



Investor Presentation

July 2026

Breakthrough Treatment. Compelling Investment.



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Changing the Treatment Paradigm for **Deep Venous Disease**

enVVe System: Treatment for Deep Venous Insufficiency (DVI)

- Severe Deep Venous Insufficiency (DVI): Progressive, Debilitating Venous Disease of the Leg with No Current Effective Treatment Options
- ~\$20B Annual Direct Medical Costs; ~3M U.S. Patients; ~\$90B U.S. TAM
- enVVe®: First-in-Class, Non-Surgical Replacement Venous Valve
- De-risked Transcatheter Evolution of a Clinically Proven Surgical Device
- FDA Alignment on Pathway to Approval
- Stakeholder Symmetry Across Patients, Physicians, Insurers
- Peer-Published Health Economics to Support Broad Reimbursement
- Ample In-House Manufacturing Capacity to Drive Elite Gross Margins and Reach Profitability
- Our Competitive Moat is as Big as an Ocean
- Pre-warmed Strategic Exit Pathway
- Multiple near-term and long-term potential value generating milestones
- Arbitrage Opportunity: Low Market Value, High Intrinsic Value

Deep Venous Insufficiency (DVI) occurs when insufficient blood returns to the heart and lungs due to permanently damaged valves in the deep veins of the leg

Severe DVI: A Progressive and Debilitating Venous Disease

Severe DVI leads to:

Blood pooling in lower leg

Increased risk for PEs and DVTs

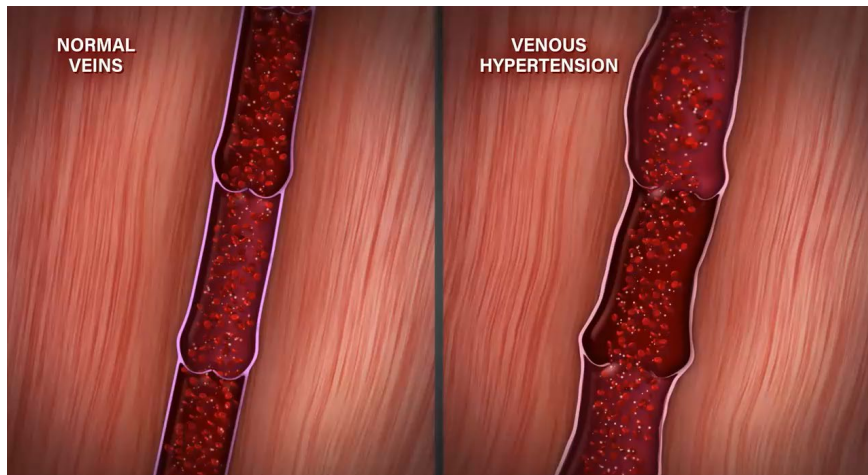
Venous hypertension

Edema (swelling)

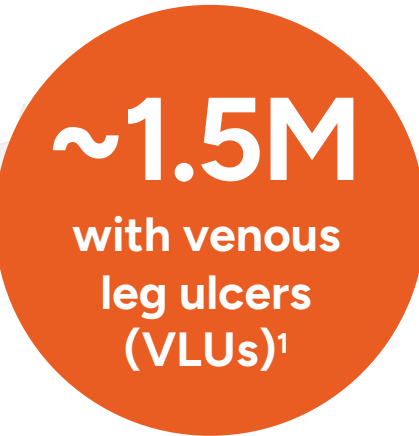
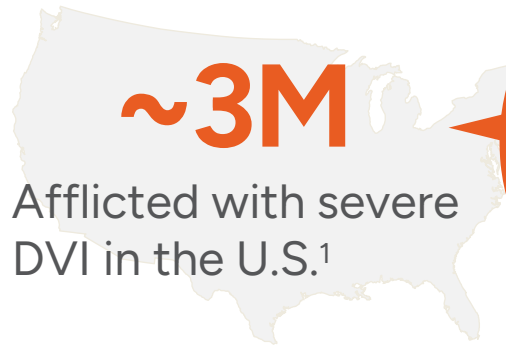
Severe Pain

Ulceration (C6 patients)

