



## Next-Generation, All-Human Fibrin Sealant and Thrombin

### Snapshot

November 2, 2007

Haemacure Corporation (“Haemacure” or “the Company”) is a specialty biotherapeutics company developing human, high-value therapeutic proteins based on a patented, high-yield **fibrinogen**<sup>†</sup> and **thrombin** extraction and purification technology. Haemacure’s product pipeline includes two next-generation biosurgical product candidates designed for use by surgeons in the operating room to achieve rapid **hemostasis**. The lead candidate is Hemaseel<sup>®</sup>HMN, a pivotal phase human **fibrin** sealant that has already demonstrated safety and efficacy in 151 human subjects and patients. Fibrin sealants are biological products used during surgery to stop bleeding, seal tissues, and speed wound healing. The Company is also developing one of the components of its fibrin sealant, Hemaseel<sup>®</sup>Thrombin, into a separate surgical **hemostatic** agent that helps blood to clot. Moreover, in one of its **plasma fractions**, Haemacure has discovered four proteins for which the Company believes that significant, expanding markets exist, as well as seven enzymes that may have potential as **Orphan Drugs**. These proteins and enzymes are at an early, investigational stage. Pending successful development, they may increase Haemacure’s revenues per liter of **plasma**. The Company estimates that its revenues per liter could be several times above industry averages, due to the high yield of its extraction technology. The Company also sells two FDA-cleared fibrin sealant delivery devices—HemaSyst<sup>™</sup> and HemaMyst<sup>™</sup>. Well over \$50 million has been invested to develop Haemacure’s extraction technology. The Company is headquartered in Montréal, Canada, with a manufacturing facility in Sarasota, Florida, that is expected to be completed in mid-2008.

### Recent Financial Data

Ticker (Exchange)	HAE.TO (TSX)
Recent Price (11/02/07)	C\$0.12
52-week Range	C\$0.06 - C\$0.29
Shares Outstanding*	163.8 million
Market Capitalization	C\$19.7 million
Avg. 3-month Volume	349,392
Insiders and Shareholders +5%	40%
Institutional Shareholders	72%
EPS (Qtr. ended 07/31/07)	(C\$0.01)
Employees	6



\* At October 31, 2007.

### Key Points

- The current worldwide hemostasis market is estimated at approximately US\$675 million, and Haemacure believes that it could expand to US\$1.5 billion by 2015.
- The Company’s intellectual property portfolio comprises various trademarks, patents, and patent applications in 24 countries, including the U.S., Canada, and countries in Europe.
- Haemacure entered into a technology acquisition alliance with UTEK Corp. (UTK-AMEX) for the search and acquisition of technologies that are compatible with the Company’s product candidates, in order to develop new applications or product lines.
- Baxter International Inc.’s (BAX-NYSE) fibrin sealant, Tisseel<sup>®</sup> VH, contains **aprotinin**, a **bovine** protein that has been associated with severe adverse reactions. Preliminary findings of a clinical trial involving Bayer HealthCare Pharmaceuticals Inc.’s Trasylol<sup>®</sup> (bovine aprotinin) suggest that aprotinin, compared to other drugs, increases the risk of death. Likewise, King Pharmaceuticals, Inc.’s (KG-NYSE) Thrombin-JMI<sup>®</sup> is of bovine origin and has, on occasion, been associated with abnormalities in hemostasis, including severe bleeding and thrombosis. In contrast, Haemacure’s next-generation product candidates use only human proteins, rather than animal proteins, and contain no aprotinin.
- Haemacure’s corporate leadership possesses an extensive understanding of the surgical hemostat marketplace as well as financing, mergers and acquisitions, restructuring, and company turnarounds.
- At September 30, 2007, liquidities were C\$7.4 million versus C\$519,300 at October 31, 2006, following the closing in January 2007 of a non-brokered private placement that generated gross proceeds of C\$12.5 million. Net proceeds to Haemacure were approximately C\$11.5 million.

<sup>†</sup>**BOLD WORDS ARE REFERENCED IN THE GLOSSARY ON PAGES 42-44.**



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## Executive Overview

*All amounts are in U.S. dollars unless otherwise specified.*

Haemacure Corporation (“Haemacure” or “the Company”) is a specialty biotherapeutics company developing high-value, human therapeutic proteins for commercialization, based on a patented, high-yield fibrinogen and thrombin extraction and purification technology. The Company has two next-generation, plasma-based product candidates: Hemaseel<sup>®</sup>HMN, a human fibrin sealant to enter pivotal Phase II/Phase III clinical trials, and Hemaseel<sup>®</sup>Thrombin, an active, absorbable hemostatic agent that has yet to undertake clinical trials. The Hemaseel<sup>®</sup>HMN fibrin sealant has adhesive and sealing properties as well as the mechanical strength to attach tissues together, lasting through the first phase of the body’s healing process. Fibrin sealant is also believed to have adhesion prevention properties and to be an efficient drug delivery vehicle. Hemaseel<sup>®</sup>Thrombin is an active, absorbable, surgical hemostatic agent and can be used alone or in combination with **biomaterials**. It is also a component of fibrin sealant. Both product candidates are for use by surgeons in the operating room to control bleeding, seal wounds, accelerate the wound healing process, and reduce potential infections, among other functions.

Furthermore, in one of its plasma fractions, Haemacure discovered **albumin, plasminogen, immunoglobulin**, and alpha-1 proteinase inhibitor (A1PI), as well as enzymes used for the treatment of **Gaucher’s, Fabry’s, Hurler’s, Pompe’s, Hunter’s, Morquio’s, and Schindler’s** diseases. However, the Company requires further analysis to determine the concentration and quality of these discovered proteins and enzymes. Haemacure seeks to develop these proteins and enzymes in collaboration with pharmaceutical and biotechnology companies.

The successful development and commercialization of the proteins and enzymes present in Haemacure’s plasma fractions may allow the Company to generate revenue from what would have been discarded plasma after the extraction of the fibrin sealant proteins. As such, Haemacure believes that it could increase its revenue per liter of plasma, the Company’s raw material, to multiples of the industry average.

In addition, the Company currently sells two FDA-cleared fibrin sealant delivery devices—HemaSyst<sup>™</sup> and HemaMyst<sup>™</sup>.

### Hemostasis

Hemostasis is the process by which bleeding is stopped and clotting begins. When bleeding occurs, fibrinogen, a blood protein, interacts with thrombin, also a blood protein, in a specific process to induce **coagulation** (clot formation). Fibrinogen is thus converted into fibrin threads, forming a web-like mesh to trap blood cells, which hardens to become a clot.

In surgical procedures, where quick control of blood flow is important, achieving rapid hemostasis is an important clinical issue. Surgeons use a variety of hemostatic agents to externally stimulate and expedite coagulation without the need to rely on natural, slower factors to execute the process. Two products commonly used to achieve hemostasis are fibrin sealants and thrombin. Surgeons also use passive hemostats, such as **gelatin** and oxidized regenerated cellulose.

### Fibrin Sealant

Fibrin sealant is a biological adhesive that can be used in almost all surgical procedures to seal and glue tissues, and quickly achieve hemostasis. It is made from the combination of two proteins: fibrinogen and thrombin. Once it is applied, fibrin sealant quickly forms a white, rubber-like mass that strengthens as it sets, creating a sealant and an adhesive that lasts through the first phase of the body’s healing process.

In addition to “gluing” tissues together, fibrin sealant is believed to have applications in drug delivery and adhesion prevention. In terms of drug delivery, Haemacure believes that fibrin sealant can deliver medication to a specific area of the body, since the sealant is gradually and safely resorbed by the body. When applied to surfaces held apart from each other, it polymerizes, or solidifies, on each surface, thereby preventing the surfaces from adhering together once they come in contact.



Fibrin sealant provides a number of benefits to physicians, patients, and the healthcare industry as a whole. These include inducing rapid and efficient coagulation, decreasing the risk of post-surgery internal bleeding, decreasing post-surgery hospital stays (which may also provide economic benefits), and reducing the number of blood transfusions during surgery as well as the potential for infection, among other functions and benefits listed in Table 5 (page 17).

In the U.S., top commercial fibrin sealants include Baxter's Tisseel<sup>®</sup> VH and OMRIX Biopharmaceuticals, Inc.'s (OMRI-NASDAQ) Evicel<sup>™</sup>. One of the components of Tisseel<sup>®</sup> VH is aprotinin, a bovine protein. As a result, the product's labeling is cautionary and relates to immunologic reactions and sensitivities to bovine products. Alternatively, Evicel<sup>™</sup> is the first non-animal fibrin sealant in the U.S. (approved for its second indication in May 2007), but is only labeled for liver or vascular surgery.

### *Thrombin*

While thrombin is a component of fibrin sealant, it also has a standalone application as an active, absorbable, surgical hemostatic agent. When compared to **sutures**, hemostatic agents (such as Haemacure's thrombin) offer notable advantages, including reduced infection and scarring and a decreased need for anesthesia (Source: MedMarket Diligence LLC's *Worldwide Surgical Sealants, Glues and Wound Closure Market, 2007*). Hemaseel<sup>®</sup>Thrombin may be used alone or in combination with biomaterials, such as **collagen** or gelatin, to create an absorbable hemostatic dressing that can be applied to the bleeding surface.

The future of thrombin usage may hinge upon the availability of a safe human thrombin preparation (Source: *Thrombosis and Haemostasis 2004*). Currently, there are only two FDA-approved thrombin products: King Pharmaceuticals' Thrombin-JMI<sup>®</sup>, which is derived from bovine plasma, and OMRIX and Ethicon, Inc.'s Evithrom, a human plasma-derived alternative to Thrombin-JMI<sup>®</sup>. Bovine proteins are known to cause potentially severe side effects and **immunogenicity** complications in humans, and are associated with abnormalities in hemostasis.

Haemacure is working toward the market introduction of safe and entirely human formulations of both fibrin sealant and thrombin. The Company uses fibrinogen and thrombin extracted from human plasma and does not use any bovine or other species' materials. A description of Haemacure's patented extraction technology is presented below.

### **Haemacure's Technology**

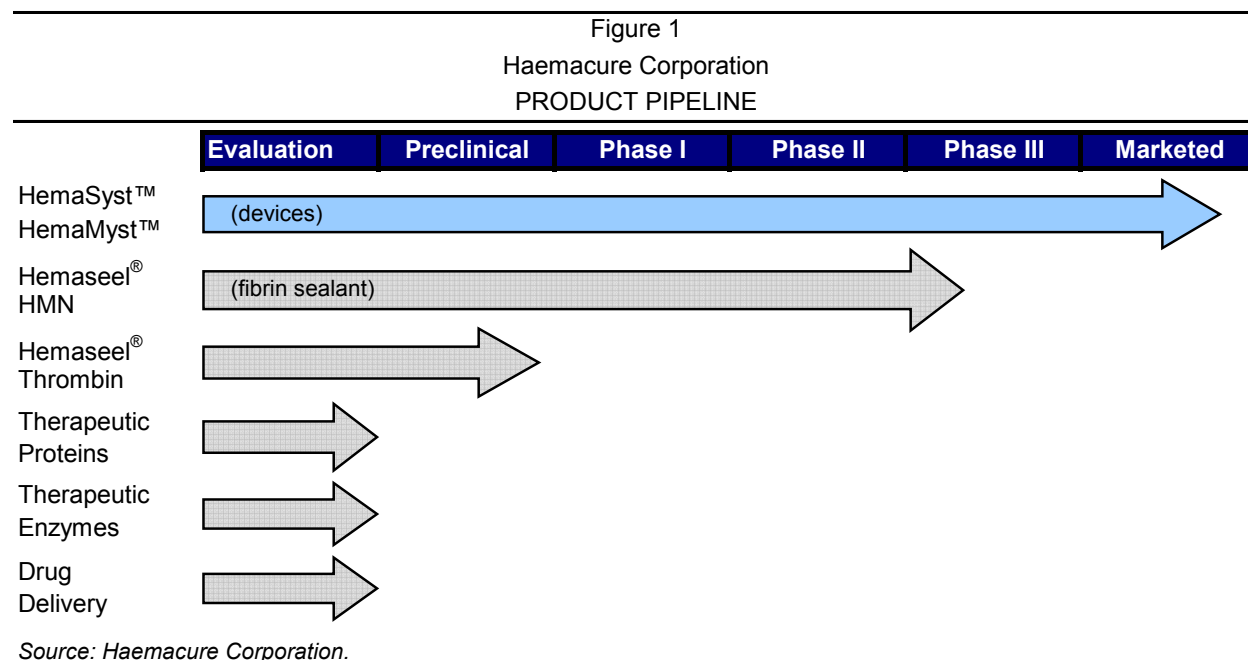
The Company's novel patented technology provides for the extraction and purification of fibrinogen and thrombin from human plasma. Plasma is the residual component of blood that remains once the red blood cells, white blood cells, and **platelets** have been removed. It is a clear liquid that consists of approximately 90% water and 10% protein molecules.

Over \$50 million has been invested to develop and patent Haemacure's fibrinogen and thrombin extraction technology, or process. The Company optimized its technology specifically for fibrinogen and thrombin, delivering fibrinogen and thrombin yields that it believes to be superior to those derived from the traditional **Cohn fractionation** process.

The traditional Cohn fractionation process was developed in the 1940s to maximize the extraction of albumin. Consequently, it delivers lower yields for fibrinogen and thrombin than Haemacure's process, resulting in higher costs of goods for extracted proteins. When compared to the Cohn process, Haemacure believes that its extraction process has the following advantages: (1) improved purification; (2) a more gentle protein separation, which could maintain protein concentration and quality versus some of the harsher aspects of the Cohn process; (3) a higher quality fibrin sealant with improved clot performance and reconstitution time; and (4) higher fibrinogen and thrombin yields. The end result is higher revenues per liter of plasma processed.

## Product Pipeline

Figure 1 illustrates Haemacure's pipeline, followed by a summary of each product and product candidate.



### *Hemaseel®HMN*

Haemacure's fibrin sealant was tested in 151 human subjects and patients. The product was found to be safe, with no reported serious adverse experiences attributable to the product. Clinical data demonstrated a shortened time to hemostasis in a vascular access graft study and suggested a trend in surgeon-dependent reduction in blood loss in total knee replacement surgery. Product quantities for the Phase II trials were manufactured by ZLB Central Laboratory Blood Transfusion Service of the Swiss Red Cross ("ZLB"), then a major shareholder of Haemacure, in Bern, Switzerland.

Haemacure is now in the process of establishing a manufacturing facility. Once the facility is completed, which is scheduled for mid-2008, the Company plans to conduct pivotal Phase II/Phase III clinical trials under its existing **Investigational New Drug (IND)** application open with the FDA. New pivotal Phase II/Phase III trials are required as Hemaseel®HMN's planned commercial manufacturing facility is different from where it was manufactured for previous clinical trials. Haemacure seeks to begin pivotal Phase II/Phase III trials during the first quarter 2009 and could receive regulatory approval in the U.S. and Europe toward the end of 2010 or beginning of 2011.

### Shipping Fibrin Sealant for Evaluation

Haemacure recently equipped and staffed a laboratory in Montréal, where the Company has commenced producing small volumes of its fibrin sealant to respond to requests from potential partners for evaluation in various applications. Haemacure plans on commencing delivery of its sample fibrin sealant to these potential partners before the end of 2007.

### *Hemaseel®Thrombin*

Thrombin is one of the two protein components of Haemacure's fibrin sealant. As such, its biological effectiveness has been reflected in its functional use in the Hemaseel®HMN clinical trials. Similarly, as a component of the Company's fibrin sealant, the safety of Haemacure's thrombin is implicit in the demonstrated safety of the fibrin sealant. Hemaseel®Thrombin leverages the safety and efficacy profile that was established in the fibrin sealant clinical trials and may, as a result, have a shorter clinical timeline



with minimized risks associated with its trials than it would otherwise. Hemaseel<sup>®</sup> Thrombin is to enter the clinical process, scheduled to occur concurrently with Hemaseel<sup>®</sup>HMN's pivotal trials.

### *Specialty Therapeutic Proteins*

Haemacure has investigational-stage specialty proteins and enzymes that it discovered in one of its plasma fractions. Fractions consist of the remaining plasma after extracting a protein. The Company's extraction technology produces two plasma fractions, one resulting from the extraction of fibrinogen and the other from thrombin. Haemacure seeks to enter into collaborations and partnerships with pharmaceutical and biotechnology companies to advance its specialty therapeutic proteins.

### *HemaSyst<sup>™</sup> and HemaMyst<sup>™</sup>*

HemaSyst<sup>™</sup> is a system of 10 tips that attach to a dual-syringe applicator, enabling use with manual sprays, malleable **cannula** shafts (soft tubes to be inserted into a body cavity), and **laparoscopic** attachments. HemaMyst<sup>™</sup> is Haemacure's proprietary aerosol device that can deliver fibrin sealant and other fluids over a broad area. It has a focused spray tip that enables access to confined spaces. Both of these products are currently being sold by Haemacure directly.

