canadian Department of National Defense, and plant and equipment amortization costs. We anticipate that marketing and business development expenses will increase in the near-term as we incur expenditures to increase the market awareness of HEMOLINK and complete the recruitment and training of a sales and marketing team for HEMOLINK.

## RESULTS OF OPERATIONS

### YEARS ENDED DECEMBER 31, 2001 AND 2000

#### NET LOSS

Our net loss increased from \$27.6 million or \$0.88 per share for the year ended December 31, 2000 to \$38.6 million or \$0.98 per share for the year ended December 31, 2001, an increase of \$11.0 million. This increase resulted from significantly higher operating expenses in 2001.

## management's discussion and analysis of financial condition and results of operations

### OPERATING EXPENSES

Total operating expenses increased from \$30.7 million for the year ended December 31, 2000 to \$42.4 million for the year ended December 31, 2001, an increase of 39%. Total spending was somewhat lower than expected due to lower than projected patient enrolment in the Company's clinical trial program. Increases for the year are attributed to increased personnel and related costs, consulting costs associated with manufacturing expansion and the Company's clinical/regulatory program, and increased expenditures in medical education and communication.

### MARKETING AND BUSINESS DEVELOPMENT EXPENSES

Marketing and business development expenses increased from \$3.4 million for the year ended December 31, 2000 to \$5.6 million for the year ended December 31, 2001, an increase of 65%. This increase was primarily due to the hiring of experienced and qualified personnel, increased market research, and medical education and communication programs in preparation for product launches in key markets.

### SCIENTIFIC AND PROCESS DEVELOPMENT EXPENSES

Scientific and process development expenses increased from \$15.4 million for the year ended December 31, 2000 to \$18.4 million for the year ended December 31, 2001, an increase of 20%. This increase was primarily due to increased personnel expenses associated with the scale-up of our pilot manufacturing facility to an annual production capacity of approximately 25,000 units and expenses related to the new commercial facility under construction.

### REGULATORY AND CLINICAL EXPENSES

Regulatory and clinical expenses increased from \$8.0 million for the year ended December 31, 2000 to \$11.8 million for the year ended December 31, 2001, an increase of 47%. This increase was due to additional personnel and various consulting services needed to support the Company's medical and clinical activities. As our clinical trials in the U.S. progress, we expect our regulatory and clinical expenses to increase substantially.

### ADMINISTRATION EXPENSES

Administration expenses include the Company's executive, financial, corporate development, and human resource functions as well as the costs of various corporate services. Corporate services includes the costs of information technology and support, security, materials management and purchasing, including hemoglobin sourcing.

Administrative expenses increased from \$3.9 million for the year ended December 31, 2000 to \$6.7 million for the year ended December 31, 2001, an increase of 72%. This increase was due primarily to increased headcount and related recruitment costs and significant increases in insurance costs related to the construction of our new facility and directors and officers liability. The Company also realized various increases associated with becoming a U.S. securities registrant. Certain costs related to corporate services were reflected in Scientific and Process Development expenses in prior years.

### INTEREST INCOME

Interest income increased from \$3.1 million for the year ended December 31, 2000 to \$3.5 million for the year ended December 31, 2001. The increase in interest income was due to substantially higher balances in cash and cash-equivalents, reflecting the completion of a financing in March 2001 in which Hemosol raised gross proceeds of approximately \$108.7 million. We expect interest expenses to increase significantly in future periods as we make drawdowns under our credit facilities.

### AMORTIZATION OF DEFERRED CHARGES

The Company commenced amortization of deferred cash and non-cash costs in 2001 related to the debt financing for the new manufacturing facility. Amortization in 2001 totaled \$360,000.

### RESEARCH AND DEVELOPMENT

During our last three fiscal years, we have allocated a substantial amount of our research and development budget towards developing HEMOLINK. The balance of our research and development budget has been allocated to other pipeline products under development. Our total research and development expenses for HEMOLINK were approximately \$18.5 million, \$20.8 million and \$27.3 million for the fiscal years ended December 31, 1999, 2000 and 2001 respectively. We anticipate that our research and development expenses for HEMOLINK will increase significantly in the near term as we conduct our clinical development program of HEMOLINK in the U.S. and pursue regulatory approval in the U.S. and Europe. Our total research and development expenses for other products under development were approximately \$2.1 million, \$2.6 million and \$2.9 million for the fiscal years ended December 31, 1999, 2000 and 2001, respectively. We anticipate that our research and development expenses for other products under development will increase in the future as we continue the development of these products through pre-clinical studies and initial clinical trials.

quarterly financial data for the years

[thousands of dollars]

	2001				2000			
	qtr 1 3/30/01	qtr 2 6/30/01	qtr 3 9/30/01	qtr 4 12/31/01	qtr 1 3/31/00	qtr 2 6/30/00	qtr 3 9/29/00	qtr 4 12/31/00
REVENUE	0	0	0	0	0	0	0	0
Loss from operations	(10,134)	(11,111)	(10,317)	(10,887)	(6,359)	(6,985)	(7,517)	(9,807)
Net loss for the period	(6,922)	(14,042)	(6,865)	(10,748)	(5,655)	(6,076)	(6,878)	(8,988)
Net loss for the period per common share	0.20	0.35	0.17	0.26	0.20	0.20	0.20	0.28



## ASSET EXPENDITURES

### CAPITAL EXPENDITURES

The Company incurred a total of \$46.1 million in capital expenditures during 2001. Of this, \$44.1 million related to the new facility and \$2.0 million related to the scale up of the current pilot facility and information technology and various lab equipment expenditures. This brings total capital assets net of depreciation to \$60.9 million at December 31, 2001, of which \$56.8 million relates to the new facility (including \$7.7 million in accounts payable).

### NEW MANUFACTURING FACILITY

The construction of our new 120,000 square-foot manufacturing facility and corporate headquarters in Mississauga, Ontario is proceeding on schedule. On December 15, 2001 we moved our offices and labs to this location. Installation of process equipment is expected to be finished in the third quarter 2002 with validation of this 300,000-unit facility to be completed in early 2003. The site will have the further potential for expanding production capacity to 600,000 units per year.

We expect that the total cost of constructing, commissioning and validating this facility will be approximately \$90.0 million. We intend to use approximately \$56.0 million of our cash resources towards its construction, of which we had expended approximately \$49.1 million as of December 31, 2001.

On November 10, 2000, we entered into a \$35 million senior credit facility with National Bank of Canada and The Bank of Nova Scotia to finance a portion of the construction costs of our new manufacturing facility. On December 14, 2000, we entered into a \$12.5 million subordinate credit facility with The Manufacturers Life Insurance Company to fund the balance of construction costs. See "Liquidity and Capital Resources" below.

Our new manufacturing facility is being constructed pursuant to two separate fixed-price contracts. The first contract provides for the design and construction of the base building and the fit-up of the warehouse, offices and laboratories. The second contract provides for the design, procurement and construction of the specialized process equipment and the utilities servicing the process equipment and the process area. These two fixed-price contracts total \$69.0 million, with the remainder of the total cost of \$90.0 million being direct owner costs.

We do not have any material commitment for corporate expenditures other than the construction of our new manufacturing facility.

### PATENTS AND TRADEMARKS

As at December 31, 2001, the Company recorded a \$1.0 million addition to its patent and trademark assets. The majority of this relates to certain drug delivery patents acquired in 2000 with payment occurring over three years plus a 4% royalty on potential product revenues.

## LIQUIDITY AND CAPITAL RESOURCES

As at December 31, 2001, we had \$69.8 million of cash, cash-equivalents and short-term investments.

