Montco blood substitute maker investing $50M to expand processing plant

HbO2 co-founder and CEO Jerry Kowalski with the Soudeton's company's filtration equipment.

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By John George – Senior Reporter, Philadelphia Business Journal

A Montgomery County medical products company is investing $50 million to expand its manufacturing facility and resume production of a blood substitute
product designed to help everyone from soldiers injured on the battlefield to patients in need of organ transplants.

HbO2 Therapeutics of Souderton, Pa., makes two hemoglobin products — Hemopure for human applications and Oxyglobin for veterinary applications — derived from bovine blood that is filtered, purified and formulated in a balanced salt solution to make it suitable for infusion into the human body.

“The products serve as a bridge before a patient can get a transfusion,” said Jerry Kowalski, the company’s co-founder and CEO.

Other applications are also in development.

Earlier this month, the first human organ transplant of a previously rejected liver — reconditioned with a warm perfusion solution oxygenated with Hemopure — was performed successfully in Holland.

The company's Hemopure product is derived from bovine blood that is filtered and purified.

Both Hemopure and Oxyglobin were developed to stabilize patients suffering from blood loss, and prevent cell and tissue damage and organ dysfunction caused by oxygen deprivation, when a blood transfusion is not an immediate option. Hemoglobin, the protein responsible for transporting oxygen is normally contained within circulating red blood cells. If patients lose large amounts of bloods for whatever reason, the oxygenation process is disrupted. When HbO2’s products are infused into the bloodstream, the chemically stabilized hemoglobin molecules carry
oxygen in the plasma and can also facilitate the release of oxygen from remaining red blood cells.

Kowalski said scenarios when “blood in not an option” include treating: Jehovah’s Witnesses, a religion which forbids blood transfusions; patients with rare autoimmune diseases; injured soldiers on the battlefield far from blood supplies; or mass casualties in disasters where the supply of blood is insufficient.

Kowalski said Hemopure and Oxyglobin do not need to be refrigerated, have a shelf life of three years, and are universally compatible with all blood types.

Hemopure has received regulatory approval for human use in South Africa and the Russian Federation. Oxyglobin has received regulatory approval for veterinary use in the United States, Europe and Hong Kong. “It’s been used for 150,000 animals with no adverse events,” Kowalski said.

HbO2 representatives met with the Food and Drug Administration earlier this year to discuss the structure of a large-scale clinical trial the company would conduct to support a new product application. “We submitted a protocol and the FDA is reviewing it,” Kowalski said. “We expect to start the trial in the first quarter of 2018.” Hemopure is available to U.S. patients under an FDA-approved expanded access program for patients with life-threatening anemia for whom allogeneic blood transfusion is not an option.

HbO2 was founded in 2014 following the bankruptcy of its predecessor company, OPK Biotech — which had previously acquired the assets of blood replacement technology developer BioPure following its own bankruptcy. OPK Biotech, which had operations in Cambridge Mass., and Souderton, was owned by Russian industrialist and oligarch Sergei Pugachev. Pugachev fell out of favor with then-Russian Prime Minister Vladimir Putin and, in 2011, fled Russia for London amid fraud charges. OPK Biotech was forced into bankruptcy in early 2014 by creditors owed several millions of dollars in debt.

Three of the company’s managers — Kowalski, COO Zaf Zafirelis and CFO Igor Serov — bought the company out of bankruptcy to further develop the products and expand their use.

Kowalski noted transplantation hasn’t changed much in more than 50 years. “Organs are harvested from a donor, packed in ice and eyeballed by a physician who either accept or rejects the organ for surgery,” he said. Kowalski noted organs typically only come from brain-dead patients and not cardiac death patients because their vascular system has stopped and their organs are no longer getting oxygen, causing tissue to start to die.
To preserve organs, some doctors will hook organs up to perfusion machines to maintain blood flow to tissues and regulate levels of oxygen.

HbO2 said that technique can be used to pump Hemopure mixed with a nutrient solution to revitalize an organ deemed not suitable for a transplant and revitalize it so it regains function. For a liver that would mean producing bile; for a kidney it would mean producing urine.

“Surgeons can look at an organ and see how it is functioning to determine whether it’s viable for a transplant,” Kowalski said. “That’s a big step up from eyeballing.:.... Not all livers are going to be OK, but there are ones that can be saved, revitalized and reconditioned.”

Dr. Robert J. Porte, chief of surgery and liver transplantation, performed the first transplant of a previously rejected liver reconditioned with Hemopure at Holland’s University Medical Center Groningen in mid-October.

“This is an important step forward in the implementation of machine perfusion technology in transplantation medicine, which can help us to increase the number of organs for transplantation,” Porte said. “It indicated we can preserve and test human organs at body temperature without the need for human blood products.”

HbO2 raised $20 million to date from friends and family and a series A venture capital round. The company is now out seeking to raised up to $30 million in a series B round to fund costs associated with the expanded Souderton plant and the late-stage clinical testing of Hemopure.

Kowalski said after acquiring OPK’s assets and setting up HbO2, one of their first actions was to consolidate manufacturing in Souderton.

“We decided to move everybody under one roof,” he said, noting the move will eliminate redundancies and reduce the company’s staffing cost by 55 to 50 percent.

The decision meant temporarily halting production of Hemopure and Oxyglobin and moving about $100 million worth of bioprocessing equipment to Bucks County. During the transition period, HbO2 has shrunk its staff to 16 people, but it expects to ramp up to 65 employees when it resumes full product by mid-year in 2018, provided the company gets all the regulatory approvals needed for the expanded plant and construction is completed.