### **Market Opportunities**

In 2005, the Freedonia Group, Inc., an international business research company, valued the U.S. medical and dental adhesive and sealant industry at approximately \$1 billion, which included fibrin sealants as well as other materials. Demand in this industry is estimated to grow by 8.4% annually through 2009 due to an increasing acceptance of using adhesives and sealants in a surgical setting and to new product introductions. Specifically, the worldwide fibrin sealant market is valued at roughly \$400 million, which Haemacure believes could expand by 5% to 10% annually over the next five years as surgeons learn more about the benefits of fibrin sealants and as next-generation products with improved efficacy and safety are introduced.

In 2006, worldwide sales of topical, absorbable, surgical hemostatic agents were estimated at roughly \$595 million and forecast to reach \$842 million by 2011. Market drivers include increasing numbers of surgeries being performed; a trend toward minimally invasive surgeries, which could benefit from improved hemostasis products; and demand growth in the European surgical marketplace. Presently, surgical wounds are the most common type of wound, with a worldwide incidence of approximately 97 million and a compound annual growth rate (CAGR) of 3.1%, which is second only to chronic wounds (CAGR of 7.4%) (Source: *Worldwide Surgical Sealants, Glues and Wound Closure Market, 2007*).

Furthermore, the plasma protein market was valued between approximately \$8.5 billion and \$9 billion in 2004 and is forecast to grow to approximately \$12.9 billion by 2010 (Source: the Marketing Research Bureau [[www.marketingresearchbureau.com](http://www.marketingresearchbureau.com)]).

### **First-Patient-In**

On October 24, 2007, Haemacure announced a two-phase manufacturing strategy that seeks to have the first patient undergo surgery in the Company's pivotal Phase II/Phase III fibrin sealant clinical trials during the first quarter 2009. The strategy entails establishing a 15,000-square foot manufacturing facility by mid-2008, where product will be manufactured for clinical trials and commercial launch, and subsequently expanding the facility by 25,000 square feet. The facility is to occupy premises currently leased by Haemacure in Florida.

Setting up the small-scale facility requires significantly lower capital expenditures than the Company originally planned. Accordingly, Haemacure will finance the first phase of its new strategy in part with existing liquidities and seek financing for manufacturing equipment. The timeline for the commercial launch of the fibrin sealant from the small-scale facility is anticipated by the end of 2010 or start of 2011.

Haemacure believes that its two-phase strategy could have the following benefits for the Company: (1) it does not require additional equity to establish the small-scale facility; and (2) it places the first patient in the clinic during the first quarter 2009.



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### *Custom Formulation and Production*

Once the Company has commenced commercial production of its products in the large-scale facility, it plans on using the small-scale facility for custom development and production of its products to meet specific formulation requirements of life sciences companies that could use Haemacure's products with their products.

In addition to exploiting the biosurgical applications of its products, Haemacure is positioning itself to become an exclusive, long-term supplier of fibrin sealant to the drug delivery and regenerative medicine markets.

### **Corporate Information**

Haemacure was incorporated on August 19, 1991, as 2743281 Canada Inc. In December 1991, the Company changed its name to H.A.C. Health Assurance Corporation and, in May 1993, to Haemacure Corporation. Haemacure completed its initial public offering (IPO) in 1996 and now trades on the Toronto Stock Exchange (TSX) under the symbol HAE.TO.

From June 1998 until the end of January 2004, the Company sold a fibrin sealant, under its trademark Hemaseel APR<sup>®</sup>, under license from Baxter Healthcare SA (a subsidiary of Baxter) in the U.S. only. This product was identical and from the same source as Baxter's Tisseel<sup>®</sup>, sold by Baxter at the time in the U.S. and other countries. The license agreement was terminated in October 2003 and Haemacure ceased all activities related to the sale of Hemaseel APR in January 2004. The Company gained significant insight into the fibrin sealant marketplace by selling Hemaseel APR over five years, including becoming acquainted with surgeons, operating room staff, and surgical applications.

After a reorganization, and ceasing all activities related to the sale of Hemaseel APR, Haemacure raised C\$5.2 million in a brokered private placement in March 2004. The Company also commissioned a feasibility study for a manufacturing facility where it could produce its products. However, the Company considered the construction costs estimate to be excessive, and thus sought contract manufacturing for its two product candidates. Yet, the lack of manufacturing control that contract manufacturing entails and recent consolidation of available contract manufacturers has caused Haemacure to opt for in-house manufacturing.

In January 2007, Haemacure raised C\$12.5 million in a non-brokered private placement, with net proceeds of approximately C\$11.5 million.

### *Headquarters and Employees*

Haemacure is headquartered in Montréal, Québec, Canada, with a product development laboratory in the Incubateur J.A. Bombardier (Montréal). The Incubateur is an initiative of the Université de Montréal and École Polytechnique. Haemacure also has a wholly owned U.S. subsidiary in Sarasota, Florida. The subsidiary, Haemacure Corporation, is incorporated in the State of Delaware. Also in Sarasota, the Company is setting up a manufacturing facility for its product candidates. Haemacure employs six full-time individuals and four consultants.



## Growth Strategy

Since its January 2007 private placement, Haemacure has repositioned itself to focus on its strengths, leverage its position as an independent developer of next-generation biosurgical and therapeutic protein products with exclusive ownership of its extraction technology, and maximize shareholder value. Leveraging assets is not limited to developing new products, but includes bringing the Company's products and product candidates into new markets and developing them for additional applications alone and in combination with other products. In addition, management has reevaluated its cost structure, redistributing costs in areas of value.

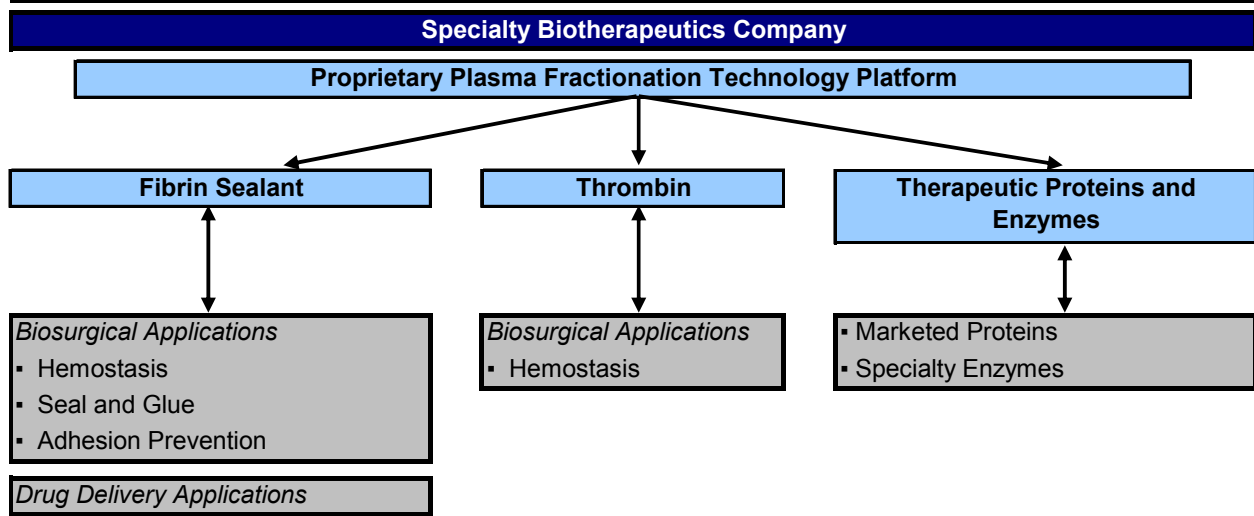
In line with its repositioned growth strategy, Haemacure has completed the steps listed below.

- Revisited and validated assumptions related to product offerings, target markets, regulatory frameworks, clinical plans, competition, financial models, capital markets, and multi-site strategies and teams
- Defined a value creation strategy through the following:
  - leveraging assets, such as the Company's technology platform, therapeutic proteins and enzymes derived from plasma fractions, management's expertise, open IND application, clinical experience, and past relationships with customers and surgeons within its target markets;
  - improving the Company's position within capital markets by promoting awareness of Haemacure's improved strategy and recent funding; and
  - engaging in business development activities.
- Assembled the pieces and is working toward the following:
  - delivering sample fibrin sealant for evaluation by third parties;
  - completing small-scale manufacturing equipment financing;
  - constructing a small-scale state-of-the-art manufacturing facility (as described on page 20);
  - having its first patient in the clinic in the first quarter 2009;
  - launching its fibrin sealant by the end of 2010 or beginning of 2011;
  - constructing a large-scale state-of-the-art manufacturing facility;
  - using the small-scale facility for custom development and production;
  - forming a Scientific Advisory Board to guide clinical programs and assess new opportunities; and
  - augmenting management's skills needed to execute clinical programs and lead the Company in synergistic growth areas.

As illustrated in Table 1 (page 9), Haemacure's business model centers around a patented extraction and purification technology, developed at a cost in excess of \$50 million. Haemacure intends to maximize the use of its technology to develop next-generation biosurgical and therapeutic protein products.

In addition, Haemacure intends to evaluate in- and out-licensing opportunities with both complementary partners and those within markets that the Company has not yet targeted.

Table 1  
Haemacure Corporation  
BUSINESS MODEL



Source: Haemacure Corporation.



## Intellectual Property

Haemacure's intellectual property portfolio comprises patents, patents pending, manufacturing know-how, product formulation and trademarks, both registered and non-registered. Four patent families cover the Company's fibrinogen and thrombin extraction technology. Haemacure also has patents for HemaSyst™, its spray fibrin sealant applicator. The majority of the technology patents are issued in Canada, the U.S., and certain European and Asian countries under the **Patent Cooperation Treaty (PCT)**.

### Patent Cooperation Treaty (PCT)

The PCT enables individuals or entities to seek patent protection simultaneously in over 130 countries by only filing one "international" patent application. The PCT does not grant an international patent, but facilitates the process of obtaining a patent in each country. In addition, member countries could grant PCT applications priority over more recent third-party applications for the same invention, provided that the applicant initiated the PCT process within one year of originally filing the application in a member country. After the PCT application is submitted, an International Searching Authority (ISA) completes an exhaustive review of published documents that could affect the application's patentability and compiles a written opinion on patentability.

Once Haemacure (or any applicant) receives this information for each of its PCT applications, it has the option of withdrawing the application. As listed at the bottom of Table 2, applications that are not withdrawn are published with the ISA's search report in the PCT database, accessible on the World Intellectual Property Organization's (WIPO) website at [www.wipo.int](http://www.wipo.int). Table 2 also lists Haemacure's patents that have been issued in the U.S.

Table 2  
Haemacure Corporation  
INTELLECTUAL PROPERTY

Issued U.S. Patents		
Patent No.	Patent Name	Issue Date
6,699,484	Fibrin sealants or adhesives comprising a hyaluronic acid derivative material	03/02/04
6,503,527	Fibrin sealants or adhesives comprising a hyaluronic acid derivative material	01/07/03
5,981,254	Process for producing thrombin from plasma	11/09/99
5,856,308	Artificial collagen	01/05/99
5,630,842	Biocompatible surgical implant	05/20/97
5,395,923	Process for the obtention of a biological adhesive made of concentrated coagulation factors by "salting-out"	03/07/95
5,290,918	Process for the obtention of a biological adhesive made of concentrated coagulation factors by acidic precipitation	03/01/94

Filed under the Patent Cooperation Treaty (PCT)		
Publication No.	Title	Pub. Date
WO 2002/005898	Spray head for applying a multi-component mixture	01/24/02
WO 1999/025782	Fibrin sealants or adhesives comprising a hyaluronic acid derivative material	05/27/99
WO 1999/023111	Process for the production of highly viral safe components for forming fibrin glue from a pool of human plasma	05/14/99
WO 1996/009376	Therapeutic grade thrombin production and products	03/28/96
WO 1995/023167	Process for the obtention of a biological adhesive comprising fibrinogen, Factor XIII, and fibronectin	08/31/95
WO 1994/002183	Biocompatible surgical implant	02/03/94

Sources: U.S. Patent and Trademark Office ([www.uspto.gov](http://www.uspto.gov)) and World Intellectual Property Organization ([www.wipo.int](http://www.wipo.int)).

### **Patent Defense**

In the past, Haemacure has had to defend its key patent (Patent #5,395,923) against claims from Aventis Behring GmbH (now CSL Behring, part of CSL Limited of Australia [CSL-ASX/CMXHF.PK-OTC]). The Company did so successfully.

### **Trademarks**

Hemaseel<sup>®</sup>, Hemaseel<sup>®</sup>HMN, Hemaseel<sup>®</sup>Thrombin, HemaSyst<sup>™</sup>, and HemaMyst<sup>™</sup> are either registered trademarks or trademarks of the Company in Canada and other countries.

### **Technology Acquisition Alliance**

In June 2007, Haemacure announced that it had entered into a technology acquisition alliance with UTEK Corp. UTEK is a specialty finance company that assists companies in acquiring technologies and intellectual property from universities and laboratory research centers. Haemacure hopes that its alliance with UTEK can provide the Company with further global intellectual property that is synergistic with its strategic vision.



## Company Leadership

### Management

Table 3 summarizes Haemacure's key management, with detailed biographies following.

Table 3  
Haemacure Corporation  
MANAGEMENT

Joseph Galli	Chairman of the Board and Chief Executive Officer
Marc Paquin	President and Director
Christian Hours, Ph.D.	Vice President, Quality and Technical Affairs
Lyne Paré, CA	Director, Finance and Administration
Gilles Lemieux, B.Com., LL.L.	Corporate Secretary, Investor Relations

*Source: Haemacure Corporation.*

#### *Joseph Galli, Chairman of the Board and Chief Executive Officer*

Mr. Joseph Galli is founder and managing partner of PENTOR Alliance Corporation and PENTOR Capital Corp. Over the past 25 years, Mr. Galli has completed dozens of restructuring, due diligence, and acquisition mandates in numerous industries on behalf of several private equity and venture capital firms and industry clients. He has directed over 200 conferences, seminars, and workshops, has been a director of several private and public organizations, and is also an investor in a number of early stage public companies. Prior to forming the PENTOR group of companies, Mr. Galli was a consultant with Ernst & Whinney (now KPMG International), where he successfully raised millions of dollars and gained expertise in insolvency, bankruptcy, and corporate restructuring.

#### *Marc Paquin, President and Director*

Mr. Marc Paquin founded Haemacure in 1991. He was also founder, director, president, and chief executive officer (CEO) of Autologous Systems, Inc., the first commercial private blood bank in Canada. Prior to founding Autologous Systems, Mr. Paquin was vice president and general manager of Syntex Diagnostic (Canada) Inc., where he was responsible for the initial set up of the Syntex Biomedical division in Canada. Mr. Paquin is the co-founder of the Canadian Institute of Biotechnology and of the Canada Bio-Industry Council.

#### *Christian Hours, Ph.D., Vice President, Quality and Technical Affairs*

Dr. Christian Hours was director of quality assurance at IAF BioVac Inc., a subsidiary of BioChem Pharma Inc. (now part of Shire plc [SHPGY-NASDAQ]) prior to joining Haemacure. Dr. Hours also has relevant experience in the regulatory process of introducing new biological products to the market, as well as in technology transfers. Before joining the industry, he spent 10 years researching molecular biology and virology. Dr. Hours holds a Master's in biology and biochemistry from Université Marseilles-Luminy, a Ph.D. in biochemistry from McGill University, and a DSA from HEC Montréal.

#### *Lyne Paré, CA, Director, Finance and Administration*

Mrs. Lyne Paré is a chartered accountant (CA). Her early career was in public accounting, where she worked as an external auditor with a national firm from 1988 to 1994. Prior to joining Haemacure in August 1996, Mrs. Paré worked for Pillard Combustion, an engineering firm, as financial and administrative controller of the North American subsidiaries of its parent company, E.G.C.I. Pillard, from France.

*Gilles Lemieux, B.Com., LL.L., Corporate Secretary, Investor Relations*

Mr. Gilles Lemieux graduated from HEC Montréal in 1975 with a B. Com. and from Université de Montréal in 1978 with a LL.L. He was called to the Québec Bar in 1979 and began his legal career in 1979 at the Montréal offices of Stikeman Elliott LLP. In October 1981, he joined Ayerst Laboratories (now part of Wyeth [WYE-NYSE]) as legal counsel and secretary, and VIA Rail Canada Inc. in 1986 as senior legal counsel, commercial and corporate. Mr. Lemieux has been a sole practitioner since 1994 and was appointed secretary of Haemacure in 1997. He has also been the secretary of three other public companies listed on the TSX. He was president of the Québec chapter of the Canadian Corporate Counsel Association from 1998 to 2002 and a director of the association from 2001 to 2005. He is a member of the Québec Association of Corporate Secretaries and General Counsels.