We raised gross proceeds of approximately \$108.7 million in March 2001 (including approximately \$14.2 million upon the exercise of an over-allotment option) from a public offering of our common shares in the U.S. and Canada. Share issue costs associated with this offering were approximately \$8.4 million.

Hemosol's investment policy is to invest our excess cash in short-term government securities and in at least R-1 mid-rated investment grade corporate commercial paper as determined by Dominion Bond Rating Service to ensure liquidity and preservation of capital. In addition, we periodically enter into forward foreign exchange rate contracts to fix a portion of our U.S.-dollar expenses.

As a result of last year's revisions to the clinical program for HEMOLINK and the subsequent extension of time lines for regulatory approval, the Company is negotiating appropriate amendments to its senior credit facility. With the considerable progress in construction of the new manufacturing facility, Hemosol also is assessing its options concerning the economics of its \$12.5 million subordinated debt facility and has not yet determined whether it will use this facility. Hemosol will not draw down under either facility until the appropriate amendments are agreed to and arrangements are finalized.

We do not currently expect that our cash resources (including our credit facilities) will be sufficient for our anticipated operating and capital expenditures through the end of 2002. Hemosol is pursuing various equity and non-equity financing alternatives. Subject to market conditions, Hemosol intends to raise additional cash reserves during 2002.

### CLINICAL, REGULATORY PROGRESS UPDATE

In November 2001, Hemosol received approval from the U.S. Food & Drug Administration (FDA) to begin a 180-patient clinical trial of HEMOLINK in primary coronary artery bypass grafting (CABG) surgery which will be conducted at centres in the U.S. and the U.K. In January 2002, Hemosol received FDA approval to proceed with a second clinical trial of HEMOLINK in 140 patients undergoing "re-do" CABG surgery which will be conducted at U.S. and European centres. These studies were designed to run concurrently and to be completed towards the middle of 2002. Upon completion of the two studies, the Company plans to review the data with the FDA and design and initiate a third study pivotal for U.S. registration.

A response from Health Canada to the Company's New Drug Submission to market HEMOLINK in Canada remains pending at the end of 2001.

Data from the primary and "re-do" studies will also be used to strengthen the Company's pending U.K. and subsequent European applications. Hemosol plans to respond to questions from the U.K. Medicines Control Agency (MCA) in the third quarter of 2002 and anticipates that the MCA will complete its review by the end of 2002. Hemosol intends to follow the Mutual Recognition Procedure, which could allow the Company to gain approval in other European countries shortly after U.K. approval. The Company has submitted protocols to the FDA for a high-dose general surgery study and a study in patients with chemotherapy-induced anemia; active discussions regarding these trials are ongoing. The variable cost of these two trials represents approximately \$2 million.

## RISKS AND UNCERTAINTIES

Our products are in development and have not yet been marketed commercially. The business of the Company entails significant risks, including: the costs and time involved to obtain required regulatory approvals; the uncertainties involved in clinical testing;

the availability of capital to continue development and commercialization of our products; and competition from other biopharmaceutical companies.

#### REQUIREMENT FOR REGULATORY APPROVALS

In the near-term, our success will depend on our ability to rapidly commercialize HEMOLINK. However, our ability to commercialize HEMOLINK is subject to the regulatory applications that have been submitted in Canada and the U.K. We also intend to market HEMOLINK in the U.S., Europe and other international markets and will require separate regulatory approval from each jurisdiction. If we do not receive the appropriate regulatory approvals, we will not be able to market or sell HEMOLINK and our business will be adversely affected. Regulatory authorities also require separate approval for each additional proposed indication for the use of HEMOLINK. We cannot guarantee that the regulatory authorities will approve HEMOLINK for each indication we propose.

#### LIMITED MANUFACTURING CAPABILITIES

To commercialize HEMOLINK successfully, we must be able to manufacture HEMOLINK in commercial quantities, in compliance with regulatory requirements, at acceptable costs and in a timely manner. To support HEMOLINK's launch in Canada, we have scaled-up our existing manufacturing facility to be capable of producing 25,000 units per year.

#### NEW MANUFACTURING FACILITY

In order to significantly shorten the time to profitable commercialization the Company is building a new 300,000 unit manufacturing facility in anticipation of regulatory approvals. The Company's profitability will be affected if we are unable to achieve sufficient capacity and timely completion and validation of the new facility. The facility will also have to be approved by regulators in the various jurisdictions in which the Company seeks marketing approval for HEMOLINK.

#### DEPENDENCE ON HEMOLINK FOR REVENUE

We will be highly dependent on HEMOLINK sales because HEMOLINK will likely account for substantially all of our revenue for the foreseeable future. To-date, the size of the market for hemoglobin-based products such as HEMOLINK has been described primarily in terms related to the estimated number of red blood cell units utilized in blood transfusions and the potential for some portion to be replaced with such products. In addition, we expect several entirely new markets to emerge for clinical indications in which red blood cells are not currently used. If our assumptions and expectations concerning applications for HEMOLINK and its markets are incorrect, we may not be able to successfully commercialize HEMOLINK and we may not become profitable.

#### PROJECTIONS

Our expectations regarding the success of HEMOLINK and our business are based on projections which may not bear out as we expect. In our press releases and other public documents, we have forecast the accomplishment of objectives material to our success, such as the commencement and completion of clinical trials, anticipated regulatory approval and time of product launch. The actual timing of these events can vary dramatically due to factors such as delays or failures in our clinical trials, the uncertainties inherent in the regulatory approval process and delays in achieving manufacturing capacity and marketing infra-

structure sufficient to commercialize HEMOLINK. We cannot assure you that clinical trials involving HEMOLINK will be successfully completed, that we will make regulatory submissions or receive regulatory approvals as forecasted or that we will be able to adhere to our current schedule for product launch. If we are unable to meet our projections, we will need additional financing in the future.

#### ADDITIONAL FINANCING

We require substantial working capital to properly develop, manufacture and market our products. Our planned cash requirements may vary materially in response to a number of factors including:

- research and development and clinical trial results;
- delays in the construction, commissioning and validation of our new manufacturing facility;
- changes in any aspect of the regulatory process; and;
- delays in obtaining regulatory approval for HEMOLINK and/or our new manufacturing facility.

Our capital-raising efforts could involve the issuance and sale of additional common shares. We may not be able to raise any debt or equity financing if and when needed, and if so, our business will be adversely impacted.

#### CLINICAL TRIALS

In order to seek regulatory approval for the marketing and sale of our products, we must first successfully complete both pre-clinical studies and clinical trials. These studies and trials must demonstrate that the products are safe and effective for the clinical use for which approval is sought.

Our other hemoglobin-based oxygen carriers under development, our hemoglobin-based drug delivery technology and our cell expansion technology for alternative sources of hemoglobin are in pre-clinical studies. We have been cleared to conduct a Phase I clinical trial in Canada for our cell and immune therapy application for our cell expansion technology.

Even if regulatory authorities approve HEMOLINK, its manufacture, marketing and sale will be subject to ongoing regulation, including inspection and market surveillance for compliance with Good Manufacturing Practice regulations in Canada and other jurisdictions. In addition, regulatory authorities could withdraw a previously approved product from the market upon receipt of newly discovered information and/or require additional and potentially expensive studies in areas outside existing approved indications. Adverse results from or unanticipated delays in our clinical trials or failure to receive the appropriate regulatory approvals could adversely impact our business. Unanticipated changes in existing regulations or adoption of new regulations could adversely affect the manufacture and marketing of our products. Ongoing government regulation and plant inspections could cause unexpected delays and adversely impact our business.

