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NEWS RELEASE

November 2008



[From the Desk of Ivan Vesely, Ph.D.](#)

Dear Colleague

This is the first of an ongoing series of Newsletters from ValveXchange Inc., a start-up company based in Denver, Colorado. ValveXchange is developing the first-of-its-kind "serviceable" bioprosthetic (i.e., tissue) heart valve.

All bioprostheses eventually wear out. This creates the dilemma of whether to implant a tissue valve or a mechanical valve in patients that are young and active. If they receive a tissue valve, they will require reoperation to replace the failed tissue valve. If they receive a mechanical valve, they will require anticoagulation therapy and will no longer be able to be active. With a serviceable heart valve, the worn-out leaflet set can be quickly exchanged without requiring traditional open-heart surgery. We expect that the ValveXchange system will be adopted by young and old patients alike, as it is being designed to offer the best combination of least-invasive reoperation and greatest longevity and durability.

If you do not wish to receive future issues of this newsletter, please unsubscribe by way of the link below. If you like what you read, please forward this newsletter to your colleagues and they can subscribe on their own.

I look forward to sharing news with you about this exciting technology in the coming months.

Press Release

ValveXchange is a featured company in the latest issue of CLSDF/Rocky Radar

October 23, 2008. Denver - Aurora-based medical device has recently been featured in an article posted by the [RockyRadar](#), a local medical device industry newsletter. The [review of the ValveXchange](#) approach is one in a series of short stories about start-up companies in the Denver-Boulder area, primarily in the areas of Life Sciences, Information Technologies and Clean Energy.

Other News

Technology Update

Full-steam progress on the exchangeable valve began in July of this year, as our \$1.6 million NIH Phase II SBIR grant became active. Although conceptually mature for some time, the two-piece exchangeable valve went through additional fine tuning of the design, and functional prototypes were completed within 4 months of commencement. We are thus on schedule and under budget, with our first animal trials expected late this year. We have been working with some outstanding contract engineering firms in Colorado and in California and are very pleased with the outcomes. As we develop new approaches to fabricating our valve prototypes, we are filing new patents on these inventions. More news will be placed in upcoming newsletters at it becomes available.

Reality Check

Reality Check is a recurring feature of this Newsletter in which I comment on some of the controversy that exists in our field of prosthetic heart valves. If you disagree with my comments or wish to add to any issue I may have discussed, I would be happy to hear from you by way of an e-mail to the address below. The topic of today's Reality Check is:

Selective Disclosure of Information.

During this long political campaign, I was struck by how information is often presented in a highly selective manner. As I have transitioned from Academia to the Corporate world, I have found that this is also a common feature in many of the News Releases that come across my mailbox. An example of such is the following: "[Transapical valve data: Climbing survival rates speak to improved skill, technology, and patient selection](#)". This article reviews some of the reported survival rates from ongoing clinical trials of the Percutaneously Implantable Valves (PIVs). Although there has been debate as to whether the transfemoral or transapical approach is better, that is a topic of a separate discussion. For now, let's look at the Transapical data and see how good it really is. In the study reported by Wimmer-Greinecker (Bad Bevensen, Germany), 30-day survival was 82%, and six-month survival was 55%. Others have reported better outcomes. For example, Walther (Leipzig Heartcenter) reported a six-month survival of 74% and Svensson (Cleveland Clinic) reported a six-month survival of 59%. Of course, these series had

patients with different risk profiles. Wimmer-Greinecker's patients had a Euroscore of 33.5, those of Walther had 27 and those of Svensson had 36.6. Clearly, the greater the Euroscore, the worse the six-month mortality.

What troubles me, however, is the way the Euroscore is being misrepresented in the lay press. Indeed, [Medical News TODAY reports](#) that transfemoral patients had 90% survival at six months. It is then stated that "*Had these very ill patients been treated with traditional open-heart surgery, the 30-day predicted survival would have been 75 percent*". How do we know that? Well, that is implied in the use of the Euroscore to judge patient mortality. The [EuroSCORE web site](#) defines the Euroscore as the probability that a patient would die during open-heart surgery. In other words, 25% of patients with a Euroscore of 25 would be expected to die during their surgery. As noted in the report, if only 75% of the patients would have survived open-heart surgery, they presumably had an average Euroscore of 25. Since 90% of the patients with the valve implanted transfemorally actually survived, using the new device was better than sending the patients for open-heart surgery and having them fitted with a conventional bioprosthetic valve.

Many surgeons would disagree, however. Since the emergence of PIVs the Euroscore has been criticized as being much too severe in predicting mortality. A recent [paper by Grossi](#) (New York) reported that patients with a Euroscore of 17 had an actual mortality of 7.8%. Dr. Grossi concludes that the "*Logistic EuroSCORE greatly overpredicts mortality*" - by more than a factor of two, apparently. With this in mind, let's look back at the data of Wimmer-Greinecker (Euroscore of 33.5, mortality of 45%), Walther (Euroscore of 27, mortality of 26%), and Svensson (Euroscore of 36.6, mortality of 41%). Although Euroscore was designed to predict only perioperative mortality, it has been reported to be [good at predicting long-term mortality in heart valve patients](#), at least for those who had low Euroscores. Looking at the above transapical data, however, it would appear that six-month mortality was actually worse than the Euroscore. One could thus argue that had these patients gone for conventional open-heart surgery, their mortality would have been less than half of their Euroscore and thus better than their actual mortality with the transapical delivery of the PIVs. Similarly, the patients with transfemorally delivered PIVs (Euroscore of 25, mortality of 10%), would have done equally well with open-heart surgery, if you accept Dr. Grossi's data,

Clearly, arguments can be made for the continued use of open-heart surgery AND the new crop of PIVs in very sick patients. Which patient is best served by either device will continue to be a point of debate. In the absence of long-term data regarding the durability of these new devices, surgeons may choose to remain conservative and stick with proven technologies. However, a provocative [article by Dr. Michael Mack](#) suggests otherwise. For heart valve surgeons that have seen CABG procedures go away, this article would have made really scary Halloween night reading...

I hope that you have found some of the above information useful and interesting. Please visit our web site for additional information and previous News Releases by way of the links below

Sincerely,

Ivan Vesely, Ph.D.
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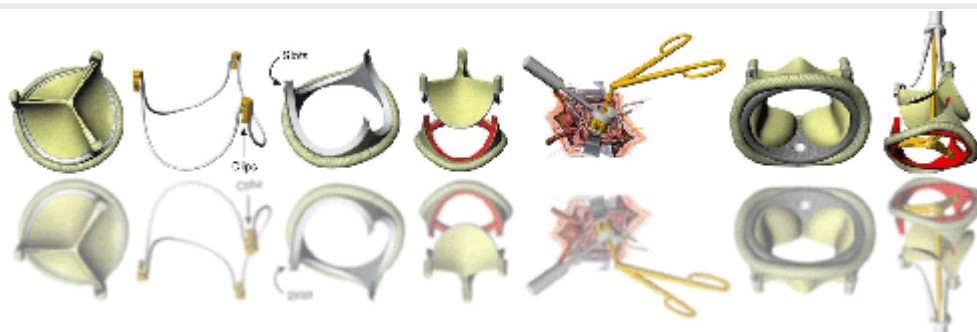
Previous News Releases

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.
ValveXchange Inc. is a featured company in Start-Up magazine. [Read Article.](#)

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



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