**Board of Directors**

Haemacure’s Board of Directors oversees the conduct of and supervises the Company’s management. Table 4 provides a summary of Board members, followed by detailed biographies.

Table 4  
Haemacure Corporation  
BOARD OF DIRECTORS

Joseph Galli	Chairman of the Board and Chief Executive Officer
Marc Paquin	President and Director
Joseph A. Akers, B.Sc., MBA	Director
Pierre Alary, CA	Director
Paul Baehr	Director
Wayne G. Johnson	Director
Neil Wiener, B.C.L., LL.B.	Director

*Source: Haemacure Corporation.*

*Joseph Galli, Chairman of the Board and Chief Executive Officer*

Biography on page 12.

*Marc Paquin, President*

Biography on page 12.

*Joseph A. Akers, B.Sc., MBA*

Mr. Joseph Akers started his career in the healthcare industry by joining Cutter Laboratories in California in 1970, which later became Bayer AG’s (BAY-NYSE) Biological Products division. Over the years, Mr. Akers held various senior and executive positions in corporate finance and administration at Bayer in Europe and the U.S. In 1999, he was appointed executive vice president and chief administrative and financial officer of Bayer Corporation (the U.S. subsidiary of Bayer AG). In 2004, he was appointed president of Bayer HealthCare’s Hematology/Cardiology business unit, from which he retired in 2007.

*Pierre Alary, CA*

Mr. Pierre Alary, a CA, spent 20 years at Ernst & Young from 1978 to 1998. During his last 10 years as a senior partner, he was responsible for providing audit and consulting services to major manufacturing and high-tech companies. He also became involved in the biotechnology industry and was active in the development of the Ernst & Young biotechnology practice in Québec. Mr. Alary co-founded the Québec Biotechnology Association, which later became BIOQuébec. Mr. Alary joined Bombardier, Inc. (BBD.B-TSX) in 1998 as vice president, finance for the rail transportation side of the business, Bombardier Transportation. In Berlin, he was responsible for the finance aspect of the acquisition and the integration



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of Adtranz, acquired by Bombardier in 2001 from DaimlerChrysler AG (now Daimler AG [DAI-NYSE]). As a member of the Management and Executive Committees, he was responsible for finance worldwide for the Bombardier Transportation group. In November 2002, Mr. Alary was promoted to vice president, finance for Bombardier Inc. and, in February 2003, to senior vice president and interim chief financial officer (CFO). Since June 2003, he has held the position of senior vice president and CFO of Bombardier Inc., with responsibility for all lines of the business.

*Paul Baehr*

Mr. Paul Baehr has served as chairman, president, and CEO of IBEX Technologies Inc. (IBT-TSX) since it became public in 1995. Mr. Baehr's business career began in product management with The Procter & Gamble Company (PG-NYSE). He joined Ciba-Geigy Canada Ltd. (now Novartis AG [NVS-NYSE]) to lead the Consumer Products division and subsequently became general manager of Ciba-Geigy's Canadian Pharmaceuticals division. In 1980, Mr. Baehr transferred to Ciba-Geigy's U.S. division as senior vice president of marketing. He joined the Eastman Kodak Company (EK-NYSE) in 1985 as corporate vice president, pharmaceuticals to lead the pharmaceutical diversification program. Mr. Baehr became executive vice president, pharmaceuticals at Sterling-Winthrop, Inc. in New York, when Kodak acquired Sterling-Winthrop in 1988. He has served on the boards of a number of U.S. and Canadian biotechnology companies and on the boards of St. Barnabas Hospital in Livingston, New Jersey, and the Fox Chase Cancer Center in Philadelphia, Pennsylvania. He also served on the Board of the National Pharmaceutical Council in Washington, D.C.

*Wayne G. Johnson*

Mr. Wayne Johnson graduated from The Creighton University in 1965 with a B.S.M.T. and has since accrued over 30 years of experience in the medical and blood products industries. He held senior management and executive positions with Johnson & Johnson (JNJ-NYSE), the Warner-Lambert Company (now Pfizer Inc. [PFE-NYSE]), and Bayer in operations, marketing, and business development. In 1991, Mr. Johnson founded BioVentures, Inc., a biomedical venture capital and business development company, and has since arranged for and provided financing and advice to numerous companies in various stages of development. He also served as a director of many private and public companies. Mr. Johnson is a co-founder and chairman of Canadian Plasma Products Inc.

*Neil Wiener, B.C.L., LL.B.*

Mr. Neil Wiener is a partner in the Montréal office of the Heenan Blaikie LLP law firm, where he has practiced since 1981. He is a member of the firm's Executive Committee. Mr. Wiener was called to the Québec Bar in 1981 after obtaining B.C.L. and LL.B. degrees from McGill University in 1980. He was called to the Ontario Bar in 1989. Mr. Wiener practices exclusively in the area of securities law, with an emphasis on public financings. He has been involved in numerous public offerings for both issuers and underwriters, including several public offerings by biotechnology companies. Mr. Wiener has also been involved in private placements, takeover bids, reverse takeovers, going-private transactions, stock exchange listings, and a broad range of other securities matters. He was a lecturer in business law at McGill University from 1989 to 2000. He also speaks regularly at conferences relating to corporate finance and securities.

## Core Story

*All amounts are in U.S. dollars unless otherwise specified.*

Haemacure Corporation (“Haemacure” or “the Company”) is a specialty biotherapeutics company that develops high-value human biosurgical products and therapeutic proteins based on a patented, high-yield fibrinogen and thrombin extraction and purification technology. The Company aims to create next-generation plasma-based products and has two product candidates in development: (1) Hemaseel<sup>®</sup>HMN, a human-derived fibrin sealant in late-stage clinical development; and (2) Hemaseel<sup>®</sup>Thrombin, an active, absorbable, surgical hemostatic agent, that is a component of the Company’s fibrin sealant yet also has uses as a standalone product or in combination with biomaterials. Both Hemaseel<sup>®</sup>HMN and Hemaseel<sup>®</sup>Thrombin have applications in the biosurgical market. Future product development will likely focus on surgical hemostats, adhesion prevention, combinations with biomaterials, and drug delivery in select therapeutic areas.

In addition, in one of its plasma fractions, Haemacure discovered four specialty proteins and seven enzymes, now in an early, investigational stage of development. The Company’s plasma fractions consist of the plasma remaining after extraction of the fibrinogen and thrombin required to produce Hemaseel<sup>®</sup>HMN and Hemaseel<sup>®</sup>Thrombin. Haemacure is seeking partnerships with pharmaceutical and biotechnology companies to advance its specialty therapeutic proteins and enzymes. The Company also sells two FDA-cleared fibrin sealant delivery devices, HemaSyst<sup>™</sup> and HemaMyst<sup>™</sup>.

Previously, Haemacure sold a fibrin sealant under license from Baxter in the U.S., under the trademark Hemaseel APR. As the Company was in this business from June 1998 until January 2004, managing to gain nearly a 30% market share against Baxter, it possesses extensive experience with the U.S. fibrin sealant marketplace. At that time, the Company also designed marketing and educational programs and tools that it plans on adapting and using to promote the sale of its new proprietary products. Haemacure believes that it is in a position to expeditiously re-initiate its past relationships with surgeons and hospitals once its fibrin sealant and hemostatic agent are ready for sale, which the Company expects to facilitate market penetration.

## HEMOSTASIS

Hemostasis is the process by which bleeding is stopped and clotting begins. It is a significant clinical issue in many situations, such as surgery, where controlling blood flow is important. Products in the hemostasis market, whether devices or therapeutic treatments, are known as hemostats. Both of Haemacure’s product candidates, fibrin sealant and thrombin, have hemostatic properties.

### Clotting

Clots typically form as part of the hemostatic process. Platelets in the blood sense tissue or blood damage and, in response, begin to break apart. Platelets are the smallest of all blood cells and are colorless, plate-shaped cells. Both platelets and fibrinogen, a plasma protein, are activated by the blood’s thrombin. After stimulation with thrombin, platelets and fibrinogen form fibrin threads to create a web-like mesh and trap blood cells. Thrombin is then absorbed into the threads to prevent excessive spreading of the clot. As fibrin threads and ensnared blood cells set, they harden to form the clot. This process of clot formation is called coagulation.

When coagulation occurs on the surface of the body, the clot is more often known as a scab. Internally, blood clots can form as a result of a burst blood vessel, which leaks blood into the soft tissue underneath the skin. Internal blood clots may also cause a bruise visible on the skin. Usually, all of these signs—clots, scabs, and bruises—signal healing; however, clots that form inside blood vessels can be very dangerous as they block the flow of blood and cut off the oxygen supply to that region of the body. For example, a stroke is the result of a clot in a brain artery that causes brain malfunctions, such as paralysis, brain damage, loss of sensory perceptions, and possibly death.

Through the use of various hemostats, surgeons can externally stimulate and expedite coagulation during surgical procedures without the need to rely on natural, slower factors to execute the process. Common



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methods to control bleeding and heal wounds are described below, with particular emphasis on Haemacure's approach to acute surgical wound care using fibrin sealant and thrombin.

### **Acute Surgical Wound Care**

Haemacure's product candidates specifically target acute surgical wound care, although they may also have a variety of other applications. Within this market, products are categorized into four classes: (1) sterile tapes and strips; (2) sutures; (3) mechanical devices, such as staplers; and (4) surgical sealants. The Company focuses on the surgical sealants segment, which can be further delineated by the following groups:

- tissue sealants;
- passive hemostats;
- anti-adhesion products;
- Percutaneous Transluminal Angioplasty (PCTA) sealants; and
- topical sealants.

Haemacure's fibrin sealant (Hemaseel<sup>®</sup>HMN) is a biological tissue sealant with adhesive properties, sealing soft tissues to stop bleeding. Haemacure's thrombin (Hemaseel<sup>®</sup>Thrombin) is an active, absorbable hemostatic agent designed to absorb blood flow, without adhesive properties. Both fibrin sealant and thrombin are further detailed below.

While not specifically targeted by the Company at this time, anti-adhesion products prevent tissue from adhering together after surgeries, and PCTA sealants are particularly useful after an angiotomy (a procedure to widen blood vessels) where these sealants close punctures in the femoral artery. Topical sealants stop bleeding due to minor wounds on the skin's surface. These types of surgical sealants may perform better than a fibrin sealant in a particular circumstance; however, the Company believes that none are as versatile for as wide of an array of procedures as fibrin sealant.

#### *Fibrin Sealant*

Fibrin sealant is a biological tissue sealant with adhesive properties, used in surgical procedures to seal tissues or wounds, stop bleeding, and help wound healing. It has the mechanical strength to attach tissues together and to last through the first phase of the body's healing process. Fibrin sealant simulates aspects of the natural coagulation process, polymerizing or hardening between tissues to create a seal. It is resorbed naturally by the human body. Once applied, it quickly forms a white, rubber-like mass that strengthens as it sets.

Potential uses of fibrin sealant include almost all surgical specialties. The use of fibrin sealant reduces the need for blood transfusions during surgery. In cardiovascular and thoracic surgery, it also controls air leakage at suture lines. Haemacure believes that fibrin sealant may have further application as an effective drug delivery vehicle, as the substance is gradually resorbed. In addition, the Company believes that fibrin sealant is also an effective anti-adhesion agent, capable of preventing the post-surgery adhesion of neighboring tissues or organs.

To understand fibrin sealant's use for both adhesion and adhesion prevention, consider the properties of standard glue, such as that from Elmer's Products, Inc. When glue is applied to two surfaces that are then immediately placed together, the glue polymerizes (sets) and creates a bond between the surfaces. This is the way that fibrin sealant works for adhesion purposes. However, when glue is applied to two surfaces that are not immediately placed together, the glue polymerizes separately on each surface. Once glue has polymerized, it will not create a bond between surfaces if placed together. Likewise, fibrin sealant applied and allowed to polymerize on two separated tissues could keep the tissues from fusing, or adhering, together (i.e., acting as an adhesion prevention agent). In this respect, fibrin sealant is also useful in combating scar tissue.

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### Advantages of Using a Fibrin Sealant

When used as an adhesive, fibrin sealant provides a number of clinical benefits to physicians, patients, and the healthcare industry as a whole. Applying fibrin sealant to stop bleeding during surgery enables surgeons to achieve hemostasis faster and more efficiently than without sealant. In turn, the application of fibrin sealant decreases the risk of post-surgery internal bleeding, which may decrease the patient's hospital stay. A shortened time in the hospital leads to economic benefits, as patients, third-party payers, and hospitals then enjoy cost savings. Moreover, roughly 8% of surgical wounds become infected in the hospital (Source: MedMarket Diligence LLC's *Worldwide Surgical Sealants, Glues and Wound Closure Market, 2007*). Yet, use of fibrin sealant has shown to reduce infection.

Additionally, fibrin- and thrombin-based products typically achieve active hemostasis more rapidly than passive hemostats developed with collagen or gelatin formulations. This is due to the particular stage in the natural coagulation process that the hemostat stimulates. For instance, a collagen-based hemostat requires a cascade of blood factors and drives the entire clotting process. Fibrin sealants act much later in the coagulation process, inducing nearly immediate hemostasis without requiring the full complement of blood factors. Functions and benefits of fibrin sealants are summarized in Table 5.

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Table 5  
Haemacure Corporation  
FUNCTIONS AND BENEFITS OF USING FIBRIN SEALANT

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- |   |  |
|---|--|
| <ul style="list-style-type: none"> <li>▪ Stops bleeding</li> <li>▪ Reduces the number of blood transfusions</li> <li>▪ Decreases the need for post-surgery adhesions</li> <li>▪ Shortens surgical procedures, thereby reducing costs</li> <li>▪ Accelerates patient recovery and rehabilitation after invasive surgery</li> </ul> | <ul style="list-style-type: none"> <li>▪ Enhances the natural clotting process</li> <li>▪ Reduces overall patient costs</li> <li>▪ Limits potential infection</li> </ul> |
|---|--|

*Source: Haemacure Corporation.*

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### *Thrombin*

Thrombin is an active, absorbable hemostatic agent used to control blood flow during surgery. It has wound healing properties but no adhesive properties. Thrombin can also be used as a therapeutic product. An article published in a 2004 edition of *Thrombosis and Haemostasis* details the many therapeutic uses of thrombin, including for the treatment of **pseudoaneurysms** (a localized rupture within an artery) and hemostasis. When compared to sutures, active, absorbable hemostatic agents offer several advantages, including reduced infection or scarring and a decreased need for anesthesia (Source: *Worldwide Surgical Sealants, Glues and Wound Closure Market, 2007*).

Additionally, the article in *Thrombosis and Haemostasis* maintains that while usage of thrombin as a therapeutic is likely to increase significantly, development may hinge upon the availability of a safe human thrombin preparation. As further described on pages 26-28, the fibrin sealant and thrombin market is moving toward products that are human-derived, as fibrin sealants and thrombin that contain or are made from a bovine protein have been shown to cause serious adverse effects and immunogenicity complications in humans.

Haemacure is working to introduce entirely human formulations of these products. The Company uses fibrinogen and thrombin that have been extracted from human plasma and its product candidates do not contain any bovine or any other species' materials. A description of Haemacure's proprietary plasma protein extraction technology is presented on the accompanying pages and is followed by summations of each of the Company's product candidates as well as its marketed products on pages 20-25.

## HAEMACURE'S TECHNOLOGY PLATFORM

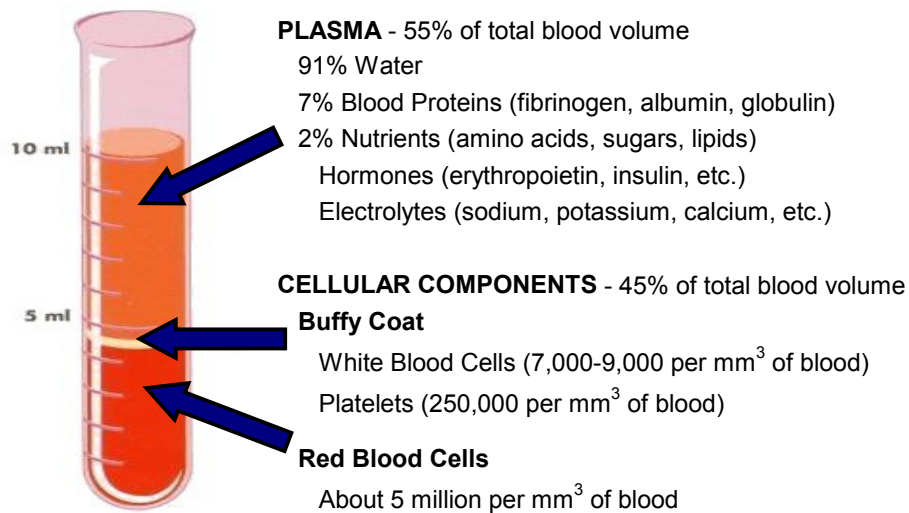
The Company's novel and patented technology was designed specifically for the extraction and purification of fibrinogen and thrombin from human plasma. Haemacure believes that its technology has significantly fewer negative effects on the other proteins and enzymes remaining in its plasma fractions than alternative technologies. Haemacure intends to develop human plasma-based products in collaboration with pharmaceutical and biotechnology companies. The Company maintains full and exclusive ownership of its technology.

