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Notice:

ValveXchange, Inc. products have not been approved by the U.S. FDA or any other Regulatory Agencies. This newsletter contains forward looking statements which represent management's best judgment, but are speculative and may not occur as projected or not at all.

NEWS RELEASE

March 2009



From the Desk of Ivan Vesely, Ph.D.

Dear Colleague

March was busy month! We wrote and submitted two SBIR grant applications to the NIH, implanted four more valves into the sheep model and performed our first valve exchange study in a sheep that had our valve implanted for two months. We have, for the first time, demonstrated the feasibility of exchanging the valve after it is fully healed in!

We are now preparing to show our exchange experience in three upcoming conferences, and are continuing to refine our exchange tool set to make the exchange procedures faster and easier.

Our CEO, Larry Blankenship, went to the Frost & Sullivan annual meeting in San Francisco to receive the honor of the 2009 North American Frost & Sullivan Technology Innovation of the Year Award on behalf of ValveXchange.

We are also happy to report that Dr. Tirone David, an internationally renowned surgeon and pioneer in the field of prosthetic heart valves, has joined the VXi Medical Advisory Board.

Finally, we are most excited to report that The Cleveland Clinic, from whom some of the ValveXchange technology is licensed, has named ValveXchange, Inc. as one of its Spin-Off Companies and has entered into an agreement to take an equity position in VXi.

For those new to this Newsletter, ValveXchange is a start-up company based in Colorado. We call ourselves "The Lifetime Tissue Valve Company" and are developing the first-of-its-kind "serviceable" bioprosthetic valve. By offering periodic, minimally invasive exchange of the worn-out leaflet set, young and physically active patients can avoid the use of a mechanical valve and the associated Coumadin® anticoagulation therapy. By adhering to the time-proven design tenets of conventional bovine pericardial valves, the ValveXchange system offers the best combination of least-invasive reoperation and greatest longevity and durability.

Coumadin® is a Registered Trademark of Bristol-Myers-Squibb

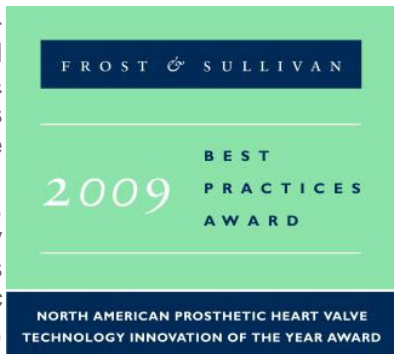
Press Release

ValveXchange Accepts Frost & Sullivan Technology Innovation of the Year Award

March 18, 2009. San Francisco, CA -

Frost and Sullivan held their annual "Excellence in Medical Technologies & Life Sciences Awards" banquet on this date, honoring companies in the bioscience and medical device fields. Among these was ValveXchange, Inc., awarded the 2009 Technology Innovation of the Year Award for its work in advancing the field of prosthetic heart valves. Mr. Larry Blankenship, CEO of ValveXchange, commented that

he was "taken by surprise" when informed about the award. According to Frost and Sullivan, this is the tenth year they have had their industry analysts proactively seek out firms who are making significant contributions in key healthcare segments.



The Frost and Sullivan Technology Innovation Award is "...bestowed upon a company (or individual) that has carried out new research, which has resulted in innovation(s) that have or are expected to bring significant contributions to the industry in terms of adoption, change, and competitive posture. This award recognizes the quality and depth of a company's research and development program as well as the vision and risk-taking that enabled it to undertake such an endeavor." Frost & Sullivan analysts observed that the ValveXchange 2-part exchangeable leaflet heart valve system "...has the potential to revolutionize the valve replacement therapy paradigm by simplifying long-term management and future valve replacements."