#### MARKET AND DISTRIBUTION RISKS

Our success will also depend on our ability to market and distribute HEMOLINK effectively. However, we do not yet have in place the sales force and other distribution arrangements we believe we will need to market HEMOLINK effectively, and we have no experience in commercial sales. In addition, HEMOLINK's commercial success will depend on its acceptance by the medical community and third-party medical insurers as clinically useful, cost-effective and safe.

#### PERSONNEL

Our products require sophisticated management, research and development, marketing and sales, regulatory and clinical development personnel. Our success depends on our ability to attract, train and retain such personnel. The market for the highly trained personnel we require is very competitive due to the limited number of people available with the necessary technical skills and understanding of our products and technology. If we fail to attract and retain qualified personnel, our business operations and product development efforts could suffer.

#### INTELLECTUAL PROPERTY MATTERS

We rely on patent, copyright, trade secret and trademark laws to limit the ability of others to compete with us using the same or similar technology. However, these laws afford only limited protection and may not adequately protect our rights to the extent necessary to sustain any competitive advantage we may have.

Third-parties may claim that our products infringe upon their intellectual property rights. This risk is exacerbated by the fact that the validity and breadth of medical technology patents involve complex legal and factual questions for which important legal principles remain unresolved.

In addition, because patent applications can take many years to issue, there may be currently pending applications of which we are unaware and which may later result in issued patents that our products infringe upon. There could also be existing patents of which we are not aware that our products may infringe upon. As we commercialize HEMOLINK and as competitors commercialize other hemoglobin-replacement products in the future, the possibility of patent infringement claims against us may increase.

#### SOURCES OF HEMOGLOBIN AND OTHER MANUFACTURING COMPONENTS

Although we expect to be able to purchase sufficient quantities of human red blood cells to support HEMOLINK's commercialization, we may need to develop other sources of hemoglobin if this source of supply is disrupted or if the market demand for HEMOLINK is greater than initially anticipated. We are advancing our proprietary cell expansion technology for the purpose of developing an additional or alternative supply of hemoglobin from cells grown outside the body. However, our cell expansion technology is still in the early stages of development.

The Company utilizes a number of other raw materials and components that are currently provided by sole sourced suppliers. The Company will need to identify and qualify alternative backup sources for these components and/or identify other actions to ensure continuous supply of key materials.

#### PRODUCT LIABILITY CLAIMS

The testing and marketing of medical products, even after regulatory approval, has an inherent risk of product liability. We maintain product liability insurance coverage in the total amount of \$30.0 million relating to Phase I, Phase II, and Phase III clinical trials. We intend to obtain more extensive coverage as the development of our products progresses. Our profitability would be adversely affected by a successful product liability claim in excess of our insurance coverage.

#### HEMOGLOBIN COULD CONTAIN INFECTIOUS AGENTS

Any product derived from human blood, notwithstanding the rigorous testing procedures now used for the selection of donor blood, can conceivably carry infectious agents, known or as yet unknown, that were present in the source blood. In the manufacture of HEMOLINK the procedure by which the hemoglobin is purified includes a sequence of validated steps to remove or inactivate viral and other potentially infectious material. While the Company is confident that its process has achieved the highest standard of purity there is a theoretical and remote risk that an infectious agent could remain in the product or resist these stringent procedures.

#### TECHNOLOGICAL DEVELOPMENTS IN THE BIOMEDICAL FIELD

The biomedical field, which is the market for our products, is characterized by rapid technological change, new and improved product introductions, changes in regulatory requirements and evolving industry standards.

Although we are currently developing a new series of products based on research and development activities conducted to-date, we may not be successful in developing or introducing to the market these or any other new products or technology. If we fail to develop and deploy new products on a successful and timely basis, we may become non-competitive and unable to recoup the research and development and other expenses we incur to develop and test new products.

#### OUTLOOK

We expect to incur substantial losses in 2002 and 2003 as a result of our clinical trial program, expenses related to regulatory approvals, increased manufacturing output and increased spending in market development activities. Assuming we obtain the necessary regulatory approvals for HEMOLINK, we anticipate that we will generate limited revenues in 2002 from the sale of HEMOLINK manufactured at our pilot facility this year. Revenues from the new facility will not occur until 2003 and will be dependent on facility regulatory approvals and levels of output achieved.

Hemosol expects operating expenses to increase as enrollment in the clinical trial program progresses. Depending on the level of patient treatment per month, expenses are expected to average approximately \$5.0 million per month for the first six months of 2002. Operating expenses beyond this period will depend on a number of factors and guidance will be updated accordingly; however, we do not expect operating expenditures for the second half of 2002 to be less than \$30.0 million.

#### FORWARD LOOKING STATEMENTS

To the extent any statements made in this document contain information that is not historical, these statements are essentially forward looking and are subject to risks and uncertainties, including the difficulty of predicting regulatory approvals, acceptance and demand for new biopharmaceutical products, the impact of competitive products and pricing, new product development and launch, reliance on key strategic alliances, availability of raw materials, the regulatory environment, fluctuations in operating results and other risks. Many risks and uncertainties are inherent in the biopharmaceutical industry; others are more specific to our business. Many of the significant risks related to our business are described in our Form 20-F filing with the SEC.

# Management's Responsibility for Financial Reporting

DECEMBER 31, 2001 AND DECEMBER 31, 2000

The accompanying financial statements of Hemosol Inc. and all the information in this annual report are the responsibility of management and have been approved by the Board of Directors.

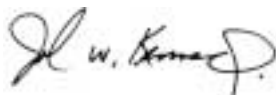
The financial statements have been prepared by management in accordance with Canadian generally accepted accounting principles. When alternative accounting methods exist, management has chosen those it deems most appropriate in the circumstances. Financial statements are not precise since they include certain amounts based on estimates and judgement. Management has determined such amounts on a reasonable basis in order to ensure that the financial statements are presented fairly, in all material respects. Management has prepared the financial information presented elsewhere in the annual report and has ensured that it is consistent with that in the financial statements.

Hemosol Inc. maintains systems of internal accounting and administrative controls of high quality, consistent with reasonable cost. Such systems are designed to provide reasonable assurance that the financial information is relevant, reliable and accurate and the Company's assets are appropriately accounted for and adequately safeguarded.

The Board of Directors is responsible for ensuring that management fulfills its responsibilities for financial reporting and is ultimately responsible for reviewing and approving the financial statements. The Board carries out this responsibility principally through its Audit Committee.

The Audit Committee is appointed by the Board and all its members are outside directors. The Committee meets periodically with management, as well as the external auditors, to discuss internal controls over the financial reporting process, auditing matters and financial reporting issues, to satisfy itself that each party is properly discharging its responsibilities, and to review the annual report, the financial statements and the external auditors' report. The Committee reports its findings to the Board for consideration when approving the financial statements for issuance to the shareholders. The Committee also considers, for review by the Board and approval by the shareholders, the engagement or re-appointment of the external auditors.

Financial statements have been audited by Ernst & Young LLP, the external auditors, in accordance with Canadian generally accepted auditing standards on behalf of the shareholders. Ernst & Young LLP has full and free access to the Audit Committee.



JOHN W. KENNEDY  
President  
& Chief Executive Officer



LEE HARTWELL  
Chief Financial Officer  
& Vice President, Corporate Development

## Auditors' Report

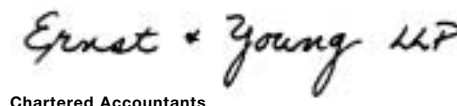
TO THE SHAREHOLDERS OF HEMOSOL INC.