Hemosiderin Staining



A Growing Healthcare and Economic Burden



\$30,000

Annual wound care
cost per patient²

~\$20B

Direct
medical costs²



30%

Unhealed
ulcers at 1-year¹



20-40%

1-year ulcer
recurrence¹

**The Solution
to a \$20B
Problem**

DVI: Current Standard of Care is Ineffective

- Poor compliance
- Does not address the underlying disease cause
- Ineffective for deep venous disease



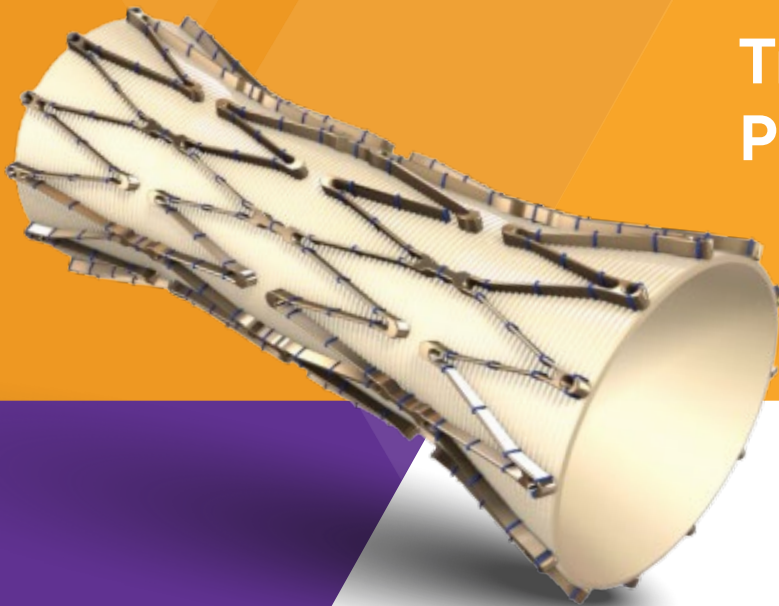
Compression Garments



Leg Elevation

enVVe[®] System

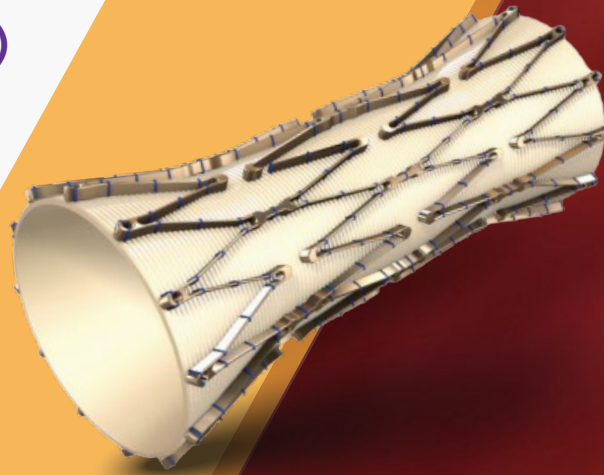
Transcatheter Evolution of Clinically
Proven Surgical Device (VenoValve)





Non-Surgical Evolution of a Clinically Validated Surgical Device

- Transcatheter-based, minimally invasive procedure requiring no overnight hospital stay
- VenoValve (surgical) lead to enVVe (non-surgical)
- Improved performance, strength and durability
- Three times the physician base compared to surgical valve
- Likely to generate significant strategic interest



The TAVVE™ Procedure



Venous Valve

[Learn More →](#)

First Came VenoValve: Surgical Replacement Venous Valve



SAVVE study enrolled 75 patients across 21 U.S. sites



Proof of concept that a single replacement venous valve is sufficient to produce meaningful and lasting clinical benefit



Validated world-wide need and demand for replacement venous valve

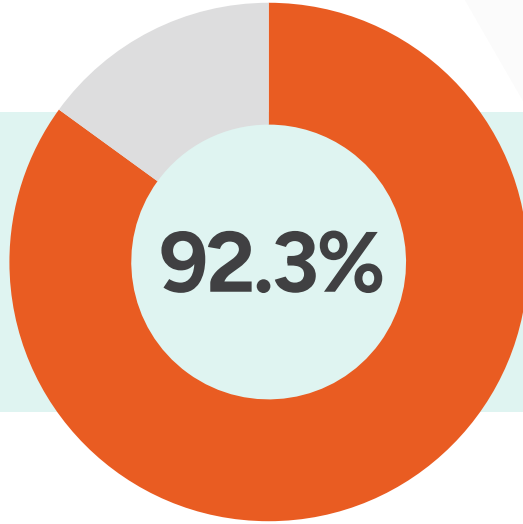


enVVe binary investment risk significantly reduced by VenoValve positive human data