ValveXchange was surrounded by prestigious fellow award recipients, each in their own area of technology expertise. These companies included Covidien, GE Medical, Philips Healthcare, Siemens Healthcare, and Intel Corporation for their new home healthcare products, among others. The Frost and Sullivan award takes no applications, petitions or nominations. Merit is determined solely by the team at Frost and Sullivan who pride themselves on maintaining the utmost in up-to-date information regarding technology and business developments in healthcare. ValveXchange is extremely honored to be among the select few to be recognized by Frost and Sullivan for its innovation, drive and potential.



Dr. Tirone David joins VXi Medical Advisory Board

March, 2009. Denver -

ValveXchange, Inc. announced that [Dr. Tirone E. David](#) has joined the VXi Medical Advisory Board. Dr. David is [recognized world-wide](#) for his pioneering work in valve sparing surgery, his remarkable surgical skills and his commitment to teaching. Doctor David is a Professor of Surgery at the University of Toronto, Chief of Cardiac Surgery at Toronto General Hospital, and the holder of the Melanie Munk Chair at the Peter Munk Cardiac Centre. He was born in Brazil and educated in his native country and in North America. His postgraduate training in surgery was at the State



University of New York, The Cleveland Clinic, and the University of Toronto. He joined the academic staff of the University of Toronto and Toronto General Hospital in 1978, and has become one of the leading cardiac surgeons in the world. Hundreds of heart surgeons from around the globe visit his operating theatre every year. Doctor David has published more than 250 peer-reviewed scientific papers, tens of chapters in medical textbooks as well as five surgical textbooks. He has developed numerous operative procedures to treat patients with heart valve disease, complications of myocardial infarction, and thoracic aneurysms. One of these operations, a procedure designed to preserve the aortic valve in patients with aortic root aneurysms, is known the [David Procedure](#). He is the developer of a [stentless bioprosthetic heart valve](#) and co-developer of a stented valve. He has been a member of the editorial board of the Annals of Thoracic Surgery, Journal of Heart Valve Disease, Journal of Cardiac Surgery and the Asia Pacific Journal of Thoracic and Cardiovascular Surgery. He was President of the American Association for Thoracic Surgery in 2004-2005. Doctor David is a member of numerous surgical and medical societies and honorary member of the European Cardio-Thoracic Association, the Brazilian Cardiovascular Society, Italian Society for Cardiac Surgery, German

Society for Thoracic and Cardiovascular Surgery, and the Southern Thoracic Surgical Association of the United States, and the Society of Cardiac Surgeons. He received the Order of Ontario in 1993 and the [Order of Canada](#) in 1996. He was elected University Professor in 2004, the highest honor the University of Toronto bestows to its professors. He received the Humanitarian Award of the Brotherhood of Beth Sholom Synagogue in 2005.

Cleveland Clinic Names ValveXchange as Spin-Off Company

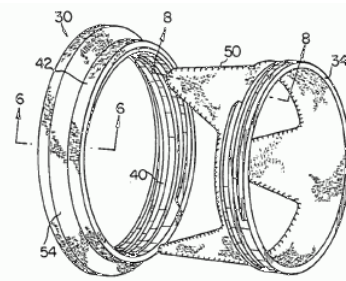
March 30, 2009. Denver - ValveXchange licensed its exchangeable valve technology patents from The Cleveland Clinic. The Clinic and ValveXchange have now entered into an arrangement whereby the Cleveland Clinic will in the future receive an equity position in ValveXchange, Inc. Larry Blankenship, CEO of ValveXchange noted that *"this is an important development in the progression of ValveXchange, Inc. We are most pleased with the Cleveland Clinic naming ValveXchange one of its spin-off companies, and are enthusiastic about working with the Clinic in this relationship."* Chris Coburn, Executive Director of CC Innovations said, *"Cleveland Clinic is pleased to be working with ValveXchange on their cardiovascular innovation in this important field of heart valve replacements."*

Other News

Technology Update

I am pleased to report we have demonstrated in an animal model, that the exchange of a fully healed-in valve is indeed possible. Skeptics of our approach said it can't be done due to the fibrotic tissue overgrowth. While this response is understandable, given the failure of previous exchangeable valves, we have learned from the experience of others, and from examining hundreds of explanted valves, and used this insight to confirm the feasibility of our approach.