We have audited the consolidated balance sheets of Hemosol Inc. as at December 31, 2001 and 2000 and the consolidated statements of loss and deficit and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with Canadian generally accepted auditing standards. Those standards require that we plan and perform an audit to obtain reasonable assurance whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation.

In our opinion, these consolidated financial statements present fairly, in all material respects, the financial position of the Company as at December 31, 2001 and 2000 and the results of its operations and its cash flows for the years then ended in accordance with Canadian generally accepted accounting principles.

Toronto, Canada,  
February 6, 2002



Chartered Accountants



- Hemosol Inc.
- (A Development Stage Company)
- Incorporated under the laws of Ontario

## consolidated balance sheets

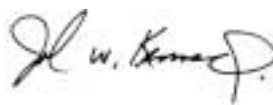
As at December 31 [thousands of dollars]	2001 \$	2000 \$
<b>ASSETS</b>		
CURRENT		
Cash and cash equivalents	2,785	42,027
Short-term investments [note 2]	67,052	–
Amounts receivable and other assets [note 7c]	3,156	1,967
Inventory and supplies [note 3]	1,731	635
<b>TOTAL CURRENT ASSETS</b>	<b>74,724</b>	<b>44,629</b>
Capital assets, net [note 4]	60,899	17,089
Patents and trademarks, net [note 5]	1,964	1,020
Deferred charges, net [note 6]	6,830	7,690
<b>TOTAL OTHER ASSETS</b>	<b>69,693</b>	<b>25,799</b>
	<b>144,417</b>	<b>70,428</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
CURRENT		
Accounts payable and accrued liabilities [note 4 (iii)]	13,605	5,358
<i>Commitments and contingencies [notes 4, 8 and 11]</i>		
SHAREHOLDERS' EQUITY		
Share capital [note 7 (a)]	306,135	192,923
Contributed surplus [note 7(b)]	8,535	8,535
Deficit	(183,858)	(136,388)
<b>TOTAL SHAREHOLDERS' EQUITY</b>	<b>130,812</b>	<b>65,070</b>
	<b>144,417</b>	<b>70,428</b>

See accompanying notes

**On behalf of the Board:**



MITCHELL J. KOSTUCH  
Director



JOHN W. KENNEDY  
Director

## consolidated statements of loss and deficit

	2001	2000
Years ended December 31 [thousands of dollars]	\$	\$
<b>EXPENSES</b>		
Research and development		
Scientific and process	18,386	15,357
Regulatory and clinical	11,771	8,008
Administration	6,731	3,864
Marketing and business development	5,561	3,439
	42,449	30,668
Loss from operations before the following	(42,449)	(30,668)
Amortization of deferred charges	(360)	–
Foreign currency translation gain	970	29
Interest income	3,488	3,069
Loss before income taxes	(38,351)	(27,570)
Provision for income taxes <i>[note 9]</i>	226	27
NET LOSS FOR THE YEAR	(38,577)	(27,597)
Deficit, beginning of year	(136,388)	(104,174)
Share issue costs	(8,893)	(4,617)
DEFICIT, END OF YEAR	(183,858)	(136,388)
BASIC AND DILUTED LOSS PER SHARE	\$ (0.98)	\$ (0.88)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING [000'S]	39,215	31,467

See accompanying notes

## consolidated statements of cash flows

	2001	2000
Years ended December 31 [thousands of dollars]	\$	\$
<b>OPERATING ACTIVITIES</b>		
Net loss for the year	(38,577)	(27,597)
Add (deduct) items not involving cash		
Amortization of capital assets	2,303	1,597
Amortization of patents and trademarks	74	75
Amortization of deferred charges	360	–
Compensation cost for non-employee stock options [note 7 (a)]	134	–
Foreign currency translation gain	(42)	–
	(35,748)	(25,925)
Changes in non-cash working capital balances related to operations		
Amounts receivable and other assets	(1,189)	(1,577)
Inventory and supplies	(1,096)	(635)
Accounts payable and accrued liabilities [note 4 (iii)]	99	(1,324)
<b>CASH USED IN OPERATING ACTIVITIES</b>	<b>(37,934)</b>	<b>(29,461)</b>
<b>INVESTING ACTIVITIES</b>		
Patent and trademark costs	(568)	(354)
Purchase of short-term investments	(87,647)	–
Sale of short-term investments	20,595	–
Purchase of capital assets [note 4 (iii)]	(38,415)	(13,286)
<b>CASH USED IN INVESTING ACTIVITIES</b>	<b>(106,035)</b>	<b>(13,640)</b>
<b>FINANCING ACTIVITIES</b>		
Proceeds on issuance of common shares	113,078	76,234
Proceeds from sale of the third party option [note 7 (b)]	–	8,535
Payment of share issue costs [note 6 (ii)]	(8,393)	(4,617)
Payment of deferred charges	–	(4,790)
<b>CASH PROVIDED BY FINANCING ACTIVITIES</b>	<b>104,685</b>	<b>75,362</b>
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS DURING THE YEAR</b>	<b>(39,284)</b>	<b>32,261</b>
Effect of exchange rates on cash and cash equivalents	42	–
Cash and cash equivalents, beginning of year	42,027	9,766
<b>CASH AND CASH EQUIVALENTS, END OF YEAR</b>	<b>2,785</b>	<b>42,027</b>

See accompanying notes

## notes to consolidated financial statements

[All dollar amounts in thousands, except as noted]

December 31, 2001 and 2000

### 1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Hemosol Inc. [the "Company" or "Hemosol"] is an integrated biopharmaceutical company developing a family of products for the treatment of human hemoglobin deficiencies. To date, the Company has not earned significant revenues and is considered to be an enterprise in the development stage.

The Company has financed its cash requirements primarily from share issuances. The Company's ability to realize the carrying value of its assets is dependent on successfully bringing its products to the market and achieving future profitable operations, the outcome of which cannot be predicted at this time. It will be necessary for the Company to raise additional funds for the continuing development of its products.

The consolidated financial statements of the Company have been prepared by management in accordance with Canadian generally accepted accounting principles within the framework of the significant accounting policies summarized below:

#### BASIS OF CONSOLIDATION

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Hemosol Research Corporation [formerly Cell Expansion Technologies Inc.], 749235 Ontario Limited, Hemosol (USA) Inc. and Hemoglobin Company Inc. All significant intercompany transactions and balances are eliminated.

#### CASH AND CASH EQUIVALENTS

The Company considers all highly liquid instruments with maturities of 90 days or less at date of acquisition to be cash equivalents.

#### SHORT-TERM INVESTMENTS

Short-term investments are generally held to maturity. Short-term investments are liquid investments with maturities between 90 days and one year from the date of acquisition and are valued at the lower of cost and market.

#### INVENTORY AND SUPPLIES

Inventory and supplies are valued at the lower of cost, determined on a first-in first-out basis, and replacement cost.

#### INVESTMENT TAX CREDITS

Investment tax credits are accrued when qualifying expenditures are made and there is reasonable assurance that the credits will be realized. The Company accounts for the investment tax credits using the cost reduction method.

#### PATENTS AND TRADEMARKS

Patent and trademark costs are carried at cost less accumulated amortization and are amortized on a straight-line basis over their economic life, which is estimated to be 17 years.

