

The Company

Alucent Biomedical, Inc., is a privately held medical technology company headquartered in Salt Lake City, Utah, formed to develop and market a novel therapy: the Alucent NVS Vessel Restoration SystemTM. Natural Vascular ScaffoldingTM technology (NVS) is designed to stent and keep open a vessel without the need for an implantable stent, a potential revolution in interventional vascular therapy. Our proprietary NVS technology is being developed for the treatment of patients with peripheral arterial disease (PAD).

In 2017, Alucent was spun out of Alumend, LLC, a scientific research organization which is part of the multi-hospital Avera Health system's Avera Research Institute. Avera has invested over \$20 million to date in the development of Alucent's technology.

The Market & Unmet Need

According to the Centers for Disease Control, approximately 9 million people in the US alone suffer with PAD. In addition, the overall prevalence of PAD in the population rises to over 20% in patients older than 65. An aging population combined with a rising global incidence of such predisposing conditions such as diabetes, obesity, and hypertension, is driving continued growth of the numbers of people suffering from PAD. Worldwide there are over 200 million people suffering with the condition.

The global market for products for peripheral vascular interventional procedures was \$3.5 billion in 2019. This is projected to grow at approximately 7% annually, reaching nearly \$5.8 billion by 2025. The US accounts for approximately 65% of the market.

Current standard therapies such as angioplasty, paclitaxel-coated balloons, metallic stents, and atherectomy have a high failure and complication rate. Depending on lesion complexity, up to 50% of patients can require retreatment within two years. Limb amputation is an all-too-common outcome.

The Technology

NVS Therapy employs a novel, light-activatable, small-molecule drug delivered in the setting of angioplasty. When activated, the NVS drug catalyzes the immediate re-linkage of the native collagen and elastin in the vessel wall, creating a scaffolding effect. This Natural Vascular Scaffold then is designed to keep the artery open, eliminating the need for a permanent implantable stent, which can cause significant complications over time.



NVS has the potential to durably treat PAD and to reduce or eliminate recoil, restenosis, or closure of the treated vessel without the use of implantable devices such as stents.

NVS was developed by Dr. Ron Utecht, a former Professor of Chemistry at South Dakota State University. Ron discovered a series of small molecules that, when activated by a particular wavelength of visible blue light, have the ability to flexibly link extracellular matrix (ECM) structural proteins, such as collagen and elastin. Furthermore, in biomechanical testing, NVS Therapy results in a treated vessel with elastic properties similar to the natural vessel wall. While the technology has multiple potential applications to human disease, at present Alucent is concentrating on the treatment of vascular conditions.

Additional Potential Vascular Markets

Alucent is focused on the treatment of lower-extremity peripheral artery disease. However, the technology could be applied to other unmet vascular needs where the ability to re-link damaged structural proteins such as collagen and elastin can be therapeutically beneficial. Additional potential vascular applications include prevention of aneurysmal progression, venous disease, coronary artery disease, and AV fistula maturation for dialysis access.

The Commercial Product

We are developing the **Alucent NVS Vessel Restoration System** *with Photoactivated Linking*, a fully-integrated, easy-to-use interventional device that is comprised of three components: the active NVS molecule, angioplasty catheter and balloon, and internal light fiber. The device is introduced into the lesion to be treated with standard angiographic techniques. The balloon is inflated, opening the vessel and delivering the NVS molecule to the vessel wall. The light fiber is then activated, causing the molecule to have its intended catalytic effect of linking native collagen and elastin.

NVS Therapy has been shown in multiple large animal experiments to both create significant increases in luminal size and repair iatrogenic dissections of the arterial wall. Further, NVS has been shown to avoid restenotic complications, in comparison to implanted stents in an animal disease model.

Current Status

Alucent has conducted multiple experiments in large and small animals as well as extensive benchtop biomechanical and scientific testing. Multiple toxicology studies have been completed. We have shown preclinical proof-of-concept of NVS technology in animal and



human cadaver models. Alucent has recently been granted approval by the U.S. FDA to initiate a human clinical trial. The trial is scheduled to begin enrolling patients in Q1 2020.

The Executive Team

Myles Greenberg, MD, MBA, President and CEO

- 20 years experience as medtech/biotech/healthcare services VC, startup executive, clinician. Previously with IntegraMed, CHL Medical Partners, Pappas Ventures, Beth Israel Deaconess / Harvard

Hank Hauser, VP, Clinical Affairs

- 25 years of clinical experience running cardiovascular device trials with multiple companies, such as Vessix, Boston Scientific, Ulthera, Rubicon, Keystone Heart; previously was cath lab technician.

Katalin Kauser, MD, PhD, DSc, VP, Biology

 Over 20 years experience in pharmaceutical industry, heading cardiovascular biology and pharmacology research. Previously with Global Blood Therapeutics, Boehringer Ingelheim, Actelion, Bayer

Bruce Krattenmaker, VP, Regulatory Affairs

- Over 30 years experience. Former VP of Regulatory Affairs for Allergan, Closure Medical / J&J, eV3, BSC

Scott Mayfield, VP, Finance and Administration

- Over 30 years experience in medtech company finance. Former CFO/Controller of Catheter Innovations, InnerDyne, Catheter Technology, Perseon

Krishna Rocha-Singh, MD, FACC, Chief Medical Advisor

- Chief Scientific Officer and Interventional Cardiologist, Prairie heart Institute. Leading KOL and founder, VIVA

Steve Tyler, VP of R&D / Engineering

- Over 20 years experience in developing novel and complex cardiovascular device and implants. Previously VP/director at Profusa, PQ Bypass, Avinger, Guidant Endovascular

Kevin Warner, PhD, VP, Pharmaceutical Development

- 15 years experience in small molecule drug development, pharmaceutical chemistry, CMC. Former Director, Small Molecule Development at Allergan

Jim Corbett, Chairman of Board of Directors

- 30+ years experience in medtech. Current CEO of CathWorks Ltd. Previous CEO/senior exec of multiple medical device companies, including eV3, BSC International, Vertos Medical, Alphatec Spine



Scientific and Clinical Advisory Board

Gary Ansel, MD

 Internationally renowned interventional cardiology expert. Has been principal investigator in many national and international cardiovascular research trials. Currently System Medical Chief, Vascular Program,
OhioHealth

Elazar Edelman, MD, PhD

- Cabot Professor of Health Sciences and Technology at MIT and Senior Attending Physician in the coronary care unit of Brigham & Women's Hospital, Boston. He and his laboratory have pioneered basic findings in vascular biology and the assessment of novel technologies.

William Gray, MD

 System Chief, Division of Cardiovascular Disease, Main Line Health, Philadelphia, PA. Dr. Gray has been in endovascular leadership roles for 20 years at Columbia Presbyterian Medical Center and Swedish Medical Center. He serves on the editorial board of JACC Cardiac Interventions and has been a principal investigator in multiple trials.

Larry Kraiss, MD

 Professor of Surgery and former Chief, Division of Vascular Surgery, University of Utah. Ran NIK-funded lab studying translational control in endothelial cells. Currently maintains and active clinical vascular surgery practice and research focused on pre-operative decision making in vascular surgery.

William Sessa, PhD

- Gilman Professor of Pharmacology and Medicine and director, Vascular Biology & Therapeutics Program, Yale University. Recipient of multiple awards in basic and translational research and author of more than 200 research articles and papers.

Craig Walker, MD

- Founder & president, Cardiovascular Institute of the South; Founder & Chairman, New Cardiovascular Horizons (NCVH); PI of multiple major cardiovascular trials; editor and editorial board member of multiple scientific and clinical publications