### Plasma

Plasma is the component of blood that remains once the red blood cells, white blood cells, and platelets have been removed. It is a clear liquid that consists of approximately 90% water and 10% protein molecules, accounting for approximately 55% by volume of blood (depicted in Figure 2). The majority of the remaining 45%, by volume, is red blood cells. Plasma can be "fractionated," or broken down, into its component parts, which comprise various proteins. Through extraction technologies, often known as plasma fractionation, proteins present in plasma can be harvested and formulated into therapeutic products. Plasma proteins include albumin, immunoglobulin, plasminogen, alpha-1 proteinase inhibitor (A1PI), and **clotting factors**, each of which address a different disease or deficiency, as well as those required by Haemacure—fibrinogen and thrombin.

Figure 2

#### SUMMARY OF BLOOD COMPONENTS



Sources: National Space Biomedical Research Institute and Michigan Community Blood Centers.

Haemacure uses only plasma collected by FDA-approved collection centers. In addition to the viral screenings performed by collection centers, the Company subjects fibrinogen to two and thrombin to three viral inactivation treatments.

### Traditional Cohn Fractionation

Current plasma protein extraction technologies (other than Haemacure's technology) are aimed at improving upon the traditional Cohn fractionation process that has been used since the 1940s. This method of isolating proteins was developed by Dr. Edwin Cohn, a chemist who found that blood proteins could be separated from human plasma. He accomplished this by using different temperatures and biochemical conditions with solvents, such as ethanol, to fractionate the plasma five times (which is harsh to proteins), each time removing certain valuable proteins from the plasma. The second step of this fractionation process is centrifugation, which has a shearing effect on proteins. The combination of alcohol and centrifugation may cause a substantial amount of protein denaturalization, thereby negatively affecting the quality of the proteins extracted. Dr. Cohn's technique is most notable for being able to produce large quantities of albumin, an easily shipped and efficiently stored protein that was used to

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replace lost blood on battlefields. The Cohn process also separated other significant proteins, such as immunoglobulins, which are used to fight many diseases.

While Cohn fractionation was highly beneficial during World War II, using this process to extract proteins today results in low yields and thus, high costs. At each step of the Cohn process, material is lost.

When compared to Cohn fractionation, Haemacure's patented technology is believed to have the following benefits:

- improved purification;
- a more gentle protein separation, which could maintain concentrations and protein quality versus some of the harsher aspects of Cohn fractionation;
- a higher quality fibrin sealant with improved clot performance and reconstitution time; and
- higher fibrinogen and thrombin yields (as described below).

### **Haemacure's Revenue Generation Due to High Yields**

Haemacure believes that its technology will likely enable it to retrieve high fibrinogen and thrombin yields from plasma, potentially increasing its revenue per liter of plasma to multiples of industry averages. Whereas Cohn fractionation is targeted for the separation of large proteins such as albumin and immunoglobulins, Haemacure's technology was designed around fibrinogen and thrombin. Consequently, the Company believes that it is likely to be able to achieve superior yields and purity for its target proteins.

Haemacure is progressing two product candidates through development: (1) the fibrin sealant, Hemaseel<sup>®</sup>HMN, and (2) the active hemostatic agent, Hemaseel<sup>®</sup>Thrombin. For both of these candidates together, Haemacure anticipates being able to generate between \$2,000 and \$2,500 in revenue per liter of plasma. In comparison, the Company estimates that the industry average is typically between \$250 and \$500 in revenue per liter, with current suppliers of fibrin sealant generating approximately \$800 of revenue per liter of plasma.

#### *Plasma Fractions*

Haemacure has undertaken an evaluation of the Company's potential to extract, develop, and commercialize other therapeutic proteins and enzymes discovered in one of its plasma fractions, as detailed on pages 23-25. The Company is identifying and assessing the quantity and quality of the proteins and enzymes remaining in its plasma fractions. The successful exploitation of these proteins and enzymes may further increase the revenues generated per liter of plasma. As raw material (plasma) costs will likely be absorbed by Haemacure's fibrin sealant and thrombin products, the Company expects that additional revenue generated by subsequent plasma proteins and enzymes can contribute directly to its bottom line.

### **Global Plasma Supply**

Haemacure does not anticipate facing a supply shortage of its requirements for human plasma and **excipients**. The Company is taking steps toward ensuring a long-term supply of plasma. Haemacure does not believe that the global plasma supply will likely decrease to a level that could cause it problems, given the maximum processing capacity of its planned manufacturing facilities. At peak capacity of the large-scale facility, the Company estimates that it can process approximately 100,000 liters of plasma annually. As the annual supply of U.S. plasma from FDA-approved collection centers near 13 million liters, Haemacure does not believe that 100,000 liters will likely impact the market's dynamics. Processing 100,000 liters per year may translate into more than \$200 million in revenue.

## Manufacturing Facility

Due to the loss or lack of control that contract manufacturing entails and a consolidation of available contract manufacturers in the industry, Haemacure made a decision to construct a manufacturing facility in Sarasota, Florida.

Haemacure intends to first establish a 15,000-square foot manufacturing facility by mid-2008, where product can be manufactured for clinical trials and commercial launch. Subsequently, Haemacure anticipates expanding the facility by 25,000 square feet, thus operating a facility with a 100,000 liter per year processing capacity. The facility is designated for premises currently leased by Haemacure in Florida.

Alfa Laval Tumba AB (ALFA-STO) of Sweden did the engineering design of the facility. Alfa Laval has also agreed to supply and install the disposable bioprocessing equipment selected by Haemacure. Funding is made available by the landlord under the lease, for leasehold improvements to be made by the latter for an estimated value of \$1.2 million. In addition, the Office of the Governor of the State of Florida granted Haemacure tax benefits estimated at \$800,000 over a five-year period, under the Qualified Tax Incentive Program. Haemacure is seeking additional financing required to complete the small-scale facility.

Figure 3  
Haemacure Corporation  
BIOPROCESSING UNIT



Source: Haemacure Corporation.

The facility incorporates a sterile bioprocessing system (as depicted in Figure 3) that employs HyNetics, LLC's single-use, plastic containers. By using disposable, plastic containers, Haemacure aims to promote significant cost savings as well as lower the risks of cross-contamination.

For instance, rather than the \$75 million that would be required for traditional stainless steel manufacturing equipment for the large-scale facility, Haemacure estimates that this disposable equipment only requires \$11 million. A part of this cost savings results from not needing the extensive infrastructure or cleaning processes that are required for the traditional stainless steel equipment. In addition, the Company believes that its capability to scale up production is enhanced with the HyNetics™ equipment. The Company further expects that its risk

of cross-contamination will likely be lower than with the traditional stainless steel equipment, as each container and component in which product is processed and circulated is used only once.

Once Haemacure has commenced commercial production of its products at the large-scale facility, it plans on using the small-scale facility for custom development and production of products to meet specific formulation requirements of life sciences companies that could use Haemacure's products with their products.

## HAEMACURE'S PRODUCT PIPELINE

While it is not the first company to introduce a fibrin sealant or thrombin into the market, Haemacure intends to offer differentiated products that are equal to or better than those available in terms of ease of use, safety, and efficacy. In addition, the Company plans on launching its product candidates in a growing market that, as such, has experience with similar companies and product classes.

### Hemaseel®HMN

The Company's lead product candidate, Hemaseel®HMN, is a human-derived fibrin sealant. It is a biological tissue sealant composed of fibrinogen and thrombin extracted from human plasma. Haemacure believes that fibrin sealant has applications in a wide variety of surgical specialties, including abdominal,

cardio-thoracic, vascular, gynecology, urology, neurosurgery, ophthalmology, reconstructive, plastic, and ear, nose, and throat procedures. Furthermore, Haemacure believes that its fibrin sealant will likely be an effective anti-adhesion agent, as well as an effective drug delivery vehicle because it is gradually resorbed into the body. Drug delivery entails the transport of a drug into the body, such as a central nervous system medication that enables regeneration of the spinal cord.

### *Development Status*

In 1996, Haemacure conducted a Phase I clinical trial, demonstrating that its product candidate was safe and suitable for further testing in humans.

With the consent of the FDA, the Company did not conduct a Phase II trial before proceeding with Phase III. The Phase III clinical trial took place from 1998 to 1999 in total knee replacement surgery. This trial showed that Hemaseel<sup>®</sup>HMN was safe, with no reported serious adverse events attributable to the product. There was an incidence of protocol violations by a number of surgeons performing the surgery, involving approximately 10% of the patients, which appeared to be a result of the surgeons' initial inexperience and lack of skill in using fibrin sealant. Consequently, the trial was suspended prior to completion. While not meeting the FDA-imposed primary endpoint for clinical efficacy based on a reduction in blood loss, the data trend strongly suggested a correlation of significant clinical efficacy with the surgeons' increase in experience at using fibrin sealant over the course of the trial.

In 1999, Haemacure licensed its fibrin sealant technology, encompassing fibrinogen and thrombin, to ZLB Central Laboratory Blood Transfusion Service of the Swiss Red Cross, which was the major shareholder of Haemacure. ZLB's clinical objective was to conduct pivotal trials in an indication involving vascular surgery. By 2000, although product suitable for clinical use was being produced at ZLB's pilot plant, the commercial-scale fibrin sealant manufacturing facility would not be completed for another year. Thus, ZLB elected to initiate a more limited Phase II trial using pilot plant product in advance of merging the study with a Phase III trial using product made in the commercial-scale facility.

During the interval between the total knee replacement trial conducted by Haemacure and the Phase II vascular access graft trial to be conducted by ZLB, the FDA expressed a preference for using a more meaningful time-to-hemostasis endpoint, as opposed to an endpoint related to blood loss as was required for the earlier Haemacure Phase III trial. Subsequently, the ZLB Phase II study using pilot plant product had to be terminated prematurely as a result of the sale of ZLB to CSL Limited. However, data on the patients who completed the trial demonstrated product safety, with no serious adverse events attributable to the product. Data analysis also clearly demonstrated a statistically and clinically significant efficacy in time-to-hemostasis.

A total of 151 human subjects and patients have received Hemaseel<sup>®</sup>HMN. Additionally, the Investigational New Drug (IND) application assigned by the FDA to Hemaseel<sup>®</sup>HMN remains open and active. It may be amended to resume clinical trials.

One year after acquiring ZLB's plasma fractionation business, which included the 1999 license granted by Haemacure to ZLB and the Hemaseel<sup>®</sup>HMN-dedicated facility that ZLB had built under the license agreement with Haemacure, CSL terminated the 1999 license and disassembled the facility. This license termination and facility dismantling delayed the market launch of Hemaseel<sup>®</sup>HMN by four years.

As Haemacure's fibrin sealant is a biologic product, product used for pivotal Phase II/Phase III clinical trials and the product approved for marketing by the FDA must be produced at the same plant. Due to the past development events described above, new pivotal Phase II/Phase III clinical trials for Haemacure's fibrin sealant are required, and Haemacure is building a manufacturing facility to manufacture product for both clinical trials and commercialization. Using observations and knowledge from prior trials, Haemacure seeks to begin pivotal trials within the next 12 months. Moreover, given the product candidate's demonstrated safety and efficacy, the Company does not expect to have serious regulatory risk in the required Phase III trials. Haemacure anticipates that it could receive regulatory approval in the U.S. and Europe during 2010. To submit for product approval, the Company must file the necessary regulatory documents, which include a **Biologic License Application (BLA)** with the FDA and a **Common Technical Document (CTD)** with the European Medicines Agency (EMA). Haemacure expects its target filing date to be in late 2009 or early 2010.



*Product Attributes*

Table 6 shows some of Haemacure’s extraction technology and fibrin sealant key attributes. As referenced in the table, thrombin activity is reported in National Institutes of Health (NIH) units. NIH units are in common use for the calibration of commercial thrombin reagents. The Company’s high-yield extraction technology produces 25,000 NIH units of thrombin per liter of plasma. In addition, the fibrin sealant production process incorporates viral inactivation processes to maximize product safety. Ease-of-use is also vital to Haemacure’s product candidates. For Hemaseel®HMN, preparation time is less than five minutes, and it does not require frozen storage.

Table 6 Haemacure Corporation HEMASEEL®HMN ATTRIBUTES		
▪ All-human plasma	▪ No aprotinin	▪ No preparation equipment required
▪ Less than five minutes to prepare	▪ Antiviral processes	▪ Fibrinogen yields 20 to 25 doses per liter of plasma
▪ High-yield thrombin, with 25,000 NIHu/L	-- Thrombin x 3	▪ The thrombin process is inclusive
	-- Fibrinogen x 2	

*Source: Haemacure Corporation.*

No Animal Components

The Hemaseel®HMN fibrin sealant does not contain any animal components, unlike the dominant fibrin sealant in the market today, Baxter’s Tisseel® VH. Baxter’s fibrin sealant contains aprotinin, a commonly used **antifibrinolytic** protein derived from bovine plasma. Haemacure believes that its human plasma-derived products are preferable to products containing bovine components, particularly as aprotinin is associated with potentially fatal hemostasis abnormalities. Products containing aprotinin, including Tisseel® VH, are accompanied by cautionary language on product inserts and prescribing information warning users of the possible side effects. As an example, Bayer’s TrasyloI® (aprotinin injection) has a **black box warning** concerning a risk of fatal allergic reactions, which have occurred in test doses of the aprotinin injection and in situations where the initial test dose had been tolerated. It was reported by the FDA, as recently as October 19, 2007, that accumulating evidence suggests that TrasyloI® increases the risk of death when compared to other drugs. TrasyloI® is administered during open-heart surgeries to reduce bleeding during and after the operation. Risk for severe, life-threatening allergic reactions is also increased among patients with prior aprotinin exposure.

Conversely, since Haemacure’s fibrin sealant only uses human proteins, it can be resorbed by the body without immunogenicity complications. Hemaseel®HMN also reduces the risk of cross-species disease transmission. Consequently, the Company believes that human plasma-derived or **recombinant** hemostats that are not animal-based could become highly sought-after alternatives to current treatments.

Epsilon-Amino Caproic Acid (EACA)

In lieu of aprotinin, Haemacure’s patented extraction technology uses **epsilon-amino caproic acid (EACA)**, a non-animal-based antifibrinolytic agent that has not been associated with dangerous or severe side effects. The Company adds EACA during the fibrinogen production process in order to facilitate the extraction of plasminogen. EACA is later removed from the final product. Haemacure has patented this process, preventing current and future fibrin sealant manufacturers from using EACA in areas where Haemacure has recognized intellectual property (detailed on pages 10-11).

A second available non-animal antifibrinolytic agent is **tranexamic acid (TA)**. TA is present in OMRIX’s Quixil® fibrin sealant, which is used as an adjunct to hemostasis in surgical procedures outside of the U.S. However, due to risks of cerebral neurological toxicity, products containing TA cannot be used in neurosurgery or any surgical procedures that may contact cerebrospinal fluid or **dura mater**, including ophthalmic and vertebral operations, among others.

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A separate fibrin sealant from OMRIX, Evicel™, does not use TA. Evicel™ is approved as an adjunct in the U.S., but as of yet, only for liver or vascular surgery. Evicel™ and Quixil® are the first and, to date, the only commercially available liquid fibrin sealants that do not contain animal-derived components.

### **Hemaseel®Thrombin**

Haemacure's Hemaseel®Thrombin product candidate is an active, absorbable, surgical hemostatic agent. It is one of the two protein components of fibrin sealant. Like fibrinogen, thrombin is extracted from plasma. As such, Hemaseel®Thrombin leverages the safety and efficacy profile that has been demonstrated in the fibrin sealant clinical trials, and may provide a shorter clinical timeline with minimized risks associated with its trials.

The Company intends to perform a clinical study to compare its thrombin to commercially available bovine thrombin. Haemacure plans on pursuing regulatory approvals in the U.S. and Europe for Hemaseel®Thrombin during 2010, with an anticipated market launch in 2011.