#### CAPITAL ASSETS

Capital assets are recorded at cost, less accumulated amortization and related investment tax credits. Amortization commences when capital assets are available for use and is provided using the straight-line method at the following annual rates, which are designed to charge operations with the cost of the assets over their estimated useful lives:

Building and building services equipment	25 years
Technical equipment	5 – 15 years
Furniture and fixtures	5 years
Computer equipment	3 years
Leasehold improvements	over term of lease

#### LEASES

Leases are classified as either capital or operating. Those leases which transfer substantially all the risks and benefits of ownership of property to the Company are accounted for as capital leases. All other leases are accounted for as operating, with rental payments expensed as incurred.

#### INCOME TAXES

The Company follows the liability method of accounting for income taxes. Under this method, future income tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities, measured using the substantively enacted tax rates and laws expected to be in effect when the differences are expected to reverse.

#### RESEARCH AND DEVELOPMENT COSTS

Research costs are expensed in the year incurred. Development costs are expensed in the year incurred unless a development project meets Canadian generally accepted accounting criteria for deferral and amortization. No development costs have been deferred to date.

#### DEFERRED DEBT ISSUE COSTS

Deferred debt issue costs represent the costs related to the establishment of the Company's senior credit facility and subordinated credit facility. The costs are being amortized using the straight-line method over the expected term of the facility.

#### STOCK-BASED COMPENSATION PLANS

The Company has two stock-based compensation plans, which are described in *note 7*. No compensation expense is recognized for these plans when the stock or stock options are issued to employees. Stock options and warrants issued to non-employees are recorded at fair value and are included in expenses. Stock options and warrants issued related to share issuances are not valued. Any consideration received on the exercise of stock options and warrants or purchase of stock is credited to share capital.

#### FOREIGN CURRENCY TRANSLATION

The Company's U.S. subsidiary, Hemosol (USA) Inc., is considered an integrated foreign operation and its accounts are translated using the temporal method. Under this method, monetary assets and liabilities denominated in U.S. dollars are translated into Canadian dollars at the year-end exchange rate. Other assets are translated at historical exchange rates. Revenues and expenses are translated at average rates prevailing during the year, except for amortization, which is translated at historical rates. Translation gains and losses are included in net loss for the year.

#### LOSS PER SHARE

The Company has retroactively adopted the new recommendations for determining loss per common share issued by The Canadian Institute of Chartered Accountants. Diluted loss per share reflects the dilution that would occur if outstanding stock options and warrants were exercised or converted into common shares using the treasury stock method. The computation of diluted loss per share does not include stock options and warrants with dilutive potential that would have an anti-dilutive effect on loss per share. The inclusion of the Company's stock options and warrants in the computation of diluted loss per share would have an anti-dilutive effect on loss per share and are therefore excluded from the computation. Consequently, there is no difference between basic loss per share and diluted loss per share. There was no impact on the consolidated financial statements as a result of the adoption of these new recommendations.

#### FINANCIAL INSTRUMENTS

The fair value of the Company's financial instruments contained within these consolidated financial statements approximates their carrying value due to the short-term maturities of these instruments.

#### USE OF ESTIMATES

The preparation of consolidated financial statements in conformity with Canadian generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the dates of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from those estimates.

### 2. SHORT-TERM INVESTMENTS

Short-term investments consist of R1 Mid to R1 High Canadian and U.S. corporate debt securities in the amount of \$36,075 and \$30,043 [U.S.\$18,859], respectively. They are carried at cost plus accrued interest of \$934, which approximates market value.

### 3. INVENTORY AND SUPPLIES

Inventory and supplies to be used in the production of Hemolink™ (hemoglobin raffiner) amounted to \$1,458 [2000 – \$553] and \$273 [2000 – \$82], respectively.



#### 4. CAPITAL ASSETS

Capital assets consist of the following:

	2001		2000	
	Cost \$	Accumulated Amortization \$	Cost \$	Accumulated Amortization \$
Land	2,782	–	2,782	–
Building and building services equipment [i]	11,239	–	9,950	–
Technical equipment [i], [ii]	47,777	8,408	9,876	7,107
Furniture and fixtures	6,868	644	681	609
Computer equipment	1,639	999	1,098	669
Leasehold improvements	8,364	7,719	8,169	7,082
	<b>78,669</b>	<b>17,770</b>	32,556	15,467
Less accumulated amortization	17,770		15,467	
<b>NET BOOK VALUE</b>	<b>60,899</b>		17,089	

[i] Construction on the manufacturing facility was partially completed when the Company took occupancy on December 15, 2001. The Company has committed to spend approximately \$30,000 on the manufacturing facility in 2002 to complete construction.

[ii] Technical equipment in the manufacturing facility is still under construction. The carrying value of technical equipment not yet available for use is \$36,611.

[iii] At December 31, 2001, capital asset obligations included in accounts payable and accrued liabilities totaled \$7,698 [2000 – \$1,800].

#### 5. PATENTS AND TRADEMARKS

Patents and trademarks consist of the following:

	2001 \$	2000 \$
Patent and trademark costs	2,455	1,437
Less accumulated amortization	491	417
<b>NET BOOK VALUE</b>	<b>1,964</b>	1,020

#### 6. DEFERRED CHARGES

Deferred charges consist of the following:

	2001		2000	
	Cost \$	Accumulated Amortization \$	Cost \$	Accumulated Amortization \$
Deferred debt issue costs [i]	7,190	360	7,190	–
Deferred share issue costs [ii]	500	500	500	–
	<b>7,690</b>	<b>860</b>	7,690	–
Less accumulated amortization	860		–	
<b>NET BOOK VALUE</b>	<b>6,830</b>	–	7,690	–

[i] Deferred debt issue costs represent costs related to the establishment of the Company's senior credit facility and subordinated credit facility [notes 7[a] and 10] in 2000. The non-cash portion of these costs amounted to \$2,900. Amortization of the deferred debt issue costs commenced in 2001 and amounted to \$860.

[ii] Deferred share issue costs in 2000 relate to the Company's prospectus filed in March 2001 which have been included in share issue costs in 2001.

## 7. SHARE CAPITAL AND CONTRIBUTED SURPLUS

### [A] SHARE CAPITAL

#### Authorized

Unlimited common shares

Unlimited special shares, issuable in series 51,786 Series D special shares, voting, ranking equally with common shares

#### Issued

The changes in issued share capital and non-employee warrants and options are as follows:

	2001		2000	
	#	\$	#	\$
<b>COMMON SHARES</b>				
Balance, beginning of year	32,269,901	190,023	24,669,301	113,789
Issued during the year for cash	8,050,000	108,678	7,072,333	74,253
Employee options exercised for cash	296,860	1,435	283,817	874
Issue of common shares under employee share purchase plan for cash	33,400	264	32,450	429
Non-employee warrants and options exercised for cash	343,700	2,701	212,000	678
Balance, end of year	40,993,861	303,101	32,269,901	190,023
<b>NON-EMPLOYEE WARRANTS AND OPTIONS</b>				
Balance, beginning of year	1,111,872	2,900	279,700	–
Issued during the year	20,000	134	1,044,172	2,900
Exercised during the year	(343,700)	–	(212,000)	–
Expired during the year	(60,950)	–	–	–
Balance, end of year	727,222	3,034	1,111,872	2,900
<b>TOTAL SHARE CAPITAL</b>		<b>306,135</b>		192,923

On January 29, 1999, 320,000 broker's warrants were issued to underwriters. During 2001, the remaining 67,700 [2000 – 212,000] broker's warrants were exercised for gross proceeds of \$217. No outstanding warrants remain related to this issuance.

On January 17, 2000, the Company issued 5,520,000 common shares at a purchase price per common share of \$8.35 for gross proceeds of \$46,092. In addition, the Company granted 276,000 after-market support options to the underwriters. Each after-market support option entitled the holder to purchase one common share at a price of \$9.00 during the period ended October 31, 2001. During 2001, all 276,000 support options were exercised.