VenoValve: Substantial and Sustained Clinical Improvement

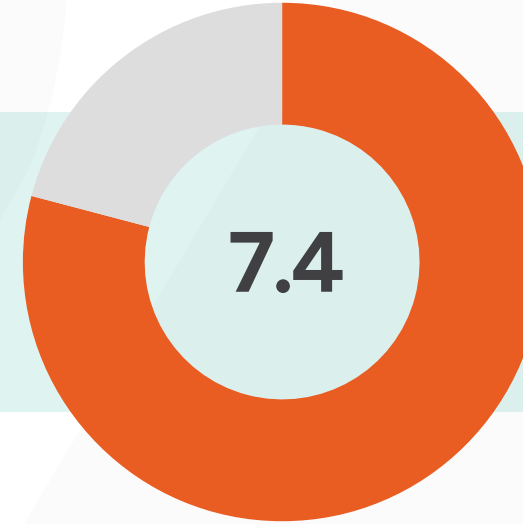
rVCSS
Improvement



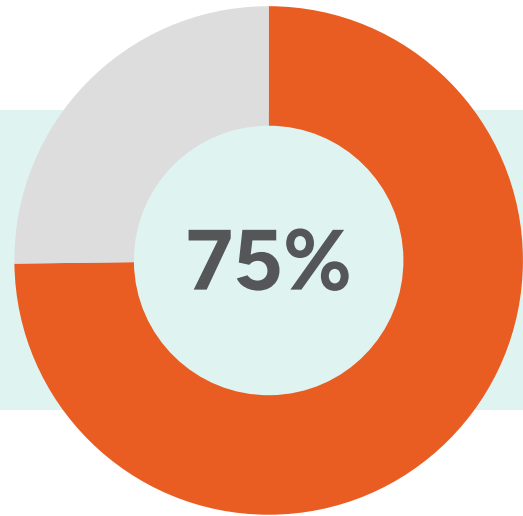
of patients with a clinical
improvement in rVCSS¹
(N=65) at one year

7.4

average point rVCSS
improvement in patients who
showed improvement

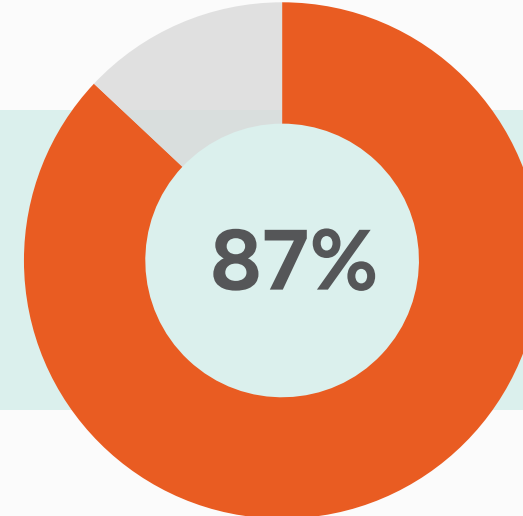


Pain
(VAS Scores)



median percent
improvement

Ulcer
Healing



median ulcer
area reduction

Ulcer Healing from SAVVE Trial Patients



Untreated leg

Treated leg,
12 months



Baseline



30 Days



3 Months



6 Months



1 Year



2 Years



3 Years

VenoValve: PMA Non-Approvable Decision

Surgical Procedure Concerns and Study Evidentiary Gaps

Surgical Safety Profile

Surgical Pocket Bleeding Surgical Incision Infections

"FDA believes the (MAE) events constitute a substantial risk to patients as many of the MAEs required rehospitalization, repeat surgery and prolonged wound care and/or antibiotic therapy."

-FDA PMA Decision

Mechanism of Action

Lack of Hemodynamic Confirmation

FDA strongly recommends that the primary effectiveness endpoint be based upon consistent improvement in venous hemodynamics (i.e., elimination or significant reduction in regurgitant velocity/volume into the lower extremity venous system).

-FDA Pre-submission

Potential Placebo/Study Effect

Is the Valve Why Patients Improved?

