ValveXchange, Inc.

The Lifetime Tissue Valve Company

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NEWS RELEASE December 2008

From the Desk of Ivan Vesely, Ph.D.

Dear Colleague

In this issue of the ValveXchange Newsletter, I am pleased to announce that Dr. Floyd Loop, former CEO of The Cleveland Clinic Foundation, has joined our Board of Directors.

In my "Reality Check" column this month, I review the current state of Tissue Engineered Heart Valves. In recent years, heart valve tissue engineering has become prominent in the bioprosthetic valve research arena with traditional research projects, such as anticalcification strategies and soft tissue mechanics, taking a back seat. How this field has progressed and where it is likely to go are reviewed.

Although I strive to be as objective as possible, I clearly bring my own views developed as a researcher in heart valve technology for over 25 years. 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.

ValveXchange is a start-up company based in Colorado, developing the first-of-its-kind exchangeable bioprosthetic valve. By offering the capability of exchanging only the leaflet set, leaving the docking station in position permanently, the replacement surgery becomes much faster, easier, and lends itself to minimally invasive techniques. Young and physically active patients will be given significant new alternatives to a mechanical valve and the associated Coumadin therapy. The ValveXchange system is being designed to provide the best combination of easiest, least-invasive reoperation and greatest longevity and durability.

NOTE: ValveXchange is still in development of this product, which is not yet available for human use. It is not yet on the market, nor has it been submitted to, or approved by, any regulatory agencies.

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

Announcement

November, 2008. Denver, Colorado - Dr. Floyd Loop, former CEO of The Cleveland Clinic Foundation, has joined the Board of Directors of ValveXchange Inc., and will also chair the Medical Advisory Board.

The son of an Indiana country doctor, Floyd D. Loop graduated from Purdue University in 1958 and received his M.D. degree from The George Washington University, Washington, D.C., in 1962. His postgraduate surgical training included appointments at The George Washington University; with the U.S. Air Force at Andrews Air Force base; and at The Cleveland Clinic Foundation.

He joined the Department of Thoracic and Cardiovascular Surgery in 1970, was named Chairman of the Department in 1975, a post he held until 1989 when he was appointed Chief Executive Officer of the Cleveland Clinic Foundation. He served as CEO and Chairman of the Board of Governors for 15 years, until October 2004.

Dr. Loop gained an international reputation in coronary artery surgery. He assembled a group of skilled, experienced thoracic and cardiovascular surgeons who have earned an unsurpassed reputation in their own right. Dr. Loop and colleagues were responsible for today's widespread use of arterial conduits in coronary artery surgery, innovations in valve repair, and they pioneered technical improvements for reoperations.

The world-famous Cleveland Clinic Department of Thoracic and Cardiovascular Surgery now performs more than 5,000 cardiac and general thoracic procedures annually. During his career as a surgeon, Dr. Loop has performed more than 12,000 open-heart operations and is author of 350 papers on all aspects of cardiovascular surgery.

Dr. Loop has served on editorial boards of numerous periodicals and was Editor of Seminars in Thoracic and Cardiovascular Surgery.

He has been a guest lecturer at many cardiology and surgical meetings internationally, and has demonstrated surgical technique in many countries. Among the awards and honors accorded him, Dr. Loop received the American College of Cardiology Cummings Humanitarian Award in 1975, the American Heart Association Citation for International Service in 1980, and the Order of Merit, the highest civilian award given in Brazil in 1982. He chaired the Residency Review Committee for Thoracic and Cardiovascular Surgery in 1993, and was President of the American Association for Thoracic Surgery 1997, and a Director of the American Board of Thoracic Surgery, 1993-1999. From 1999-2002, Dr. Loop served on the Medicare Payment Advisory Commission (MedPAC). He has received Honorary Doctor of Science degrees from Cleveland State, St. Louis, and Purdue Universities.