Although a component of Hemaseel®HMN, Hemaseel®Thrombin can be used as a standalone product or in combination with biomaterials, such as collagen or gelatin, to create an absorbable hemostatic dressing that can be applied to the bleeding surface. Alternatively, when used independently, it can accelerate the natural clotting process for internal bleeding.

#### *No Animal Components*

Like Hemaseel®HMN, Hemaseel®Thrombin does not contain animal-derived components. Haemacure believes that developing a human plasma-derived thrombin rather than utilizing a bovine thrombin provides significant clinical advantages, particularly by avoiding the safety concerns that surround bovine thrombin.

Since bovine-derived thrombin is foreign to the human body, it can induce the body to produce antibodies against the treatment, which cross-react with certain human blood proteins—increasing the risk of side effects and bleeding complications as well as decreasing efficacy. An article published in a 2001 edition of the *American Journal of Pathology* details the evolution of knowledge concerning the side effect profile of bovine thrombin. In the early 1980s, it was recognized that patients could develop antibodies against bovine thrombin; however, it was not until the 1990s that the scientific and medical communities began to understand that the induced antibodies subsequently cross-reacted with other plasma proteins as well, causing significant adverse effects. In a trial of approximately 150 patients treated with bovine thrombin, more than 95% of participants developed antibodies to the bovine proteins and roughly 50% had cross-reactivity to the corresponding human proteins (Source: *Annals of Surgery* [2001]). Adverse clinical outcomes were increased in patients who had already had previous bovine thrombin exposure.

Currently, there are two FDA-approved thrombin formulations. The first of these is King Pharmaceuticals' Thrombin-JMI®, which is bovine-derived. It contains a black box warning in the U.S. with cautionary language related to various adverse events. Yet, in fiscal year 2006, Thrombin-JMI® had \$246.5 million in net sales. The second thrombin, OMRIX and Ethicon, Inc.'s Evithrom, was approved by the FDA on August 27, 2007. Evithrom is a human plasma-derived alternative to Thrombin-JMI®, which is believed to have a decreased side effect profile as it does not contain bovine components.

### **Additional Therapeutic Proteins**

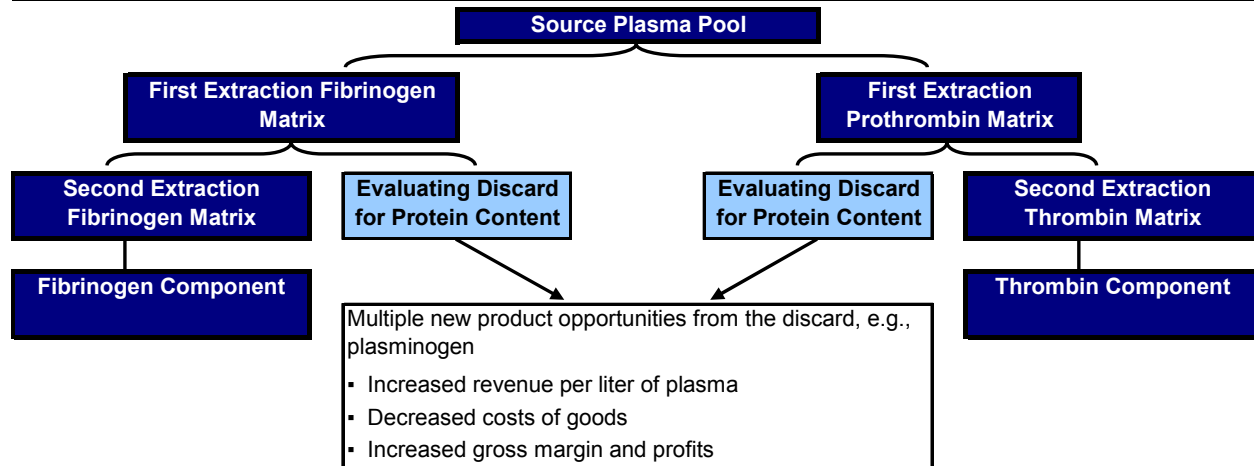
After extracting fibrinogen and thrombin from plasma, a quantity of plasma remains. This plasma fraction still holds many specialty, high-value therapeutic proteins that are available for extraction. Table 7 (page 24) depicts the process to produce Haemacure's plasma fractions. Haemacure identified four valuable specialty proteins and seven enzymes that it intends to develop in partnership with pharmaceutical and biotechnology companies. However, further research is required before the Company could be able to present product development proposals to potential partners. Yet, if developed, Haemacure expects that revenue generated by the sale of these therapeutic proteins and enzymes can contribute directly to the Company's bottom line, as revenues from Hemaseel®HMN and Hemaseel®Thrombin are anticipated to bear the plasma and operating costs.



Table 7

Haemacure Corporation

ADDITIONAL GROWTH AND VALUE OPPORTUNITIES IN THE FORM OF THERAPEUTIC PROTEINS



Source: Haemacure Corporation.

Preliminary Analysis of the Plasma Fraction

In June 2007, Haemacure reported preliminary findings from its analysis of one of two plasma fractions. The Company was able to confirm the presence of albumin, plasminogen, immunoglobulin, and A1PI. Discovering albumin greatly benefits Haemacure, as this protein is used in the production of the Company's fibrin sealant. By being able to extract albumin and then use it in production, Haemacure may realize annual cost savings of more than \$500,000 at full large-scale production capacity. Moreover, the remaining albumin not used in the fibrin sealant production process could be commercialized.

Plasminogen has potential for conversion into the plasmin enzyme, which can prevent clot formation. Immunoglobulin, one of the best selling proteins in North America with estimated U.S. sales in excess of \$1 billion in 2006, can treat a variety of immunological, neurological, and other disorders. The current need for immunoglobulin is projected to be seven times greater than current capacity on a global basis. Additionally, the American Lung Association estimates that there are approximately 100,000 people in the U.S. who are A1PI deficient. A1PI deficiencies cause a type of hereditary **emphysema** that affects 1 in every 50 people with emphysema (Source: the National Jewish Medical and Research Center). Table 8 summarizes the product market for a variety of plasma-derived proteins, including albumin, immunoglobulin, A1PI, and fibrin sealant.

Table 8

PLASMA PRODUCT MARKET BY CLASS AND PRODUCT, 2004

Product	Total market, US\$B	Plasma-derived market, US\$B	Recombinant market, US\$B	Hyperimmunes market, US\$B
Intravenous immunoglobulin (IVIG)	2.3	2.3		
Human serum albumin	0.9	0.9		
Plasma-derived Factor VIII	0.9	0.9		
Plasma-derived Factor IX	0.2	0.2		
Alpha-1 Proteinase Inhibitor (and others)	1.4	1.4		
Fibrin sealants	0.3	0.3		
Recombinant Factor VIII	1.7		1.7	
Recombinant Factor IX	0.25		0.25	
Hyperimmune globulins	0.54			0.54
<b>Total</b>	<b>US\$ 8.5 Billion</b>	<b>US\$ 5.8 Billion</b>	<b>US\$ 2 Billion</b>	<b>US\$ 0.5 Billion</b>

Source: The Marketing Research Bureau, Plasma Industry Handbook, 29 July 2005 (Citigroup), Biopharma (Biotechnology Information Inst.), September 2004.

Haemacure also found a selection of seven enzymes in one of its two plasma fractions. Four of these are listed in Table 9 along with the addressable indication and the approximate market size. According to Cowen and Company, LLC, **enzyme replacement therapies (ERTs)** could reach \$3.1 billion in 2011. ERTs intravenously administer a select enzyme that a patient is lacking in order to treat a variety of disorders that result from specific enzyme deficiencies. In addition to those in Table 9, Haemacure has identified three other enzymes, used to treat Hunter's, Morquio's, and Schindler's diseases.

Table 9  
Haemacure Corporation  
POTENTIAL MARKETS FOR HAEMACURE'S THERAPEUTIC ENZYMES

Indication	2006 Est. Sales (in US\$)	Discovered Enzyme
Gaucher's Disease	\$1 billion	beta-glucosidase
Fabry's Disease	\$359 million	alpha-galactosidase
Hurler's Disease	\$96 million	alpha-iduronidase
Pompe's Disease	\$30 million	alpha-glucosidase

Sources: Haemacure Corporation and Crystal Research Associates, LLC.

### Marketed Delivery Devices

Despite terminating its sales force following the end of the license agreement with Baxter, the Company continued to market its two fibrin sealant delivery devices—HemaSyst™ and HemaMyst™ (briefly described below). Both of these products have been cleared by the FDA. Haemacure's sales revenues in fiscal years 2007, 2006, and 2005 were entirely derived from sales of these delivery devices. The Company handles all warehousing and deliveries of its HemaSyst™ and HemaMyst™ products.

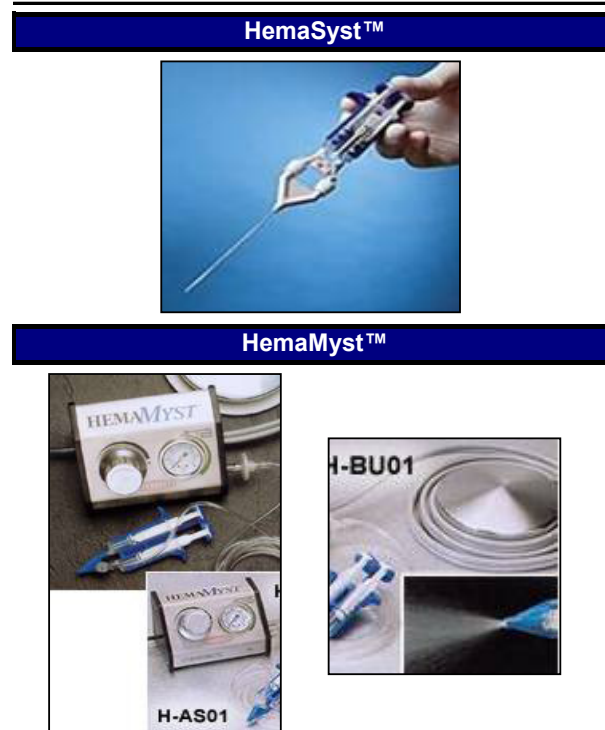
#### HemaSyst™

Depicted in the top portion of Figure 4, HemaSyst™ is a dual-syringe applicator that has an adapter to enable use with manual sprays, malleable cannula shafts (soft tubes to be inserted into a body cavity), and laparoscopic attachments. This applicator offers several advantages: it can prevent clogs by keeping solutions separate and incorporates a removable plunger to ensure an accurate solution ratio. Moreover, this applicator offers specialized delivery options for many surgical requirements, enabling use in a wide variety of surgeries.

#### HemaMyst™

HemaMyst™, illustrated in the bottom half of Figure 4, is an aerosol device that can deliver fluids over a broad area. It has a focused spray tip that enables access to confined spaces. The Company is considering additional accessories for HemaMyst™, such as laparoscopic applications. As is, the device is useful in many soft tissue surgeries (e.g., liver, kidney, and pancreas) where a fibrin sealant is finely sprayed over the tissue.

Figure 4  
Haemacure Corporation  
MARKETED DELIVERY DEVICES



Source: Haemacure Corporation.



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## MARKET OPPORTUNITIES

Haemacure intends to initially target the North American and European markets. The Company would partner with local companies to enter Japan as well as selected emerging markets.

The Company's fibrin sealant and thrombin product candidates aim to address the hemostasis segment of the wound care market. Offering Hemaseel<sup>®</sup>HMN or Hemaseel<sup>®</sup>Thrombin as a combination product with third parties' products, including therapeutics or biomaterials, or using Hemaseel<sup>®</sup>HMN in anti-prevention and drug delivery capacities may enable Haemacure to expand its focus to include the wound healing market segment as well. Furthermore, the Company will likely attempt to enter the human plasma-derived therapeutic proteins market via collaboration agreements and partnerships to advance its newly discovered therapeutic proteins and enzymes.

Haemacure believes that the area of specialty biotherapeutics is expanding, as demonstrated by recent developments with other companies within this field, including OMRIX, ZymoGenetics, Inc. (ZGEN-NASDAQ), Talecris Biotherapeutics, Inc., Grifols S.A. (GRF-MCE), Life Therapeutics Ltd. (LFE-ASX/LFEFY.PK-OTC), and Nabi Biopharmaceuticals (NABI-NASDAQ). For instance, in June 2007, ZymoGenetics announced that it had established a global collaboration with Bayer HealthCare for the development and commercialization of rThrombin, a recombinant human thrombin. Under the agreement, which provides Bayer with product rights to all markets outside of the U.S., ZymoGenetics may receive up to \$198 million plus royalties, including up to \$70 million during 2007.

Also in June 2007, Talecris announced that its Talecris Plasma Resources subsidiary agreed to purchase three plasma collection centers from International BioResources, LLC, and open up to 10 additional centers to supply Talecris's growing plasma demand. Previously, Talecris had acquired 58 plasma centers from International BioResources. Grifols has also recently expanded its plasma collection centers to include new U.S. locations. Its plasma fractionation capacity is now 3.6 million liters of plasma a year, anticipated to increase by another 700,000 liters annually over the next few years.

Further, in September 2007, Nabi entered into a definitive agreement to sell its biologics strategic business unit to Biotest Pharmaceuticals Corporation (a wholly owned subsidiary of Biotest AG [BIO-FRA]) for \$185 million. Biotest has agreed to acquire the biologics unit's products, including Nabi-HB<sup>®</sup> (a Hepatitis B Immune Globulin [Human]), and other plasma business assets, which consist of a plasma protein production plant and nine FDA-certified plasma collection centers across the U.S. Haemacure believes that this transaction indicates the value that the plasma industry places on the U.S. market, as well as on having a manufacturing presence in this market.

### Fibrin Sealant and Thrombin Market Dynamics

The Company views the fibrin sealant and thrombin market segments essentially as oligopolies, with high margins and significant barriers to entry. For example, competitors OMRIX and ZymoGenetics had market capitalizations of \$561 million and \$916 million, respectively, as of November 1, 2007, based on each company's development of next-generation fibrin sealant and thrombin products. Each of these companies is described in the Competition section on pages 29-31. With its present market capitalization of nearly \$21 million, Haemacure believes that it has the potential for appreciation based on its growth strategy, current market dynamics, and valuations.

In particular, Baxter's first-generation fibrin sealant currently holds a significant portion of the U.S. fibrin sealant market. Management believes that other companies looking to enter this field would need between 5 and 10 years and over \$50 million to develop the necessary intellectual property, effectively establishing significant barriers to entry.

### *Fibrin Sealant Market Size*

In 2005, the U.S. medical and dental adhesive and sealant industry was valued at roughly \$1 billion, which included fibrin sealants as well as orthodontic bonding agents, silicone, and a variety of other materials (Source: The Freedonia Group, Inc.). Further, demand in this industry was estimated to grow by 8.4% annually through 2009 due to an increasing acceptance of using adhesives and sealants in

a surgical setting as well as new product introductions. Moreover, surgical wounds are the most common type of wound, with a worldwide incidence of approximately 97 million and a compound annual growth rate (CAGR) of 3.1%, which is second only to chronic wounds (CAGR of 7.4%) (Source: *Worldwide Surgical Sealants, Glues and Wound Closure Market, 2007*). MedMarket Diligence estimates that approximately 70 million of these surgical wounds, of which over 20 million are in the U.S., have potential for treatment with surgical closure products.

The worldwide fibrin sealant market is estimated at approximately \$400 million (Source: *EQUITIES Magazine* June 2007). Of that amount, the largest segments are believed to be Japan with \$145 million annually and the U.S. with \$116 million each year (Source: ThermoGenesis Corp. [KOOL-NASDAQ], a manufacturer of automated blood processing systems). Haemacure estimates that fibrin sealant sales in the U.S. could increase at double-digit rates annually over the next five years as surgeons learn more about the benefits of fibrin sealants and as next-generation products with improved efficacy and safety are introduced. The Company views fibrin sealant development as leading to an all-human, liquid product that is ready to use or that can be rapidly reconstituted in less than five minutes and comes pre-packaged in loaded syringes.

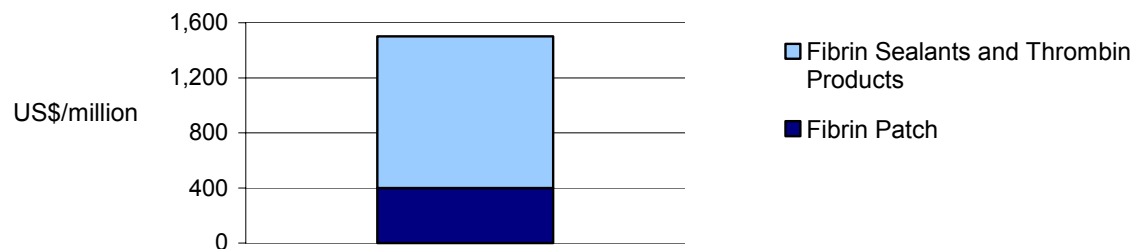
#### *Hemostatic Agents' Market Size*

In 2006, sales of topical, absorbable hemostatic agents were estimated at roughly \$595 million and forecast to reach \$842 million by 2011 (Source: *Worldwide Surgical Sealants, Glues and Wound Closure Market, 2007*). Market drivers include more surgeries; a trend toward minimally invasive surgeries, which could benefit from improved hemostasis products; and demand growth in the European surgical marketplace.