FDA believes there is substantial uncertainty that the clinical improvement observed in some subjects and patient reported benefits in the SAVVE study were due to the study device.

-FDA PMA Decision

TAVVE: TrAnscatheter Venous Valve Endoprosthesis

Pivotal Trial

Prospective, Randomized, Multi-Center Trial with No Open Surgical Safety Concerns and Measuring Both Hemodynamic Improvement and Clinical Benefit

Study Design



12 Mo. Data
for PMA



Up to 40
clinical sites



~165 subjects
treatment arm



~55 subjects
control arm

Primary Safety Endpoints (30 Days)

- Composite of all cause death and device related events

Primary Efficacy Endpoints (12 Mos)

- Change in regurgitant volume
- Clinical Improvement

VenoValve: PMA Non-Approvable Decision



Surgical Safety Profile

Surgical Pocket Bleeding
Surgical Incision Infections

No open surgical procedure.



Mechanism of Action

Lack of Hemodynamic
Confirmation

**Hemodynamic endpoint:
improvement in regurgitant
volume versus control group.**



Potential Placebo/Study Effect

Is the Valve Why
Patients Improved?

**Randomized comparative
study.**



enVVe/TAVVE Addresses All FDA Concerns

Stakeholder Appeal Symmetry: Patients; Physicians; Insurers.

• Patients (want it)

- Replace years of ineffective compression therapy and wound care
- No open surgery, general anesthesia, or overnight hospital stay
- Address the underlying cause of the disease, not just symptoms



• Physicians and Hospitals (adopt it)

- User friendly procedure and device
- Vascular Surgeons, Interventional Radiologists, Interventional Cardiologists
- New category of billable procedure



• Insurers (cover it)

- Application pending for New CPT III code
- New Tech APC pathway or Transitional Pass-Through payment
- Cost savings of \$32,153 per patient over 5 years



Compelling Manufacturing and Commercial Capabilities

Manufactured by highly skilled technicians at our own

14,000 ft²

Irvine facility
with clean rooms

Irvine facility has capacity to manufacture up to

30,000

Valves per year

- **Projected ASP: \$30,000**
- **Initial Profit Margin: Elite 80's**
- **Revenue Capacity (existing facility): \$900M**

Competitive Landscape

- Multi-Year Headstart
 - 10 years of development
 - Engineering, testing, clinical data
- Degree of Technical Difficulty
 - Decades of failed attempts
 - Limited bio-prosthetics know-how
- Steep Regulatory Hurdle
 - Class III device
 - Independent clinical evidence
- Broad Patent Protection
 - Applications pending throughout the world
 - Patents beginning to issue
- Currently no competitors in the clinic

**Our
Competitive
Moat is as Big
as an Ocean**

Recent Cardiovascular Device Exists that Defined New Markets



FlowTrievers/ ClotTrievers

- Mechanical Thrombectomy
- Venous Clot Removal PE/DVT
- Minimally Invasive, Catheter-Based
- Vascular Surgeons, Interventional Radiologists, Interventional Cardiologists
- US TAM ~\$6 Billion

Acquired by:

stryker

\$4.9 Billion

Feb. 2025



IVL System

- Intravascular Lithotripsy
- Calcified Cardiovascular Device
- Minimally Invasive, Catheter-Based
- Vascular Surgeons, Interventional Radiologists, Interventional Cardiologists
- US TAM ~\$1.8 Billion

Acquired by:

Johnson&Johnson

\$13.1 Billion

May 2024



Enroute

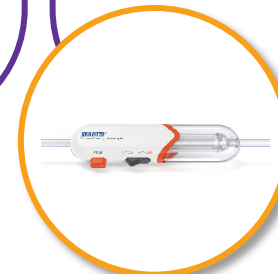
- Transcarotid Artery Revascularization (TCAR)
- Carotid Stenting and Reverse Blood Flow
- Minimally Invasive, Catheter-Based
- Vascular Surgeons, Interventional Radiologists, Interventional Cardiologists
- US TAM ~\$1 Billion

Acquired by:

**Boston
Scientific**

\$1.16 Billion

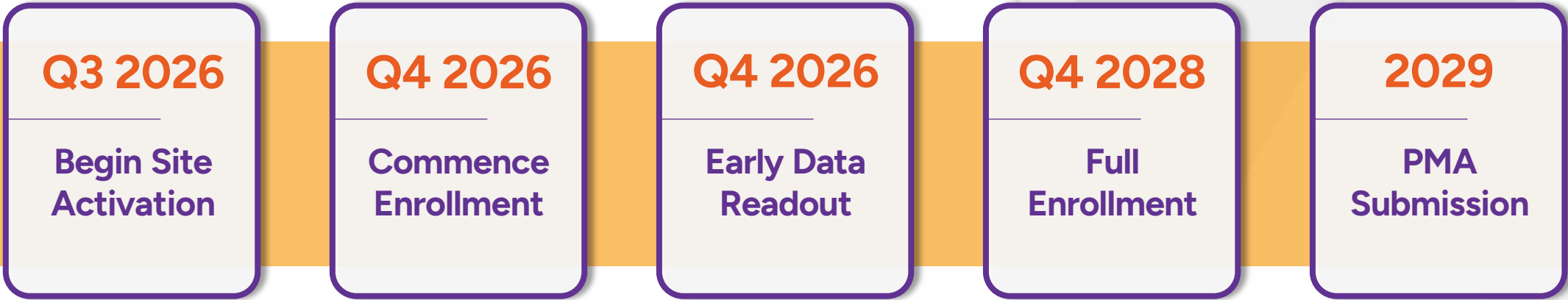
Sept. 2024



Corporate Overview

Capital Efficient Strategy to Fund Value Generating Milestones

Interim Data Readouts at Prestigious Medical Conferences



Capital Needs Align Directly With TAVVE Trial Execution Milestones

~\$25M* Cash & Investments As of March 31, 2026	~\$5M Expected Quarterly Cash Burn	2027 Current Runway	No Debt	667,669 Common Stock Outstanding As of May 1, 2026
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Proven Management Team With Broad Medical Device and Commercialization Experience



Robert Berman

Chief Executive Officer, Director

- Former CEO, Anixa Biosciences (Nasdaq:ANIX)
- Former COO, Acacia Research (Nasdaq:ACTG)
- B.S.
- JD, North Wharton, Univ. of Pennsylvania Eastern Law



Marc Glickman, M.D.

Senior Vice President and Chief Medical Officer

- Board Certified Vascular Surgeon
- Director of Vascular Services, Sentara Health Care
- Past President, Vascular Society of America



Sandy Prietto

Vice President, Marketing

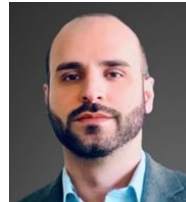
- Seasoned MedTech marketing executive
- Former - Head of Worldwide Marketing at Endologix
- Oversaw successful launch of the DETOUR System



Jennifer Bright

Chief Financial Officer

- Over 25 years financial experience
- Certified Public Accountant
- B.A.. Business Administration, Accounting, University of Washington



Hamed Alavi, Ph.D.

Senior Vice President and Chief Technology Officer

- Edwards Lifesciences, Medtronic
- PhD Biomedical Engineering – U.C. Irvine
- M.S. Biomedical Engineering, B.S. Mechanical Engineering



AVI Sharma

SVP, Clinical, Regulatory and Quality

- Senior roles at Medtronic Cardiovascular, Edwards Lifesciences, Accelerant, and Endologix
- Graduate degrees in Electrical Engineering and Biomedical Engineering, University of Southern California

Collective Industry
Experience:

Medtronic



Board of Directors



Dr. Francis Duhay

- Former Chief Medical Officer – Edwards Lifesciences
- Expert in surgical and transcatheter heart valves
- General manager Acendra business unit



Dr. Sanjay Shrivastava

- Business Development – Johnson and Johnson
- 18 years – VP Marketing and Strategy, R&D
- BTG, Medtronic, Abbott Vascular, Edwards Lifesciences



Matthew Jenusaitis

- Chief of Staff and Chief of Innovation and Transformation – UC San Diego Health System
- Former President Boston Scientific – Peripheral Division
- Four successful vascular company exits



Bob Gray

- Former Chief Financial Officer – Highmark, Inc.
- Health insurer with over 20 years subscribers
- Rate setting and reimbursement negotiations

Collective Industry
Experience:

Medtronic

Johnson & Johnson

Abbott
Vascular

HIGHMARK.

Edwards

Boston
Scientific

BTG

Arbitrage Opportunity

Low Market Value/High Intrinsic Value