On March 27, 2000, the Company issued 1,219,000 common shares at a purchase price per common share of \$19.00 for gross proceeds of \$23,161. In addition, the Company granted 60,950 after-market support options to the underwriters. Each after-market support option entitled the holder to purchase one common share at a price of \$19.00 during the period ended October 5, 2001. During 2001, all 60,950 support options expired.

On November 8, 2000, the Company issued 333,333 common shares for gross proceeds of \$5,000 in a private placement transaction. In addition, a 16-month option was granted to purchase an additional 222,222 common shares at \$22.50 per share [note 8]. To date, none of these options have been exercised.

On November 10, 2000, the Company issued 85,000 common share purchase warrants at an exercise price of \$18.00 per share in connection with the finalization of the senior credit facility [note 10[a]]. These warrants have been recorded at an estimated fair value of \$624 using the Black-Scholes option pricing model and are exercisable at any time until their expiry date in November 2005. To date, none of these warrants have been exercised.

On December 14, 2000, the Company issued 400,000 common share purchase warrants at an exercise price of \$18.00 per share in connection with the finalization of the subordinate credit facility [note 10[b]]. These warrants have been recorded at an estimated fair value of \$2,276 using the Black-Scholes option pricing model and are exercisable at any time until their expiry date in December 2005. To date, none of these warrants have been exercised.

On March 1, 2001, the Company issued 7,000,000 common shares in the United States at a purchase price per common share of \$13.50 (U.S.\$8.78) for gross proceeds of \$94,500 (U.S.\$61,460). In addition, the Company granted 1,050,000 over-allotment options entitling the underwriters to purchase one common share at a price of \$13.50 (U.S.\$8.78) during the period ended March 31, 2001. During 2001, all 1,050,000 over-allotment options were exercised for gross proceeds of \$14,175 (U.S.\$9,219).

notes to consolidated financial statements

During 2001, the Company granted 20,000 options with a fair value determined using the Black-Scholes option pricing model of approximately \$134 to external consultants for services performed. These options have an expiry date of 10 years from issuance and vest over a three-year period. The fair value of these options is included in net loss for the year. To date, none of these options have been exercised.

[B] CONTRIBUTED SURPLUS

During 2000, the Company sold its transferable option to purchase Hemosol shares related to an arrangement with a third party for net proceeds of \$8,535, which has been recorded as contributed surplus in the consolidated balance sheets.

[C] EMPLOYEE STOCK PURCHASE PLAN

During 1999, the Company implemented an employee stock purchase plan [the "ESPP"] to enable non-management employees to purchase up to 1,000 shares in the Company at 90% of the then current stock price [as defined in the ESPP]. The ESPP also provides non-interest bearing loans to designated employees to be used to subscribe for common shares. Loans are repayable over a maximum three-year period. Employees shall have one year from the date on which they are notified of eligibility to participate in the plan. During the year ended December 31, 2001, 33,400 [2000 - 32,450] common shares were issued to employees under this plan for gross proceeds of approximately \$264 [2000 - \$429]. As at December 31, 2001, loans to employees under the ESPP, which are collateralized by the underlying securities, totaled \$382 [2000 - \$339] with a market value of common shares of \$456 [2000 - \$747] and are included in amounts receivable and other assets.

[D] EMPLOYEE STOCK OPTION PLAN

The Company has granted options to purchase common shares of the Company to certain of its directors, executive officers and key employees.

The options expire 10 years from the date of issuance. Options granted prior to December 7, 2000 vest over a four-year period and options granted subsequent to December 7, 2000 vest over a three-year period. In 2001, 296,860 [2000 - 283,817] options were exercised for cash consideration of approximately \$1,435 [2000 - \$874].

A summary of the status of the Company's employee stock option plan as at December 31, 2001 and 2000, and changes during the years ended on those dates, is presented below:

	2001		2000	
	Shares #	Weighted average exercise price \$	Shares #	Weighted average exercise price \$
OUTSTANDING, BEGINNING OF YEAR	1,812,665	8.81	1,449,564	4.17
Granted	793,700	8.24	685,917	16.00
Exercised	(296,860)	4.83	(283,817)	3.08
Forfeited	(196,583)	9.85	(38,999)	4.71
OUTSTANDING, END OF YEAR	2,112,922	9.05	1,812,665	8.81
OPTIONS EXERCISABLE, END OF YEAR	757,653	7.74	732,798	5.69

The following table summarizes information relating to the employee stock options as at December 31, 2001:

Range of exercise prices \$	Outstanding			Exercisable	
	Weighted #	Weighted average remaining contractual life [years]	average exercise price \$	Weighted #	average exercise price \$
1.70 to 2.75	281,546	5.27	2.15	218,906	2.12
3.85 to 5.70	462,355	7.81	4.91	209,710	5.05
6.30 to 9.90	543,757	8.66	6.49	108,557	6.90
11.15 to 16.65	726,729	8.93	14.68	175,552	15.14
18.80 to 22.60	98,535	8.34	20.92	44,928	20.87
1.70 to 22.60	2,112,922	8.10	9.05	757,653	7.74

## 8. DOMPÉ AGREEMENT

In October 2000, the Company entered into a memorandum of understanding with Dompé Farmaceutici S.P.A. ["Dompé"], an Italian pharmaceutical company, pursuant to which the Company agreed to negotiate exclusively with Dompé to form a strategic alliance for the promotion, marketing and sale of Hemolink™ (hemoglobin raffimer) in Southern and Eastern Europe.

Pursuant to the memorandum of understanding, in November 2000, Dompé invested \$5,000 in the Company by purchasing 333,333 common shares. In addition, the Company granted Dompé a 16-month option to purchase an additional 222,222 common shares at \$22.50 per share [note 7[a]].

## 9. INCOME TAXES

Significant components of the Company's future tax assets and liabilities as at December 31, are as follows:

	2001	2000
	\$	\$
Future tax assets		
Non-capital losses	5,491	5,581
Investment tax credits	18,843	12,091
Scientific research and experimental development expenses	45,217	40,871
Share issue costs	2,432	1,672
Capital assets and patents and trademarks	1,579	1,437
	73,562	61,652
Valuation allowance	(73,562)	(61,652)
Future tax liabilities	-	-
<b>NET FUTURE TAX ASSETS</b>	<b>-</b>	<b>-</b>

The provision for income taxes recorded during fiscal 2001 of \$226 [2000 – \$27] relates to Large Corporations Tax and U.S. Federal income tax payable.

The Company has available research and development expenditures for income tax purposes, which may be carried forward indefinitely to reduce future years' taxable income. The potential income tax benefits associated with these expenditures have not been recorded in the accounts. The total of such expenditures accumulated to December 31, 2001 is approximately \$150,000 [2000 – \$122,000].

At December 31, 2001, the Company has accumulated tax losses for federal and provincial purposes in Canada. The Company also has unclaimed Canadian scientific research investment tax credits. The losses and investment tax credits can be used to offset future years' Canadian taxable income. The tax losses and investment tax credits expire as follows:

	Federal \$	Ontario \$	Investment tax credits \$
2003	-	2,659	1,865
2004	-	2,016	1,820
2005	-	5,910	1,908
2006	597	9,018	1,743
2007	-	1,827	2,151
2008	12,102	12,102	2,117
2009	-	-	3,077
2010	-	-	6,647
2011	-	-	5,581
	12,699	33,532	26,909

## 10. CREDIT FACILITIES

[A] On November 10, 2000, the Company entered into a \$35 million senior credit facility [the "Facility"]. The Facility consists of a non-revolving construction loan which may be converted by the Company or the lenders into a term loan. Borrowings under the construction loan will bear interest at a rate of prime plus 3% per annum. Any such borrowings collateralized by cash will bear interest at a rate of prime plus 0.25% per annum. The principal amount outstanding under the construction loan, together with all interest accrued thereon, will be due and payable on June 30, 2003.