Perhaps the first exchangeable heart valve attempt was that of Tascon Medical, described in their 1987 patent [4,680,031](#). Tascon was acquired by Medtronic in the 80's and a few of these valves were apparently manufactured and implanted into patients. Unfortunately, when it was time to exchange the valve, the two pieces did not come apart. The image shown in the



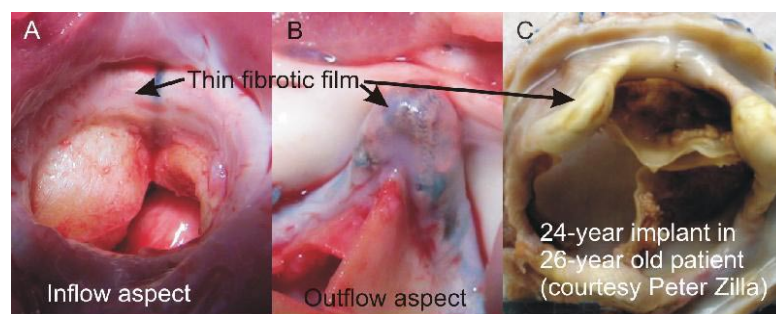
Tascon patent hints at some of the reasons. First of all, the two components of the Tascon valve are joined by relatively large square threads. Any minor fouling of the threads would have made unscrewing the two components from each other very difficult by hand. Moreover, even if a hand-force to unscrew them was sufficient, there was no provision to hold onto the sewing cuff component as torque was applied

to the removable component. The torque would be transferred directly to the heart tissue. Although it was clearly a failed product concept, it nevertheless showed the appeal of the idea and taught us valuable lessons on which others could build.

The ValveXchange technology suffers from none of these limitations. We do not use metal-to-metal contact that could corrode together, nor threads that would be difficult to twist apart. We use a clip mechanism that is insensitive to fouling. Most importantly, however, is the integrated tool set for valve exchange that stabilizes the permanent docking station as the leaflet set is pulled out. Force is applied between the stabilizer and the extraction tool, much like brake calipers, so that the extraction force is not applied directly to the heart.

The role of fibrosis has also been greatly overemphasized by those without adequate knowledge of the phenomenon. During my 9 years at the Cleveland Clinic, I examined nearly every piece of valve tissue that came out of patients, beside my colleague Dr. Ratliff, a renowned cardiac pathologist. Through this experience, I felt that fibrosis can be managed with the appropriate technology. Even when fixed in formalin and much stronger than raw tissue, the pannus overgrowth can be torn readily and with relatively low forces. We confirmed this in our first exchange experiment. We removed the leaflet set, which was overgrown with pannus tissue, quite easily with minimal force being applied to our hand tool.

Another important finding from our early exchange experiments is the degree of pannus overgrowth that occurs in the sheep model over time. The sheep model is now recognized as being hyperfibrotic - that is, it generates a far more robust fibrotic overgrowth over time than is seen in the human condition. We performed our first exchange at 50 days post implant, which we anticipated would produce pannus tissue similar to that seen in human explanted valves. The thickness of the fibrotic peel on the inflow surface of the sewing cuff from the sheep was measured to be 0.4 mm, roughly the same as the thickness of the fibrotic overgrowth on bioprosthetic valves explanted from humans at 15 years.



Details of the pannus overgrowth can be seen in the figures above. Images A and B show the inflow and outflow aspects of the healed-in valve. A thin, continuous but translucent fibrotic film is visible on all Dacron surfaces of the valve. This film is very similar to that which occurs

in long-term implants of bioprosthetic valves. Perhaps the longest implant documented for these characteristics was reported by my colleague Dr. Peter Zilla who has a unique experience with the use of tissue valves in young patients in Cape Town, South Africa. Twenty-four years after a tissue valve was implanted into a 26 year-old patient, it failed and needed to be explanted. In this most likely worst case scenario of fibrotic overgrowth, the pannus is still relatively thin and translucent. We now have confirmation that doing valve exchange studies at two months will be appropriately representative. This shortens our timeline and better calibrates the types of tools that we will need for subsequent human clinical trials.