During this 15-year tenure as chief executive, Dr. Loop selected a new administrative team which reorganized the clinic and added greatly to the academic enterprise. A new health delivery system was established in Cleveland by acquiring eight Cleveland hospitals and building 14 outpatient clinics. In Florida, new clinics and hospitals were built in Ft. Lauderdale and Naples. The revenues grew from $675 million in 1989 to $3.6 billion in 2004. The Cleveland Clinic is consistently recognized as one of the 10 top hospitals in the United States and honored as one of the best managed medical centers. Beginning in 1990, each year has brought a new record for patient activity and overall academic performance. Dr. Loop retired in October 2004 after serving 15 years as chief executive.

Dr. Loop serves on the boards of three public and four private corporations.

Other News

Technology Update

After 5-months of development work, the exchangeable valve is nearing completion. Both one-step, and two-step implantation procedures (docking station first, then snap on leaflet set) were done in two acute animal studies using direct hand-placement of the leaflet set. As expected, much was learned from the experience to guide the design of the delivery and exchange tools. We are happy to be working with two outstanding Academic Institutions performing our animal testing and their teams of highly skilled and experienced veterinary surgeons. In the new year, acute studies will be augmented by chronic implants in which valves will be periodically exchanged in on-pump and off-pump leaflet replacement procedures. We look forward to updating you on our progress.

Reality Check

Surprisingly, the field of Tissue Engineering is not new. As early as the 1960's, experiments in propagating dermal fibroblasts suggested that

artificial skin is a therapeutic possibility. Skin grafting with cultured autologous keratinocites was demonstrated in the '70's and valvular tissue engineering emerged in 1991 with a demonstration that endothelium could be cultured on detoxified, glutaraldehyde-fixed bovine pericardium. The seeds of valvular tissue engineering, however, were sown in the early '80s with the filing of some key patents on the process of decellularizing animal valves for the purpose of implanting them into humans. Given that it has been in existence for at least 25 years ....

Where is Heart Valve Tissue Engineering now?

The early work with decellularized porcine aortic valves lead to clinical use in 2000 in the pediatric population. Arguably, children have few options when they need cardiac valve replacement since they tolerate mechanical valves and Coumadin poorly, their bioprosthetic valves wear out quickly and need replacement every few years, and homograft valves are only marginally better and hard to find in small sizes. A tissue-engineered valve with potentially unlimited availability in all sizes is thus an attractive and much-needed option for these patients. Unfortunately, decellularized porcine valves did very poorly in early clinical applications and were quickly withdrawn from the market. Details of this experience are provided in a review paper on this topic published in Circulation Research in 2005.

The other approaches to tissue engineering - remodeling of bioresorbable matrixes in situ, and fabrication of leaflets from reconstituted collagen and fibrin, are far less advanced even though many experts in the field are pursuing them. Bioresorbable matrixes have never made it out of the sheep model and valves fabricated out of reconstituted collagen and fibrin still lack functional integrity. On the commercial side, several companies attempted to develop tissue engineered valves in the mid to late 1990's (St.Jude with Advanced Tissue Sciences, and Medtronic with LifeCell), but all large-scale commercial projects were abandoned in the late '90's due to lack of short-term progress.

Research in heart valve tissue engineering is healthy, judging from the presence of tissue-engineered valve presentations at the recent TERMIS conference in La Jolla, and remarkably steady. Based on a cursory exam of published literature, 55 papers on heart valve tissue engineering were published during 2002-2003 and 58 papers were published 5 years later during 2007-2008. While the NIH funding crisis can be blamed for this lack of growth in academic knowledge, the reality is that developing a tissue-engineered heart valve that can compete with commercially available devices is extremely difficult. Valvular tissue engineering has been, and will likely continue to be, a technology of the future.

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.

Best wishes to you and your families for the Holidays! BTW, the image above is a view from the window of our offices here at ValveXchange. ;-)

Sincerely,

Ivan Vesely, Ph.D.
Founder and Chief Scientific Officer
ValveXchange Inc.
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Previous News Releases

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. 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.

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.