The Company may convert outstanding principal amounts under the non-revolving construction loan into a non-revolving amortizing term loan of up to \$35 million at any time prior to June 30, 2003 if certain conditions are met. The maximum term of the term loan is three years from the date the construction loan is converted into a term loan, provided that the term loan may not mature beyond November 10, 2005. Quarterly principal payments on the term loan will be required based on an amortization of 10 years, with the remaining outstanding principal balance due and payable on the maturity of the term loan. Borrowings under the term loan will bear interest at a rate of prime plus 2.25% per annum. Any such borrowings which are collateralized by cash will bear interest at a rate of prime plus 0.25%.

Borrowings under the Facility became available when the Company expended approximately \$40 million on the construction of the manufacturing facility.

The availability of the Facility is subject to certain covenants and conditions. The Facility is collateralized by a first charge over all of the Company's real and personal property. The Company will also be required to provide, concurrently with each borrowing under the Facility, cash collateralization equal to approximately 50% of the principal amount of each borrowing. This required cash collateralization reduces upon the Company's achievement of specific milestones and financial ratios.

[B] On December 14, 2000, the Company entered into a \$12.5 million subordinate credit facility which consists of a non-revolving construction loan that may be converted by the Company or the lender into a term loan. Borrowings under the construction loan will bear interest at a rate of 15% per annum.

The Company may convert outstanding principal amounts under the construction loan into a non-revolving non-amortizing term loan of up to \$12.5 million at any time prior to June 30, 2003 if certain conditions are met. The maximum term of the term loan is three years from the date the construction loan is converted into a term loan, provided that the term loan may not mature beyond December 14, 2005. Borrowings under the term loan will bear interest at a rate of 15% per annum.

The availability of the subordinate credit facility is subject to the same covenants and substantially the same conditions as the Facility and is secured by a second charge over all of the Company's real and personal property.

## 11. LICENSE AGREEMENTS

The Company has entered into a license agreement with the Canadian Department of National Defence dated July 30, 1986, as amended and restated March 1, 1999, pursuant to which it was granted exclusive world-wide licenses to certain inventions and processes related to HEMOLINK. The agreement expires upon the last to expire of [i] the patent rights licensed thereunder and [ii] any patents obtained by the Company related to the patent rights licensed by the Canadian Department of National Defence.

Under this agreement, the Company would be required to pay royalties at rates based upon the net selling price of any products which may be produced which embody these licensed technologies, as well as a percentage of any consideration received for sub-licensing such technologies.

This agreement also commits, and the Company is paying, a minimum annual royalty at the greater of \$10 or 20% of royalties due in the immediately preceding year. The Company has the right to commute future royalties in consideration of the payment of the greater of \$4,000 or five times the previous year's annual royalties.

## 12. RESEARCH AND DEVELOPMENT PROJECT

The Company is focused on the development of a portfolio of products for the treatment of hemoglobin deficiencies, or anemia. The Company's focus is the commercialization of their first product, HEMOLINK, which is a highly purified, human-derived hemoglobin replacement product. HEMOLINK is designed to provide safe, immediate oxygen-carrying capability and to eliminate the need for donor red blood cell transfusions in patients suffering from acute anemia. HEMOLINK is currently being evaluated for use in cardiac surgery, orthopedic surgery and chemotherapy-induced anemia.

Research and development costs cumulative from July 11, 1985 through December 31, 2001 related to HEMOLINK amounted to \$137,979.

## 13. UNITED STATES GENERALLY ACCEPTED ACCOUNTING PRINCIPLES

The Company prepares its consolidated financial statements in accordance with Canadian generally accepted accounting principles ["Canadian GAAP"], which differ in certain material respects from those applicable in the United States ["U.S. GAAP"].

The material differences as they apply to the Company's consolidated financial statements are as follows:

[A] Balance sheet adjustments:

	2001	2000
	\$	\$
<b>AMOUNTS RECEIVABLE AND OTHER ASSETS</b>		
Balance under Canadian GAAP	3,156	1,967
Adjustment for employee stock purchase loans [i]	(382)	(339)
<b>BALANCE UNDER U.S. GAAP</b>	<b>2,774</b>	1,628
<b>PATENTS AND TRADEMARKS</b>		
Balance under Canadian GAAP	1,964	1,020
Adjustment for patents and trademarks [ii]	(1,964)	(1,020)
<b>BALANCE UNDER U.S. GAAP</b>	<b>-</b>	-
<b>SHARE CAPITAL</b>		
Balance under Canadian GAAP	306,135	192,923
Adjustment for share issue costs [iii]	(20,457)	(11,564)
Adjustment for employee stock purchase loans [i]	(382)	(339)
<b>BALANCE UNDER U.S. GAAP</b>	<b>285,296</b>	181,020
<b>DEFICIT</b>		
Balance under Canadian GAAP	(183,858)	(136,388)
Adjustment for share issue costs [iii]	20,457	11,564
Adjustment for patents and trademarks [ii]	(1,964)	(1,020)
<b>BALANCE UNDER U.S. GAAP REFERRED TO AS "DEFICIT ACCUMULATED DURING THE DEVELOPMENT STAGE" [note 13/f]</b>	<b>(165,365)</b>	(125,844)

[i] **Employee stock purchase plan**

Under Canadian GAAP, loans provided to employees for the purchase of shares may be either recorded as accounts receivable or deducted from share capital, depending on certain criteria. Under U.S. GAAP, such loans must be deducted from share capital.

[ii] **Patents and trademarks**

Under Canadian GAAP, patent and trademark costs are carried at cost less accumulated amortization and are amortized on a straight-line basis over their estimated economic life. Under U.S. GAAP, specifically Statement of Financial Accounting Standard ["SFAS"] No. 2, "Accounting for Research and Development Costs," patent and trademark costs that have no alternative future uses, and therefore no separate economic values, must be expensed as incurred.

[iii] **Share issue costs**

Under U.S. GAAP, the carrying value of capital stock is shown net of share issue costs. Under Canadian GAAP, share issue costs are reported as an adjustment to deficit.

[iv] **Short-term investments**

In accordance with Canadian GAAP, the Company's short-term investments are carried at the lower of cost or market based on quoted market prices. Under U.S. GAAP, these investments would have been classified as held-to-maturity, and would be recorded at amortized cost. There is no significant difference between cost under Canadian GAAP and amortized cost for U.S. GAAP. Accrued interest is included in the short-term investments balance, which in total approximates fair value.

