

# Healing with Human Blood

**Haemacure's human plasma-derived *Hemaseel HMN* is looking to change surgery as we know it.**

BY ARNALDO ARROYO

**C**EO Joseph Galli, a veteran financing, mergers, acquisitions, and restructuring executive, took the helm of Haemacure Corporation (TSX: HAE) in February in the hope of generating a turnaround and shortening the company's time to market.

"One of the reasons I decided to invest in the company and later step in as CEO is Haemacure's very compelling, disruptive plasma protein extraction technology," says Galli, who has been chairman since 2005. "It's a rapidly growing marketplace in the US and Europe, and this disruptive technology will allow the company to carve out a very profitable niche for itself."

Haemacure's lead product candidate, *Hemaseel HMN*, is a human-derived fibrin sealant in late stage clinical development for biosurgical applications. Used in surgical procedures to stop bleeding, fibrin sealant is biological-tissue glue made of human plasma proteins. Its second product candidate is human thrombin, a component of fibrin sealant that helps blood to clot. It also has applications as a standalone product in the expanding biosurgical market, and in



**Chairman and CEO Joseph Galli has made investing in Haemacure Corporation a family affair. "I've invested my own money, my kid's money, my brother's money, my uncle's money, and my friends' money."**

combination with biomaterials.

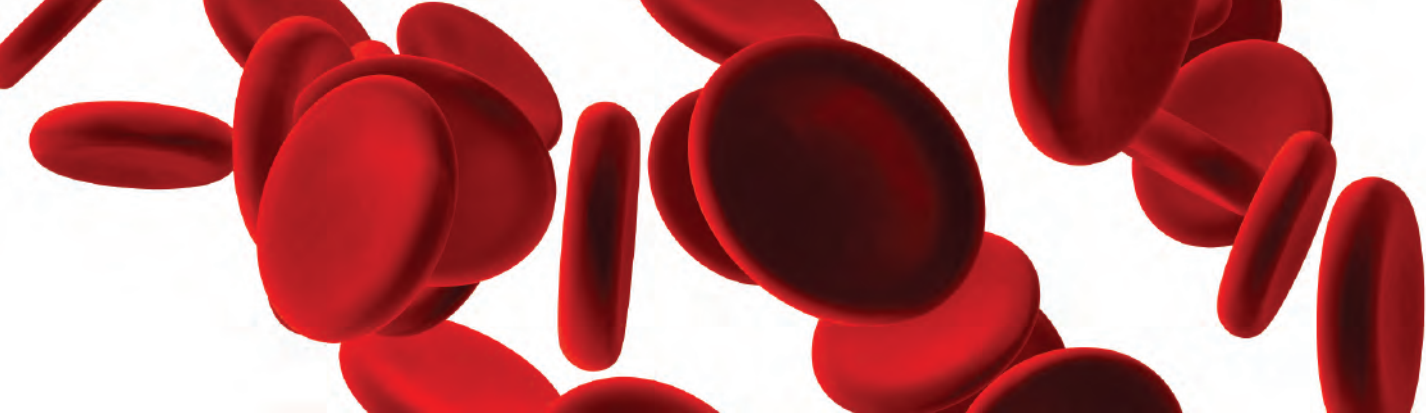
Galli estimates that the current world market for fibrin sealant and thrombin exceeds \$675 million and anticipates this market will reach about

\$900 million by 2010, when Haemacure expects to introduce its products to the market. Estimates also value the market at about \$1.5 billion in 2015.

Boding well for Haemacure is the fact that it's playing in protected markets with pharmaceutical-like margins. "These markets are essentially oligopolies and monopolies, which means high margins and high barriers to entry," he says. "It would take a new player between five and ten years plus over \$50 million to develop the IP."

The Canadian biotech also has a strong and secure intellectual property position. "In a business like this, IP is key. One of the things that really gave me reassurance is that a couple years back, a very large European pharma group with deep pockets challenged our key patent, and we successfully defended it," he says. "That told me from an IP standpoint, we had a technology that was sought after, and that our investment was solid."