#### *Fibrin Sealant with Thrombin Market Size*

The current global market for both fibrin sealant and thrombin is estimated at \$675 million, a value that Haemacure believes could reach \$1.5 billion by 2015. In 2010 to 2011, when the Company anticipates being able to begin launching its products, management estimates that the market could be at \$900 million. Haemacure believes that in 2015 this field will likely be composed largely of fibrin sealants and thrombin products, as well as fibrin patches, as depicted in Figure 5. Accordingly, the Company anticipates that usage of both fibrin sealants and human thrombin is expected to continue to expand, encompassing broader labels and innovative new applications.

Figure 5  
ESTIMATED GLOBAL FIBRIN SEALANT AND THROMBIN MARKET BY 2015, IN U.S. MILLIONS



Source: Haemacure Corporation.

#### **Therapeutic Proteins**

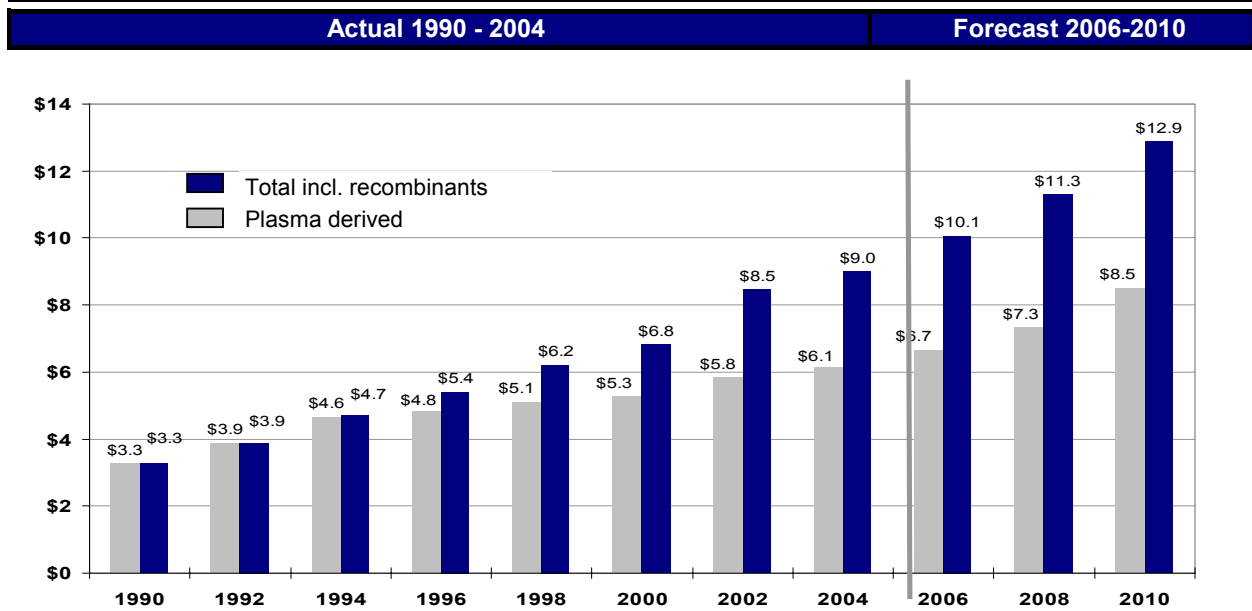
Plasma proteins extracted from human blood are valuable specialty products produced by a few fractionators (entities employing a technology to break down a substance into its component parts) and marketed principally to hospitals for use in the treatment of a variety of medical conditions, such as **hemophilia**, shock, trauma, burns, and immune disorders.



According to the Marketing Research Bureau, the protein plasma market was valued between approximately \$8.5 billion and \$9 billion in 2004 and is forecast to grow to approximately \$12.9 billion by 2010. Within this market in 2004, \$6.1 billion was related to plasma-derived proteins and \$2 billion to \$2.9 billion was related to plasma proteins that were produced recombinantly, as presented in Figure 6.

Figure 6

THE GLOBAL PLASMA PROTEIN PRODUCT MARKET (in billions)



Source: ProMetic Life Sciences Inc. (PLI.TO-TSX), a biopharmaceutical company and plasma fractionator.

## Competition

Within the acute surgical wound care market, the Company will likely compete against products used to control bleeding or heal wounds, polymer-based adhesives, collagen and gelatin-based hemostats, and even traditional staple or suture products to close wounds. Certain of these products may also be used in combination with fibrin sealants to further increase efficacy. In addition, commercialized fibrin sealants and thrombin, as well as companies that are developing other next-generation forms of recombinant, **autologous** (derived from the patient), or human plasma-derived fibrin sealants and thrombin, may pose significant competition for Haemacure as it introduces its products. Some of the key companies developing tissue sealants (which include fibrin sealant) or thrombin hemostatic agents are presented in Table 10 and summarized thereafter. This is not an exhaustive listing of potential competitors within this space, but is indicative of the type of competition that Haemacure may face as it seeks to commercialize its product candidates.

Table 10  
Haemacure Corporation  
COMPETITION

Company Name	Symbol (Exchange)	Last Trade (11/01/07)	52-week Range (\$)	Avg Vol (3 month)	P/E	Market Cap (\$)
<b>Tissue Sealants</b>						
Baxter International, Inc.	BAX (NYSE)	\$59.26	43.38 - 60.98	3,096,360	23.43	38.21B
CryoLife, Inc.	CRY (NYSE)	\$7.62	5.89 - 15.20	286,777	50.46	209.41M
Omxix Biopharmaceuticals, Inc.	OMRI (NASDAQ)	\$33.14	19.34 - 40.90	324,794	27.85	561.49M
Ethicon, Inc.	private	—	—	—	—	—
CSL Limited*	CSL (ASX)/ CMXHF.PK (OTC)	\$32.00	30.10 - 97.10	415	—	—
Kaketsuken	N/A	—	—	—	—	—
<b>Thrombin</b>						
King Pharmaceuticals, Inc.	KG (NYSE)	\$10.42	10.05 - 22.25	4,194,300	8.24	2.55B
Omxix Biopharmaceuticals, Inc.	OMRI (NASDAQ)	\$33.14	19.34 - 40.90	324,794	27.85	561.49M
Ethicon, Inc.	private	—	—	—	—	—
ZymoGenetics, Inc.	ZGEN (NASDAQ)	\$13.42	10.87 - 16.81	609,220	—	915.62M

\* Data shown is for CSL's Over-the-Counter (OTC) listing.

Sources: Crystal Research Associates, LLC and Yahoo! Finance.

### Tissue Sealants

#### *Baxter International, Inc.*

Baxter's BioScience business provides biopharmaceuticals derived from human plasma or recombinant technology to treat hemophilia, immune deficiencies, and other blood-related disorders. This business segment also provides vaccines for the prevention and treatment of certain infectious diseases, as well as biosurgery products. Baxter's biosurgery products include the following: (1) FloSeal™ Hemostatic Matrix, a high viscosity gel that stops bleeding in less than two minutes; (2) CoSeal® Surgical Sealant, a synthetic sealing agent for vascular reconstruction; and (3) Tisseel® VH, a fibrin sealant that consists of a two-component fibrin biomatrix with highly concentrated human fibrinogen to seal tissue and stop diffuse bleeding. Baxter's Tisseel® VH fibrin sealant contains a bovine fibrinolysis inhibitor, aprotinin, which may lead to severe allergic reactions. On June 20, 2007, Baxter announced that it signed licensing agreements with Intercytex Group (ICX.L-LSE) and Spinal Restoration, Inc. to evaluate Tisseel® VH as a drug delivery vehicle in various regenerative medicine therapies, including as a combination therapy with Intercytex's ICX-SKN, an investigational skin replacement therapy, and Spinal Restoration's Biostat Biologix™ Fibrin Sealant, which is specifically for the intervertebral disc area of the spine.



Separately, Baxter's Critical Care unit leverages its plasma fractionation experience to design innovative therapeutics developed from human serum albumin. The company also markets Aralast™ for patients with congenital A1PI deficiencies.

#### *CryoLife, Inc.*

CryoLife is dedicated to improving health through biosurgical devices and the transplantation of human tissues. The company maintains that it was the first biomedical company to commercially develop low temperature preservation of human heart valves for transplant. CryoLife's BioGlue® Surgical Adhesive uses bovine albumin and **glutaraldehyde**. BioGlue® can be dispensed with either a reusable delivery "gun" or a disposable syringe, such as CryoLife's BioGlue® Syringe, which was launched in May 2004 for use with the company's BioGlue®. The sealant reaches bonding strength within two minutes. BioGlue® is approved in more than 60 countries, including the U.S., Canada, Australia, and the EU.

#### *OMRIX Biopharmaceuticals, Inc. and Ethicon, Inc.*

OMRIX develops and markets biosurgical and passive immunotherapy products, utilizing a proprietary protein purification technology. OMRIX has partnered its biosurgical product line for hemostasis with Ethicon, a Johnson & Johnson company. OMRIX's passive immunotherapy product line includes antibody-rich products and product candidates for the treatment of immune deficiencies and infectious diseases as well as for potential biodefense applications. Its biosurgical line includes products and product candidates for hemostasis as well as other surgical applications. OMRIX currently markets two fibrin sealants: Evicel™ in the U.S. and Quixil® outside of the U.S. Evicel™ is a next-generation fibrin sealant that is indicated as an adjunct to hemostasis for use in patients undergoing liver or vascular surgery. The FDA approved Evicel™ in May 2007. Quixil® is indicated for use as a general adjunct to hemostasis in Europe, Israel, and several other countries. OMRIX aims to expand Evicel™ to include a general indication for hemostasis by the first quarter 2008, and has already submitted the required regulatory documents to both the FDA and the EMEA.

In addition, the company is developing a fibrin patch in collaboration with Ethicon. It is expected to help surgeons heal bleeding wounds by acting as an immediate barrier to stop bleeding and by utilizing a biological component that promotes clot formation at the site of the wound. The fibrin patch is in Phase I development in Israel. Furthermore, OMRIX's Adhexil™ is in early development for the prevention of adhesion in gynecological procedures.

#### *CSL Limited*

CSL is a global specialty biopharmaceutical company that is divided into three operating units: CSL Behring (formerly ZLB Behring), CSL Biotherapies, and CSL Bioplasma. CSL Bioplasma has been Australia's national fractionator of plasma-derived therapeutics since 1952, and is now the national plasma fractionator of New Zealand, Hong Kong, Malaysia, and Singapore as well. CSL Biotherapies creates biological products and markets medications for international partners, and CSL Behring provides plasma-derived and recombinant products. Specifically, CSL Behring produces coagulation therapies, immunoglobulins, A1PI, and wound-healing agents for surgeries. CSL Behring's fibrin sealant—Beriplast® P CombiSet—contains plasma-derived fibrinogen and thrombin as well as aprotinin. However, this product is not licensed for use in the U.S. CSL Behring also markets human albumin under a variety of product names based on location, as well as human fibrinogen and human **prothrombin** concentrates.

#### *Kaketsuken*

Kaketsuken originated in Kumamoto Medical College's Institute of Experimental Medicine in 1926. Its initial focus was on microbiology, immunology, and **serology**, as well as the production and supply of vaccines, anti-serums, and diagnostic antigens. After World War II, the institute was revived as Kaketsuken, the Chemo-Sero-Therapeutic Research Institute. Kaketsuken markets a variety of blood plasma products, including Bolheal™, an adhesive for living tissue during surgeries, as one of its main products. Like several other currently commercialized sealants, Bolheal™ contains human fibrinogen and thrombin, but also aprotinin. Kaketsuken additionally sells human albumin, immunoglobulin, and other plasma proteins. Kaketsuken focuses on the utilization of plasma proteins to prevent and treat diseases.

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## Thrombin

### *King Pharmaceuticals, Inc.*

King Pharmaceuticals is a vertically integrated pharmaceutical company developing therapies and technologies for cardiovascular and metabolic indications, neuroscience, and hospital and acute care. Among its many product offerings, the company sells Thrombin-JMI<sup>®</sup>, a bovine-derived hemostat. This product is distributed by a wholly owned subsidiary of King Pharmaceuticals, Jones Pharma Inc. Thrombin-JMI<sup>®</sup> is accompanied by a variety of delivery systems, including vials, spray kits, and syringe spray kits. In January 2006, King Pharmaceuticals was named one of the “Top 9 Best Managed Drug Companies” by *Fortune*. Prior to the recent FDA approval of OMRIX and Ethicon’s Evithrom (detailed below), Thrombin-JMI<sup>®</sup> was the only marketed standalone thrombin.

### *OMRIX Biopharmaceuticals, Inc. and Ethicon, Inc.*

As detailed on page 30, OMRIX and Ethicon partner for the development of biosurgical products. In addition to the companies’ fibrin sealants, a human thrombin has also been created through this partnership. On August 27, 2007, the FDA approved OMRIX’s BLA (submitted in November 2006) to market a standalone thrombin product, Evithrom<sup>™</sup>, for general hemostasis in surgery. Evithrom<sup>™</sup> uses the same thrombin component as the Evicel<sup>™</sup> and Quixil<sup>®</sup> products. Like Haemacure’s Hemaseel<sup>®</sup>Thrombin, OMRIX’s thrombin is derived from human plasma instead of bovine materials. As such, it is believed to be able to decrease side effects. Ethicon is marketing Evithrom<sup>™</sup> as both a standalone thrombin and in conjunction with an absorbable gelatin sponge. The product is anticipated to be commercially available in the U.S. during the fourth quarter 2007.

### *ZymoGenetics, Inc.*

ZymoGenetics is focused on the discovery, development, and commercialization of therapeutic proteins, and has contributed to the discovery or development of six recombinant protein products now marketed by other companies. The company’s patent portfolio includes more than 295 issued or allowed U.S. patents. ZymoGenetics is developing a recombinant thrombin product, rThrombin, which is designed to be an alternative to currently marketed products derived from either human or animal blood sources. As a hemostatic agent, rThrombin has completed clinical trials and is in the pre-registration stage, with a BLA accepted for review by the FDA. The product candidate’s Phase III trials demonstrated that it had comparable efficacy and immunogenicity to marketed bovine thrombin. ZymoGenetics is also evaluating rThrombin in other indications, including as a component in surgical sealants where either bovine-derived or human plasma-derived thrombin is currently used. ZymoGenetics collaborates with Bayer HealthCare to develop and commercialize rThrombin. In addition, the company has an rThrombin spray in Phase II development.

On August 23, 2007, ZymoGenetics announced that, after submitting a significant amount of additional manufacturing information to the FDA, the FDA delayed the **Prescription Drug User Fee Act (PDUFA)** date for its BLA by three months until January 17, 2008.



## Potential Milestones

Haemacure aims to achieve the milestones listed in Table 11 over the next 12 to 24 months.