[B] The components of stockholders' equity under U.S. GAAP are as follows:

	2001	2000
	\$	\$
Share capital	285,296	181,020
Contributed surplus	8,535	8,535
Deficit accumulated during the development stage	(165,365)	(125,844)
	<b>128,466</b>	63,711



notes to consolidated financial statements

[C] Reconciliation of net loss under Canadian and U.S. GAAP

	2001	2000
	\$	\$
Net loss for the year, under Canadian GAAP	(38,577)	(27,597)
Adjustment for patents and trademarks	(944)	(279)
<b>NET LOSS AND COMPREHENSIVE LOSS, UNDER U.S. GAAP</b>	<b>(39,521)</b>	<b>(27,876)</b>
<b>NET LOSS PER SHARE, UNDER U.S. GAAP</b>	<b>(1.01)</b>	<b>(0.89)</b>
<b>WEIGHTED AVERAGE NUMBER OF SHARES, UNDER U.S. GAAP [ROUNDED TO THE NEAREST THOUSAND SHARE]</b>	<b>39,168</b>	31,452

[D] Cash flow adjustments:

	2001	2000
	\$	\$
<b>OPERATING ACTIVITIES</b>		
Balance under Canadian GAAP	(37,934)	(29,461)
Adjustment for patents and trademarks (additions)	(568)	(354)
Adjustment for employee stock purchase loans	43	232
<b>BALANCE UNDER U.S. GAAP</b>	<b>(38,459)</b>	<b>(29,583)</b>
<b>INVESTING ACTIVITIES</b>		
Balance under Canadian GAAP	(106,035)	(13,640)
Adjustment for patents and trademarks	568	354
<b>BALANCE UNDER U.S. GAAP</b>	<b>(105,467)</b>	<b>(13,286)</b>
<b>FINANCING ACTIVITIES</b>		
Balance under Canadian GAAP	104,685	75,362
Adjustment for employee stock purchase loans	(43)	(232)
<b>BALANCE UNDER U.S. GAAP</b>	<b>104,642</b>	<b>75,130</b>

[E] Stock-based compensation:

The Company accounts for compensation expense for certain members of its employee stock option plan under the provisions of Accounting Principles Board Opinion 25, "Accounting for Stock Issued to Employees". No such expense is required to be determined under Canadian GAAP. Since the exercise price of the Company's employee stock options equals the market price of the underlying stock on the date of grant, no compensation expense has been recognized under U.S. GAAP.

Had compensation cost for the employee stock option plan been determined based upon fair value at the grant date for awards under this plan consistent with the methodology prescribed under SFAS No. 123, "Accounting for Stock-based Compensation", the Company's net loss and loss per share would have changed to the pro forma amounts indicated below:

	2001	2000
	\$	\$
Net loss under U.S. GAAP	(39,521)	(27,876)
Estimated stock-based compensation costs	(2,644)	(885)
<b>PRO FORMA NET LOSS FOR THE YEAR</b>	<b>(42,165)</b>	<b>(28,761)</b>
<b>PRO FORMA NET LOSS PER SHARE</b>	<b>(1.08)</b>	<b>(0.91)</b>
<b>WEIGHTED AVERAGE FAIR VALUE OF STOCK OPTIONS GRANTED DURING THE YEAR</b>	<b>7.77</b>	10.48

The fair values of all options granted during 2001 and 2000 were estimated using the Black-Scholes option pricing model with the following weighted average assumptions:

	2001	2000
Expected option life [years]	5	5
Volatility	0.659	0.539
Risk-free interest rate	4%	4%
Dividend yield	-	-

The Black-Scholes model, used by the Company to calculate option values, as well as other accepted option valuation models, were developed to estimate fair value of freely tradable, fully transferable options without vesting restrictions, which significantly differ from the Company's stock option awards. These models also require highly subjective assumptions, including future stock price volatility and expected time until exercise, which greatly affect the calculated values. Accordingly, management believes that these models do not necessarily provide a reliable single measure of the fair value of the Company's stock option awards.

[F] DEVELOPMENT STAGE ENTERPRISE

Under U.S. GAAP, specifically SFAS No. 7, "Accounting and Reporting of a Development Stage Enterprise," the following additional disclosures are required:

[i] Consolidated statement of loss and deficit

	Cumulative from July 11, 1985 through December 31, 2001
	\$
REVENUE	7,285
Research and development	147,555
Administration	30,332
Marketing and business development	9,000
	186,887
Loss from operations before the following	(179,602)
Interest income	14,909
Amortization of deferred charges	(360)
Foreign exchange gain	999
Loss before income taxes	(164,054)
Provision for income taxes	(253)
NET LOSS FOR THE PERIOD	(164,307)
Deficit, beginning of period	-
Dividends	(933)
Share redemption premium	(125)
DEFICIT, END OF PERIOD	(165,365)

notes to consolidated financial statements

[ii] Consolidated statement of cash flows

	Cumulative from July 11, 1985 through December 31, 2001
	\$
CASH USED IN OPERATING ACTIVITIES	(143,731)
CASH USED IN INVESTING ACTIVITIES	(138,516)
CASH PROVIDED BY FINANCING ACTIVITIES	284,990
Effect of exchange rates on cash and cash equivalents	42
NET INCREASE IN CASH AND CASH EQUIVALENTS DURING THE PERIOD	2,785

[iii] Share capital:

	#	Cumulative from July 11, 1985 through December 31, 2001 \$
<b>COMMON SHARES</b>		
Shares issued for cash	39,752,129	296,347
Employee options exercised for cash	655,532	2,446
Issue of common shares under ESPP for cash	28,150	418
Compensation warrants exercised for cash	596,000	3,508
Shares returned and cancelled	(100,000)	-
	40,931,811	302,719
<b>NON-EMPLOYEE WARRANTS AND OPTIONS</b>		
Issued relating to equity issuances	838,872	-
Issued relating to credit facilities	485,000	2,900
Issue of options to non-employees	20,000	134
Exercised	(555,700)	-
Expired	(60,950)	-
	727,222	3,034
Share issue costs		(20,457)
		285,296

**15. COMPARATIVE CONSOLIDATED FINANCIAL STATEMENTS**

The comparative consolidated financial statements have been reclassified from statements previously presented to conform to the presentation of the 2001 consolidated financial statements.

# hemosol

## Shareholder Information

**Annual Meeting:**

The Annual General Meeting of Shareholders will be held May 2, 2002 at 10:00 a.m. The Toronto Stock Exchange Auditorium  
2 First Canadian Place, 130 King Street West  
Toronto, Ontario

**Stock Listing:**

Toronto Stock Exchange Symbol HML  
Nasdaq National Market Symbol HMSL

**Transfer Agent:**

Computershare Trust Company of Canada  
Stock & Bond Transfer Department  
100 University Avenue, 9th Floor  
Toronto, Ontario M5J 2Y1

For change of address, lost stock certificates and other related inquiries, please write to the above address or [caregistryinfo@computershare.com](mailto:caregistryinfo@computershare.com)

**Auditors:**

Ernst & Young, LLP, Toronto, Ontario

**Shareholder Information:**

For annual and quarterly reports, news releases and other investor information, please contact:

**Hemosol Investor Relations**

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Toll Free: 800-789-3419  
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[www.hemosol.com](http://www.hemosol.com)

Certain statements in this Annual Report concerning Hemosol's future prospects constitute "forward-looking statements" under the United States Private Securities Litigation Reform Act of 1995. There can be no assurances that future results will be achieved, and actual results could differ materially from forecasts and estimates. Important factors that could cause actual results to differ materially from forecasts and estimates include, but are not limited to: Hemosol's ability to obtain regulatory approvals for its products; Hemosol's ability to successfully complete clinical trials for its products; technical or manufacturing or distribution issues; the competitive environment for Hemosol's products; the degree of market penetration of Hemosol's products; and other factors set forth in filings with Canadian securities regulatory authorities and the U.S. Securities and Exchange Commission. These risks and uncertainties, as well as others, are discussed in greater detail in the filings of Hemosol with Canadian securities regulatory authorities and the U.S. Securities and Exchange Commission. Hemosol makes no commitment to revise or update any forward-looking statements in order to reflect events or circumstances after the date any such statement is made.

**HEMOSOL INC.**

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