Unlike first generation products, Haemacure's fibrin sealant does not contain any animal component. The dominant player in the \$450 million global fibrin sealant market, Baxter's fibrin product, contains aprotinin, a bovine protein. King Pharmaceuticals,



with its bovine thrombin, sells approximately \$300 million a year, primarily in the US.

“The challenge with bovine origin is that people are concerned about anything animal-derived being used in humans,” says Galli. “Consequently, human plasma related or recombinant proteins are very sought after alternatives.”

Haemacure has a couple of major advantages over current suppliers of fibrin sealant. First, since its fibrin sealant contains human only proteins, it is fully resorbed by the body without complications. Second, Haemacure’s technology has the ability to deliver very high yields and generate a significant amount of revenue per liter of plasma.

“What’s disruptive is our ability to generate approximately \$2,500 of revenue per liter of plasma that we start with,” he says. “The industry average is between \$250 to 500. So, our technology allows us to have a yield that at best would be eight times, and at worst, five times those of existing players.”

Surprisingly, Galli has discovered that there is still valuable stuff that can be mined in the plasma residue after extraction of the two fibrin sealant’s proteins. To illustrate, he says, “After a miner takes gold from the ground, there’s also silver, zinc and copper. We’ve started to look at these other assets and are getting encouraging results. Extracting additional proteins will serve to dramatically increase the revenue per liter that Haemacure can generate.”

Since the company’s raw material costs are fully borne by the fibrin sealant, Galli says that every dollar generated by additional proteins go directly to the bottom line.

He believes that the company’s fibrin sealant may also play a major role in the economics of patient hospitalization.

“Stopping bleeding is a major clinical issue in surgery. Application of fibrin sealant allows surgeons to achieve hemostasis faster and more efficiently than without fibrin sealant. The result is a much reduced risk of internal bleeding after surgery. This may translate to a shorter hospitalization for the patient, sometimes measured in days, who then needs not be kept under observation for as long as one who was not treated with fibrin sealant,” he notes.

Over the next 12 to 24 months, Haemacure plans to advance its clinical program for fibrin sealant and thrombin. Fibrin sealant has been dosed in 151 patients right up to Phase III without any serious side effects attributable to the product. Safety and efficacy data has also been compiled for thrombin, as a component of fibrin sealant.

Haemacure raised funds in order to finance its operations going forward. In January, Galli completed a C\$12.5 million non-brokered private placement. The company’s B warrants are expected to add another C\$12.5 million to its coffers. In addition, as part of a settlement, CSL Ltd., one of the world’s largest plasma fractionators, is to pay Haemacure \$4.5 million upon meeting milestones related to the manufacturing facility and clinical trials.

The cash will be used mainly to complete construction of a 52,000 square foot manufacturing facility in Sarasota, Florida. The plant will have a \$225 million production capacity at pharmaceutical margin levels. Its core manufacturing equipment will consist of disposable bio-processing plastic containers. This manufacturing strategy will result in significantly lower capital expenditures and operating costs, and significantly reduced risks associated with cross contamination between production batches.

**RISKS:** *Haemacure Corporation has been around since 1991 and has not generated any profit. While the markets for fibrin sealant and thrombin products are expected to continue to grow, they may not grow as expected by Haemacure, and its assumptions may prove incorrect for a number 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.*

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TSX: HAE

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**SHARE DATA**

Recent Price:	C\$0.13
52-Week Price Range:	C\$0.29 - 0.06
Shares Outstanding:	164 million
Market Cap	C\$21 million

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**BALANCE SHEET DATA**  
**(as of January 21, 2007)**

Total Assets:	C\$13.4 million
Long-Term Debt:	C\$1.2 million
Shareholders' Equity:	C\$12 million
Book Value per Share:	N/A