Table 11  
Haemacure Corporation  
PROJECT MILESTONES TO PRODUCT APPROVAL

Milestone	Timeline
▪ Hire additional key employees	Ongoing
▪ Identify additional proteins and enzymes from discard	Ongoing
▪ Develop multiple partnerships/collaborations	Ongoing
▪ Produce and ship laboratory materials to potential partners	Fourth Quarter 2007
▪ Select a contract research organization (CRO)	First Quarter 2008
▪ Finalize clinical protocol	First Half 2008
▪ Complete manufacturing facility	Second Half 2008
▪ Produce clinical material	Second Half 2008
▪ Amend IND to launch into pivotal trials	Second Half 2008
▪ Commence pivotal trial for fibrin sealant (Hemaseel <sup>®</sup> HMN)	First Quarter 2009
▪ Commence clinical trials for thrombin (Hemaseel <sup>®</sup> Thrombin)	First Half 2009

*Source: Haemacure Corporation.*

## Key Points to Consider

*All amounts are in U.S. dollars unless otherwise specified.*

- Haemacure Corporation is a development-stage specialty biotherapeutics company that develops high-value, human therapeutic proteins for commercialization, based on a patented, high-yield fibrinogen and thrombin extraction technology. In February 2007, the Company reorganized and now focuses on delivering next-generation products with a shortened time to market.
- Haemacure's patented extraction technology delivers higher product yields than the traditional Cohn fractionation process. In turn, improved yields enable the generation of greater revenue per liter of source plasma. The Company's yields result from optimizing its extraction process for fibrinogen and thrombin instead of albumin and immunoglobulin, such as with the Cohn process. Haemacure believes that its technology can deliver superior fibrin sealant and higher quality proteins.
- The Company's pipeline comprises two clinical-stage programs: (1) its lead product candidate, Hemaseel<sup>®</sup>HMN, which is an all-human fibrin sealant to enter pivotal Phase II/Phase III clinical trials; and (2) Hemaseel<sup>®</sup>Thrombin, an active, absorbable hemostatic agent. Hemaseel<sup>®</sup>Thrombin is a component of Haemacure's fibrin sealant that can be used as a standalone product or in combination with biomaterials.
  - Furthermore, Haemacure has discovered therapeutic proteins and enzymes in one of its two plasma fractions. The Company is seeking to develop and commercialize these proteins and enzymes in collaboration with pharmaceutical and biotechnology companies, a step that could create new market opportunities and revenue generation for Haemacure.
  - The Company also continues to sell its two U.S. Food and Drug Administration (FDA)-cleared fibrin sealant delivery devices: (1) HemaSyst<sup>™</sup>, a dual-syringe applicator system with 10 specialty functional adapters; and (2) HemaMyst<sup>™</sup>, an aerosol device to deliver fluids over a broad area. Sales in fiscal years 2007, 2006, and 2005 were entirely derived from these delivery devices.
- Both Hemaseel<sup>®</sup>HMN and Hemaseel<sup>®</sup>Thrombin are made with only human proteins, unlike the dominant fibrin sealant today, which contains aprotinin, a bovine-derived protein, and the dominant thrombin, which is also of bovine origin. Since Haemacure's product candidates are entirely human, they can be used without immunogenicity complications, thereby reducing side effects as well as the risk of cross-species disease transmission.
  - There is a significant trend among companies developing hemostats to develop products using human proteins. To this effect, an article published in a 2004 edition of *Thrombosis and Haemostasis* maintains that, while usage of thrombin in particular is likely to significantly increase, its therapeutic development hinges upon the availability of a safe human preparation.
  - Moreover, Hemaseel<sup>®</sup>Thrombin is a component of the Company's fibrin sealant. Thus, as a standalone product, it leverages the safety and efficacy profile established in the fibrin sealant clinical trials. Accordingly, Hemaseel<sup>®</sup>Thrombin may have a shorter clinical timeline with minimized risks associated with its trials.
- Haemacure is progressing to a registration process, with a manufacturing facility expected to be in place by mid-2008; a presently open Investigational New Drug (IND) application with the FDA from which to initiate fibrin sealant Phase II/Phase III trials; and 151 human subjects and patients who have received Hemaseel<sup>®</sup>HMN without any reported serious adverse events relating to the product.



- The worldwide fibrin sealant market is valued at approximately \$400 million. Of that amount, the largest segments are believed to be Japan, with \$145 million, and the U.S., with \$116 million. Additionally, in 2006, sales of topical, absorbable hemostatic agents were estimated at roughly \$595 million and forecast to reach \$842 million by 2011. Haemacure believes that the global market for both fibrin sealant and thrombin could reach \$1.5 billion by 2015. Furthermore, the therapeutic protein plasma market was valued between approximately \$8.5 billion and \$9 billion in 2004 and is forecast to grow to approximately \$12.9 billion by 2010.
- The Company believes that it operates in markets that deliver high gross margins and that have significant barriers to entry. Entrants are believed to require from 7 to 10 years of research and development and between \$50 million to \$100 million in investments to develop competing products, including intellectual property, formulation, and production know-how.
- Haemacure's intellectual property comprises various trademarks and several patents for the production of its fibrin sealant and thrombin. The Company's patents are issued in the U.S. and 24 other countries, including Canada and countries in Europe and Asia, under the Patent Cooperation Treaty (PCT). Further, Haemacure has successfully defended its key patent against claims from Aventis Behring GmbH (now CSL Behring, part of CSL Limited) in the past.
- Haemacure's management has domain and technical expertise, with an extensive understanding of the Company as well as a broad array of fields. Mr. Joseph Galli (chairman and chief executive officer [CEO]) has a record of financing, mergers and acquisitions, restructuring, and company turnarounds; Mr. Marc Paquin (president) is the founder of Haemacure with hands-on industry experience; Dr. Christian Hours (vice president of quality and technical affairs) is knowledgeable in scientific and regulatory matters as well as in technology transfer; and both Mrs. Lyne Paré (director of finance and administration) and Mr. Gilles Lemieux (corporate secretary, investor relations) have been with the Company for the past 10 years.
- At September 30, 2007, cash, cash equivalents, and temporary investments were C\$7.4 million versus C\$519,300 at October 31, 2006. Haemacure anticipates that the balance of its required funding can come from collaboration agreements and partnerships.
- Haemacure raised C\$12.5 million in a non-brokered private placement in January 2007, for net proceeds to the Company of approximately C\$11.5 million. Firebird Global Master Fund, Ltd. and Firebird Global Master Fund II, Ltd., both affiliated with New York-based Firebird Management LLC, were lead investors in Haemacure's private placement for an aggregate amount of C\$2.5 million.
- As part of the Company's January 2007 private placement, Haemacure issued Warrants entitling holders to acquire one Common Share of Haemacure for a period of five years from the closing date of the placement at a price of C\$0.20. Haemacure maintains the right to force the exercise of these Warrants if the closing price of its Common Shares on the Toronto Stock Exchange (TSX) is C\$0.40 or greater for 20 consecutive trading days. Should Haemacure call the Warrants, and all holders exercise the Warrants, this would generate C\$12.5 million for the Company.
- Based upon the achievement of certain milestones, the Company expects to receive \$4.5 million from CSL Behring. This payment is to be made in three equal installments: (1) the first upon the commissioning of the manufacturing plant; (2) the second upon amendment of the IND with the FDA; and (3) the last upon enrollment of 50% of the patients for the required fibrin sealant clinical trials. On August 20, 2007, CSL advised Haemacure that it believes that CSL is no longer obliged to pay this sum, due to Haemacure's unsatisfactory progress with the project. Haemacure disputes the position of CSL and intends to aggressively defend its right to the future payment of this sum. This has no impact on Haemacure's current financial position.

## Historical Financial Results

Tables 12, 13, and 14 summarize Haemacure's key historical financial statements: its Consolidated Statements of Operations, Consolidated Balance Sheets, and Consolidated Statements of Cash Flows. The Company's fiscal year end is October 31.

*All financial statements are in Canadian Dollars (C\$).*

(Unaudited)	Three months ended July 31,		Nine months ended July 31,	
	2007	2006	2007	2006
	\$	\$	\$	\$
Sales	31,674	31,409	88,537	116,389
Cost of sales	18,731	14,367	48,640	48,974
Gross margin	12,943	17,042	39,897	67,415
<b>Expenses (income)</b>				
Selling and marketing	—	13,105	—	41,168
General and administrative	734,286	522,444	2,531,999	1,758,514
Research and development, net	158,534	188,980	529,574	527,030
Loss on foreign exchange	5,923	864	26,129	40,949
Amortization of property, plant, and equipment	17,927	14,516	38,116	44,007
Amortization of other assets	872	872	2,615	2,615
Interest on obligation under capital leases	581	732	1,857	2,301
Interest on long-term debt	15,435	12,750	45,241	33,638
Other financial expenses	29,085	—	64,275	—
Investment income	(92,821)	(13,058)	(227,702)	(65,422)
	869,822	741,205	3,012,104	2,384,800
<b>Net loss for the period</b>	<b>(856,879)</b>	<b>(724,163)</b>	<b>(2,972,207)</b>	<b>(2,317,385)</b>
Weighted average number of				
outstanding Common Shares	163,800,917	38,800,917	132,381,210	38,800,917
Basic and diluted loss per Common Share	(0.01)	(0.02)	(0.02)	(0.06)

*Source: Haemacure Corporation.*



All financial statements are in Canadian Dollars (C\$).

Table 13  
Haemacure Corporation  
CONSOLIDATED BALANCE SHEETS

(Unaudited)	As at July 31, 2007 \$	As at October 31, 2006 \$
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	4,292,487	78,300
Temporary investment	4,007,200	441,000
Accounts receivable - trade	12,313	12,431
Other receivables	92,368	80,540
Inventories	25,644	34,167
Prepaid expenses	96,080	74,974
	8,526,092	721,412
Property, plant, and equipment	3,176,371	1,959,679
Other assets	23,742	15,107
	11,726,205	2,696,198
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>Current liabilities</b>		
Accounts payable and accrued liabilities	257,744	447,539
Current portion of obligation under capital leases	11,403	10,933
	269,147	458,472
Obligation under capital leases	28,118	36,730
Lease obligation	55,842	29,851
Long-term debt	1,235,004	1,189,764
	1,588,111	1,714,817
<b>Shareholders' equity</b>		
Share capital	100,666,948	92,266,948
Additional paid-in capital	7,710,326	2,540,912
Deficit	(98,245,962)	(93,826,479)
Accumulated other comprehensive income	6,782	—
	10,138,094	981,381
	11,726,205	2,696,198

Source: Haemacure Corporation.



All financial statements are in Canadian Dollars (C\$).

Table 14  
Haemacure Corporation  
CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)	Three months ended July 31,		Nine months ended July 31,	
	2007	2006	2007	2006
	\$	\$	\$	\$
<b>OPERATING ACTIVITIES</b>				
Net loss for the period	(856,879)	(724,163)	(2,972,207)	(2,317,385)
Items not affecting cash:				
Amortization of property, plant, and equipment	17,927	14,516	38,116	44,007
Amortization of other assets	872	872	2,615	2,615
Accrued interest on long-term debt	15,434	12,750	45,240	33,638
Accrued interest on accounts receivable from a supplier	—	—	—	(15,859)
Stock-based compensation expense	110,168	—	674,558	40,463
Rent expense	8,226	—	25,991	—
Foreign exchange loss on cash and cash equivalents	11,665	3,653	14,944	12,100
Unrealized gain/loss on available for sale investments	(42,563)	—	6,782	—
Unrealized foreign exchange loss (gain)	—	(1,136)	—	16,196
	(735,150)	(693,508)	(2,163,961)	(2,184,225)
Net change in non-cash working capital balances related to operations	(296,557)	76,287	(175,677)	1,167,435
<b>Cash flows relating to operating activities</b>	<b>(1,031,707)</b>	<b>(617,221)</b>	<b>(2,339,638)</b>	<b>(1,016,790)</b>
<b>FINANCING ACTIVITIES</b>				
Issuance of units	—	—	12,500,000	—
Share issue costs	—	—	(1,052,420)	—
Repayment of obligation under capital leases	(2,752)	(2,602)	(8,142)	(7,698)
<b>Cash flows relating to financing activities</b>	<b>(2,752)</b>	<b>(2,602)</b>	<b>11,439,438</b>	<b>(7,698)</b>
<b>INVESTING ACTIVITIES</b>				
Acquisition of temporary investment	(4,007,200)	—	(4,007,200)	—
Disposition of temporary investment	—	659,316	441,000	1,151,298
Acquisition of property, plant, and equipment	(308,737)	(102,271)	(1,254,808)	(795,827)
Acquisition of other assets	(11,250)	—	(11,250)	—
Accounts payable related to property, plant, and equipment	—	—	(38,411)	—
<b>Cash flows relating to investing activities</b>	<b>(4,327,187)</b>	<b>557,045</b>	<b>(4,870,669)</b>	<b>355,471</b>
Effect of exchange rate changes on cash and cash equivalents	(11,665)	(3,653)	(14,944)	(12,100)
<b>Net change in cash and cash equivalents</b>	<b>(5,373,311)</b>	<b>(66,431)</b>	<b>4,214,187</b>	<b>(681,117)</b>
Cash and cash equivalents at beginning of period	9,665,798	199,978	78,300	814,664
<b>Cash and cash equivalents at end of period</b>	<b>4,292,487</b>	<b>133,547</b>	<b>4,292,487</b>	<b>133,547</b>
<b>Supplemental information</b>				
Interest paid	29,666	732	66,132	2,301

Source: Haemacure Corporation.



## Risks

Some information in this report relates to future events or future business and financial performance. Such statements can be only predictions and the actual events or results may differ from those discussed due to, among other things, the risks described in Haemacure's reports in its Annual Information Form (AIF), press releases, and other forms filed from time to time. The content of this report with respect to Haemacure has been compiled primarily from information available to the public and released by the Company through news releases and System for Electronic Document Analysis and Retrieval (SEDAR) filings. Haemacure is solely responsible for the accuracy of that information. Information about other companies has been prepared from publicly available documents and has not been independently verified by Haemacure. For more complete information about Haemacure, refer to the Company's website at [www.haemacure.com](http://www.haemacure.com).

One should carefully consider the risks and information about Haemacure's business described below. One should not interpret the order in which these considerations are presented as an indication of their relative importance. The risks and uncertainties described below are not the only ones the Company faces. Additional risks and uncertainties not presently known or those it currently considers immaterial may also have an adverse effect on its business. If any of the matters discussed in the accompanying risk factors were to occur, Haemacure's business, financial condition, results of operations, cash flows, or prospects could be materially adversely affected.

### Foreign Currency Risk

Haemacure operates internationally and a substantial portion of its expense activities is in U.S. dollars. A significant adverse change in the currency exchange rate between the Canadian dollar relative to the U.S. dollar could have a material effect on the Company's consolidated results of operations, financial position, or cash flows. Haemacure has not hedged its exposure to currency fluctuations.

### Reliance on External Financing

Haemacure will require additional financing to fund operations, complete projects, and obtain the required regulatory approvals. Such funding may come from further equity investments or borrowings. No assurance can be given that such funding will be available.

### Uncertainties Related to Commercialization and Development

Haemacure's fibrin sealant is fully developed, has been dosed in 151 human subjects and patients without any severe adverse event attributable to the product being reported, and is to enter pivotal Phase II/Phase III clinical trials. The Company's thrombin product is also developed and is to enter clinical trials. The Company has not received marketing approval for these products from any regulatory body. The Company's devices were cleared for sale by the FDA.

The development and commercialization of new products is highly uncertain, as is the timing associated with these activities. Among other things, potential products that may appear to Haemacure to be promising may not reach the market for any number of reasons, including the possibility that they are found to be ineffective or cause harmful side effects during clinical trials, that they fail to receive the necessary regulatory approvals, that they prove to be difficult to manufacture on a commercial scale or uneconomical, that they fail to achieve market acceptance, or that they are precluded from commercialization because of proprietary rights held by third parties. No assurance can be made that any of the Company's development programs will be successfully completed, that clinical trials will yield the anticipated results, or that such trials will begin or be completed as planned.

### Absence of Profitability

Haemacure commenced operations in 1991 and has not realized profit from operations since then. There can be no assurance that the Company will attain and maintain profitability in the future. There is currently a growing market for fibrin sealant and thrombin products, and Haemacure believes that this market will

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likely continue to grow. However, the market may not grow as expected by Haemacure, and its assumptions may prove incorrect for a variety of reasons, including the failure to obtain the required regulatory approvals, competition from other products, and the degree of commercial viability of the Company's products.

### **Product Liability Claims**

The development, manufacture, and sale of Haemacure's products may expose the Company to product liability claims. There can be no assurance that it will not experience losses due to product liability claims in the future. The Company currently has general liability insurance. However, there can be no assurance that such coverage will be available to it in the future or on reasonable terms, if at all. In addition, there can be no assurance that all of the activities encompassed within Haemacure's business are or will be covered under its policies. Any claims or series of claims against the Company, regardless of their merit or eventual outcome, could have a material adverse impact on business, financial position, and operating results.

### **Intellectual Property**

Haemacure places great importance on the protection of its intellectual property and has a portfolio of patents that it intends to enforce. However, unauthorized parties may infringe on the Company's patents or obtain information that is proprietary, and there can be no assurance that the Company will be able to successfully defend its existing patents in the case of infringement. If Haemacure is unable to protect its intellectual property rights, its competitors may develop and market products with similar features that may reduce demand for the Company's products and the effective commercialization of Haemacure's products may be inhibited.

### **Dependence on Key Personnel**

Haemacure depends on certain members of its management and scientific staff. The loss of services of one or more of said persons could adversely affect the Company. While it has been able to attract and retain skilled and experienced personnel in the past, no assurance can be given that it will be able to do so in the future.

### **Competition**

Some of the Company's potential competitors have greater financial, marketing, and other resources than Haemacure. There can be no assurance that the Company will be able to compete successfully with potential competitors. Haemacure believes that other fibrin sealant and thrombin products may be approved in the U.S. for use before the Company files BLAs for its products. There is no guarantee that any new products from competitors will not have a material adverse impact on the Company's sales in the future.