Upcoming Conferences

With our animal exchange experience accumulating, we will be presenting our work at the some upcoming heart valve conferences. We will be in Dallas on April 22 presenting at the [InsynCVentures](#) conference for Emerging Cardiovascular Companies, and also attending for the [Dallas-Leipzig International Valve Congress](#) in Dallas, on April 23rd. We will then be presenting our technology and results to date at the [ACTS 2009](#) Conference in New York City on May 6-7. After that, we will be attending the [AATS](#) in Boston on May 9-13, and the [Society of Heart Valve Disease](#) meeting in Berlin on June 27. I hope to connect with you in the near future at some of these upcoming meetings.



Sincerely,

Ivan Vesely, Ph.D.
Founder and Chief Scientific Officer
ValveXchange Inc.
vesely@valveXchange.com

Previous News Releases

February, 2009. Denver - ValveXchange Inc. announced that it is the recipient of the 2009 North American Frost & Sullivan Technology Innovation of the Year Award. According to Frost & Sullivan Research Analyst S.R. Priya, *"The ValveXchange Heart Valve System represents a safe and less invasive alternative to conventional therapies.... Overall, the ValveXchange system provides the innate hemodynamic and non-thrombogenic benefits of tissue valves to patients of all ages, thus*

obviating the need for expensive and potentially problematic anti-coagulation therapies and major lifestyle modifications." concludes Priya.

February, 2009. Denver - ValveXchange Inc. announced that of Dr. Joseph Sabik, Chair of Cardiothoracic Surgery, The Cleveland Clinic Foundation, will serve as the Chair of the VXi Medical Advisory Board. [Read More.](#)

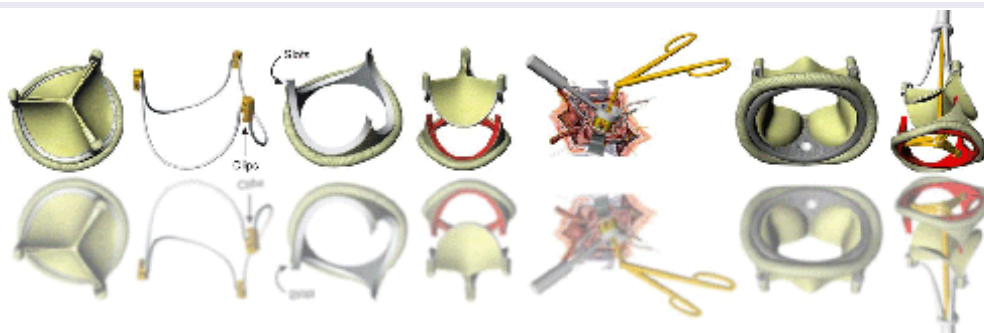
January 30, 2009. Denver - ValveXchange Inc. announced that it has begun long-term animal testing of its proprietary exchangeable valve technology. [Read More.](#)

October 13, 2008. Denver - Aurora-based medical device company ValveXchange Inc. announced today that it has been awarded a European patent (EP1,671,608) entitled Cardiovascular Valve Assembly, authored by Dr. Ivan Vesely, the company's Founder and Chief Scientific Officer. [Read More.](#)

July 29, 2008. Denver - Aurora-based medical device company ValveXchange Inc. announced today that they have received a \$1.6 million grant from the National Institutes of Health (NIH) for funding under the SBIR Program related to research and development of its proprietary two-piece heart valve technology. [Read More.](#)

January 1, 2008. Denver - ValveXchange Inc. is a featured company in Start-Up magazine. [Read Article.](#)

December 7, 2007. Denver - ValveXchange Wins The Third Annual Faegre & Benson Venture Showcase Award, Presented At BioWest 2007. [Read More.](#)



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