### **Ability to Manage Future Growth**

Future growth, if any, may cause a significant strain on Haemacure's management and its operational, financial, and other resources. The Company's ability to manage growth effectively will require it to implement and improve operational, financial, manufacturing, and management information systems and to expand, train, manage, and motivate employees. These demands may require the addition of management personnel and the development of additional expertise by management. Any increase in resources devoted to research, product development, and marketing and sales efforts without a corresponding increase in operational, financial, manufacturing, and management information systems could have a material adverse effect on the Company's business, financial condition, and results of operations.



## Recent Events

*All amounts are in U.S. dollars unless otherwise specified.*

**10/24/2007**—Haemacure Corporation announced its First-Patient-In objective for the first quarter 2009 and its two-phase manufacturing strategy. These are further detailed on pages 6-7.

**08/31/2007**—Released the results of its third quarter ended July 31, 2007. Revenues amounted to C\$31,674 versus C\$31,409 for the same quarter last year. The consolidated net loss for the quarter amounted to C\$856,879, or (C\$0.01) per share, versus C\$724,163, or (C\$0.02) per share, for the same quarter last year.

**06/21/2007**—Haemacure and UTEK Corporation announced entering into a technology acquisition alliance. Haemacure believes that the alliance will likely provide the Company with global access to intellectual properties that can leverage its product candidates. This alliance was entered into under UTEK's previously announced Master Alliance Agreement with Rodman & Renshaw's Acumen Biofin division. Through its technology acquisition alliances, UTEK assists companies in enhancing new product pipelines with the acquisition of proprietary intellectual capital from universities and laboratory research centers. Technology acquisition alliances are generally cancelable by either party with 30 days advance written notice.

**06/14/2007**—Haemacure announced the preliminary findings of the content analysis of one of its plasma discards. Preliminary findings confirm the presence of a number of proteins and enzymes with applications in significant worldwide markets, including albumin, plasminogen, immunoglobulin, and alpha-1 proteinase inhibitor (A1PI). These findings have a strategic significance for Haemacure as revenues eventually generated from the commercial exploitation of these proteins and enzymes could constitute a direct contribution to the bottom line. This may occur as the cost of the plasma will likely be fully borne by Haemacure's fibrin sealant and hemostatic agent once these products are commercialized. As advised, these findings are preliminary and the full value of these proteins and enzymes cannot be realized without U.S. Food and Drug Administration (FDA) approval. Haemacure continues identification work on its plasma discard and seeks partnerships with pharmaceutical and biotechnology companies that could fund the development and clinical activities required to bring these proteins and enzymes to market, and with which the Company would share sales revenues.

**06/01/2007**—Released the results of its second quarter ended April 30, 2007. Revenues amounted to C\$24,757 versus C\$36,918 for the same quarter last year. The consolidated net loss for the quarter amounted to C\$1.3 million, or (C\$0.01) per share, versus C\$741,327, or (C\$0.02) per share, for the same quarter last year.

**04/04/2007**—Announced that Mr. Joseph A. Akers (biography on page 13) was appointed to the Board of Directors and the Audit Committee. While at Bayer HealthCare, Mr. Akers acquired valuable experience in the development, production, and marketing of plasma protein products that may prove beneficial to Haemacure in its new development plan.

**03/02/2007**—Released the results of its first quarter ended January 31, 2007. Revenues amounted to C\$32,106 versus C\$48,062 for the same quarter last year. The consolidated net loss for the quarter amounted to C\$813,253, or (C\$0.01) per share, versus C\$851,895, or (C\$0.02) per share, for the same quarter last year.

**02/05/2007**—Provided an update on its Hemaseel<sup>®</sup> project. The project consists of completing the development of two proprietary products, the Hemaseel<sup>®</sup>HMN fibrin sealant and the Hemaseel<sup>®</sup>Thrombin hemostatic agent. Both products are derived from Haemacure's patented plasma protein extraction technology and contain only human plasma proteins. They do not contain any bovine protein, thereby eliminating immunological risks associated with such components.

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**02/05/2007**—Announced that Mr. Joseph Galli (biography on page 12) was appointed chief executive officer (CEO) of Haemacure, effective February 1, 2007. Mr. Galli is also chairman of the Board of Haemacure. Mr. Marc Paquin (biography on page 12) continues to hold the office of president and to serve as a director of Haemacure.

**01/23/2007**—Announced the results of the fiscal year ended October 31, 2006. Haemacure recorded revenues of C\$147,134 in fiscal 2006 versus C\$258,153 the prior year. This decrease in sales revenues results from the discontinuance in November 2003 of all sales and marketing activities associated with the fibrin sealant Hemaseel<sup>®</sup>APR sold under license from Baxter. Haemacure incurred a net loss of C\$3.0 million in fiscal 2006, or (C\$0.08) per share, up from a net loss of C\$1.9 million, or (C\$0.05) per share, for the prior year.

**01/16/2007**—Announced that it held a final closing of its private placement by issuing 30 million additional units at a price of C\$0.10 per unit, for additional gross proceeds to Haemacure of C\$3 million. By holding the final closing, Haemacure reached its objective of raising C\$12.5 million. An initial closing of the private placement was held on January 5, 2007, for gross proceeds to Haemacure of C\$9.5 million.

**01/08/2007**—Announced that it held a closing of its private placement by issuing 95 million units at a price of C\$0.10 per unit, for gross proceeds to Haemacure of C\$9.5 million. Each unit consists of one Common Share, one-half of a Series A Common Share Purchase Warrant, and one-half of a Series B Common Share Purchase Warrant. Each full Series A Warrant entitles its holder to acquire one additional Common Share for a period of five years from the closing date of the placement, at a price of C\$0.30. Each full Series B Warrant entitles its holder to acquire one additional Common Share for a period of five years from the closing date of the placement, at a price of C\$0.20. Haemacure has the right to force the exercise of the Series B Warrants if the closing price of its Common Shares on the Toronto Stock Exchange (TSX) is C\$0.40 or greater for 20 consecutive trading days.

**12/11/2006**—Announced that it is in the process of effecting a private placement in a maximum amount of C\$12.5 million, the proceeds of which were intended to be used primarily to finance the development of Hemaseel<sup>®</sup>HMN and Hemaseel<sup>®</sup>Thrombin.

**03/27/2006**—Announced that at its annual and special meeting held on March 16, 2006, its shareholders approved, by way of special resolution, an amendment to the terms and conditions of a compensation option and of 2,760,000 Warrants previously granted, so as to extend the expiry date and adjust the exercise price thereof. Included in the 2,760,000 Warrants are 520,000 Warrants to be issued upon the exercise of the compensation option. As a result of the amendment, the expiry date of the compensation option and Warrants has been extended by one year until March 19, 2007.

**02/01/2006**—Commented on news published on the internet of a Warning Letter received recently from the FDA. The Company's current activities to build a new Hemaseel<sup>®</sup>HMN fibrin sealant manufacturing plant were not a part of the Warning Letter's focus. Haemacure reported that it has already undertaken to remedy the deficiencies noted in the letter. Haemacure has communicated its remediation plan to the FDA and intends to work closely with the FDA to show its commitment and progress in addressing the items raised in the Warning Letter. The Warning Letter cited certain document deficiencies relating to two marketed devices, which had sales of \$258,000 in 2005. No safety issues have been reported regarding these devices, and the Warning Letter does not affect Haemacure's permission to market both devices.

**01/19/2006**—Announced that it received payment of \$1 million from Baxter, as per the terms of the October 2003 Settlement, Termination, and Release Agreement providing for the termination of the Hemaseel<sup>®</sup>APR fibrin sealant license and supply agreements. Under the terms of this agreement, Baxter undertook to pay Haemacure approximately \$5.4 million over a period ending in January 2006. With this recent payment, Baxter has now paid this sum in full, in compliance with the agreement. Haemacure used this payment for operations, including the Hemaseel<sup>®</sup>HMN and Hemaseel<sup>®</sup>Thrombin manufacturing project.

## Glossary

**Albumin**—A class of simple, water-soluble proteins that can be coagulated by heat and are found in egg white, blood serum, milk, and many other animal and plant tissues. Albumin is the most prevalent protein in the bloodstream and a key regulator of osmotic pressure. It is distributed throughout virtually all tissues of the body.

**Antifibrinolytic**—Inhibiting the breakdown of fibrin, the blood component that forms the essential portion of a blood clot.

**Aprotinin**—An intravenously administered protein that helps prevent bleeding following cardiac surgery. It works by blocking the action of certain enzymes in the bloodstream that dissolve blood clots.

**Autologous**—A transfer of material, such as bone marrow, blood, or skin, from a donor to him or herself. To make this possible, donated material is removed and stored prior to the procedure where the donor will need the autologous material.

**Biologic License Application (BLA)**—A request to the FDA to authorize a company to market a biological product in interstate commerce.

**Biomaterials**—A natural or synthetic material that is suitable for introduction into living tissue especially as part of a medical device.

**Black Box Warning**—A warning that appears on prescription drugs that may cause serious adverse effects, as indicated in medical studies. The U.S. Food and Drug Administration (FDA) can require a pharmaceutical company to place a black box warning on the labeling of a prescription drug or in literature describing it. It is the strongest warning that the FDA requires.

**Bovine**—Pertaining to, characteristic of, or derived from cattle.

**Cannula**—A small flexible tube inserted into a body cavity for draining off fluid or introducing medication.

**Clotting Factors**—Any of various plasma components involved in the clotting of blood, including fibrinogen, prothrombin, thromboplastin, and calcium ion.

**Coagulation**—(of blood) To form a clot.

**Cohn Fractionation**—A plasma separation process developed during World War II to provide stable albumin for combat casualties. Fractionation is the separation of a mixture (plasma) in successive stages, each stage removing from the mixture some proportion of one of the substances, as by differential solubility in water-solvent mixtures.

**Collagen**—A long protein fiber that connects and strengthens various tissues.

**Common Technical Document (CTD)**—A set of specifications for the registration of medicines designed to be used across Europe, Japan, and the U.S. It was developed by the EMEA, the FDA, and the Ministry of Health, Labor, and Welfare (Japan).

**Dura Mater**—The outermost of three membranes protecting the brain and spinal cord. It is tough and leather-like.

**Emphysema**—A chronic, irreversible disease of the lungs.

**Enzyme Replacement Therapies (ERTs)**—Therapeutic approaches for genetic disorders whereby the missing enzyme is manufactured separately and given intravenously to the patient on a regular basis.

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**Epsilon-Amino Caproic Acid (EACA)**—An antifibrinolytic agent.

**Excipients**—Inactive ingredients used to stabilize or dilute a formulation. These are easily procured on the chemical product market.

**Fabry's Disease**—An inherited disease that is associated with a deficiency of an enzyme that would typically help the body break down certain complex sugars. Lesions and disease states that exist in patients with Fabry's disease include red skin lesions in males, diseased nerves affecting involuntary bodily functions, and blood vessel diseases that block blood flow to the brain, heart, eye, and kidney.

**Fibrin**—An elastic, insoluble, whitish protein produced by the action of thrombin on fibrinogen and forming an interlacing fibrous network in the coagulation of blood.

**Fibrinogen**—A protein in the blood plasma that is essential for the coagulation of blood and is converted to fibrin by the action of thrombin in the presence of ionized calcium.

**Gaucher's Disease**—An inherited metabolic disorder in which harmful quantities of a fatty substance called glucocerebroside accumulate in the spleen, liver, lungs, bone marrow, and sometimes in the brain.

**Gelatin**—A colorless, water-soluble glutinous protein in animal tissues, such as bone and skin.

**Glutaraldehyde**—A compound used in an aqueous solution as a disinfectant and a sterilizer.

**Hemophilia**—A hereditary bleeding disorder, where blood does not clot normally. People with the disorder bleed for longer periods of time, which is of greatest concern when bleeding occurs internally—in the joints, tissues, muscles, and especially the vital organs, such as the brain. Many hemophiliacs rely on regular transfusions of the clotting factor in plasma.

**Hemostasis**—Stopping bleeding through natural (clot formation, constriction of blood vessels), artificial (compression, ligation), or surgical means.

**Hemostatic**—Pertaining to a small surgical instrument used to clamp blood vessels or an agent used to control or stop bleeding.

**Hunter's Disease**—A rare sex-linked hereditary disorder that varies widely in its severity but is generally characterized by some degree of dwarfism, mental retardation, and deafness. The disease affects only males and makes its first appearance during the first three years of life. Many patients die before age 20.

**Hurler's Disease**—A hereditary disease consisting of an error in mucopolysaccharide metabolism and characterized by severe abnormalities in development of skeletal cartilage and bone as well as mental retardation.

**Immunogenicity**—The ability of a substance to elicit an immune response, often the production of antibodies against the substance.

**Immunoglobulin**—Any of a group of large glycoproteins that are secreted by plasma cells and that function as antibodies in the immune response by binding with specific antigens. There are five classes of immunoglobulins: IgA, IgD, IgE, IgG, and IgM.

**Investigational New Drug (IND)**—Refers to the FDA's program by which a pharmaceutical company obtains permission to ship an experimental drug across state lines (usually to clinical investigators) before a marketing application for the drug has been approved. The FDA reviews the IND for safety to assure that research subjects are not subjected to unreasonable risk. The application has three main sub-sections: Animal Pharmacology and Toxicology Studies; Manufacturing Information; and Clinical Protocols and Investigator Information.

**Laparoscopic**—Relating to a method of conducting surgery using specially designed instruments and cameras that are inserted through small incisions.



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**Morquio's Disease**—A metabolic disorder that can cause various respiratory abnormalities. Patients who live into adulthood are likely to develop upper airway problems and respiratory failure.

**Orphan Drugs**—A drug to treat either a rare disease that affects fewer than 200,000 people or a common disease that has been ignored because it is less prominent in the U.S. than in developing nations. According to the National Institutes of Health, there are approximately 6,000 Orphan diseases.

**Patent Cooperation Treaty (PCT)**—Provides a unified procedure for filing patent applications to protect inventions in approximately 130 countries. A single filing results in a single search accompanied with a written opinion (and optionally a preliminary examination), after which the examination (if provided by national law) and grant procedures are handled by the relevant national or regional authorities. The PCT does not lead to the grant of an “international patent,” which does not exist.

**Plasma Fractions**—The remaining plasma after the desired components are extracted. Haemacure's extraction technology produces two plasma fractions: one from the extraction of fibrinogen, and the other from thrombin. See *plasma* (below).

**Plasma**—The liquid portion of the blood that remains once red blood cells, white blood cells, and platelets have been removed. It contains coagulation factors and is used to treat patients who develop bleeding problems during major surgery or massive trauma. Because some of the factors lose effectiveness quickly, plasma must be frozen in order to preserve its functions.

**Plasminogen**—An inactive form of plasmin that occurs in plasma and is converted to plasmin by organic solvents. Plasmin is a degrading enzyme of many proteins of blood plasma, but particularly of fibrin clots.

**Platelets**—Cellular fragments. Their primary function is to prevent bleeding.

**Pompe's Disease**—A rare genetic disorder that belongs to a group of diseases known as glycogen storage diseases. Affecting only 1 in every 40,000 people in the U.S., Pompe's disease is characterized by the inability to break down excess glycogen.

**Prescription Drug User Fee Act (PDUFA)**—Enacted in 1992 and renewed in 1997 and 2002, the PDUFA authorizes the FDA to collect fees from companies that produce certain human drug and biological products. The PDUFA established three types of user fees: application fees, establishment fees, and product fees. User fees have an important role in expediting the drug approval process.

**Prothrombin**—A substance found in circulating blood that interacts with calcium salts to form thrombin, which is necessary for blood clotting.

**Pseudoaneurysm**—A vascular abnormality (e.g., an elongation or buckling of the aorta) that resembles an aneurysm in radiography.

**Recombinant**—Containing genetic material not present in either parent, often resulting from the splicing or combining of different DNA fragments.

**Schindler's Disease**—An autosomal recessive disorder with deficient activity of alpha-N-acetylgalactosaminidase resulting in the accumulation of glycoproteins and other substrates that are deposited in terminal axons, primarily in gray matter.

**Serology**—The branch of science dealing with the measurement and characterization of antibodies and other immunological substances in body fluids, particularly serum.

**Suture**—The stitches used to hold tissue together or to close a wound.

**Thrombin**—An enzyme that acts on fibrinogen in blood, causing it to clot.

**Tranexamic Acid (TA)**—A synthetic derivative of the amino acid lysine with antifibrinolytic activity. TA inhibits the activation of plasminogen to plasmin, resulting in inhibition of fibrinolysis. At higher concentrations, this agent inhibits plasmin.

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# Crystal Research

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