

INFLOW

Novel transcatheter aortic heart valve implants (TAVI)

proprietary **polymeric** and **biological** variants with a unique self-positioning delivery system

Innovations for Heart and Vessels Ltd. Investment opportunity



UNMET CLINICAL PROBLEMS TO BE SOLVED

Problems unsolved by current biological valve technologies



01.

Ageing population with rising prevalence of aortic heart valve disease: 17% in population >70 y.o.

02. **TAVI not available** for younger patients <75 y.o.

03. Limited durability of currently available **TAVI systems**

04. High price of TAVI systems









SAVR



05.

Ineligibility of many patients for SAVR due to high perioperative risk

06.

Limited availability of biological material; costly and time consuming manufacturing process

07.

Waiting time for the procedure (many patients dying on the waiting lists)





BREAKTHROUGH CONCEPT AND SOLUTION WITH STRONG IP PROTECTION



The INFLOW polymeric valve stands as a groundbreaking innovation, offering extended durability exceeding 20 years, surpassing traditional biological valves. The polymeric valve allows to approach a broader market, by making the valves applicable for younger patients.



Self-positioning implantation

















MARKET SNAPSHOT





Medical and Venus Medtech, tier 3 comprises of: JenaValve Technology, Suzhou Jiecheng Medical, Peijia Medical, Meril Life Sciences and others





INFLOW POLYMERIC VALVE – DISRUPTIVE TECH

Medical-grade polymer material, low production costs. No polymeric TAVI competitors present on the market





01.

for aortic valve

POLYMER MATERIAL REMOVES THE NEED FOR ANIMAL HUSBANDRY – PRODUCTION IS **EXTREMELY SIMPLIFIED, MUCH CHEAPER AND ENVIRONMENT-FRIENDLY**



INFLOW polymeric valve features

02.

Medical-grade polymer material

Proven biocompatibility and mechanical strength (preclinical studies)

03.

Potential for endothelization of leaflet surface

04.

Exceptional durability – over 20 years, specifically suitable for younger patients

Technology for production

Vent like concept

02.

Sutureless – polymer attached to the metal frame using proprietary electrospinning method

03.

Simple commissure formation by attachment of suspensions to the stent frame

04.

Low production costs environmentfriendly solutions



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INFLOW BIOLOGICAL VALVE – UNIQUE SOLUTION

Our INFLOW biological valve is characterized by high biocompatibility and resistance to degeneration.



OUR OWN SUPPLY OF HIGH QUALITY BIOLOGICAL MATERIAL FOR VALVE PRODUCTION IS A KEY COMPETITIVE ADVANTAGE



INFLOW biological valve features



Decellularized biological material

Proven biocompatibility and mechanical strength (preclinical studies)



High resistance to valve leaflet degeneration

Technology for production



Vent like concept for aortic valve

2.

Simple commissure formation by attachment of suspensions to the stent frame



Proprietary biological material derived from the pericardium of genetically modified domestic pig





BENEFITS OF OUR INFLOW BIOLOGICAL & POLYMERIC VALVES



Benefits for **patients**

Faster recovery, shorter stay at the hospital, reduced trauma and pain, less noticeable scars

> Shorter waiting time for the procedure

A lower risk of perioperative complications and death rate

The INFLOW Polymeric Valve stands as a revolutionary innovation, which can be applied for a larger patient population due to its **extended durability >20 years – especially** applicable for younger patients.









POLYMERIC INFLOW VALVE PRECLINICAL STUDY RESULTS



30DFU

180DFU





Source: Mateusz Kachel, Piotr Buszman et al., Frontiers in Cardiovascular Medicine, 2022 Frontiers | Temporal, biomechanical evaluation of a novel, transcatheter polymeric aortic valve in ovine aortic banding model





BIOLOGICAL INFLOW VALVE PRECLINICAL STUDY RESULTS









Source: Piotr Buszman, Mateusz Kachel et al., Cardiology Journal, 2023 6-Month Evaluation of a Transcatheter Aortic Valve (Myval) in a Novel Ovine, Supra-Aortic Banding Model - PMC





PRODUCT ROADMAP

Obtaining 4 crucial patents with full intellectual property rights and attracting the first international investor

2020-2021

Patent protection expanded, all IP rights purchased, Seal of Excellence award of **EUR 2.5m from EIC** ↔ another grant of **EUR** 6.9m obtained from PARP

2022-2023

Developing the manufacturing line of the **final** valve TAVI implant in accordance with **ISO** and **MDR**, **GLP-compliant** pre-clinical studies



INFLOW TAVI commercialization, pivotal **randomized** clinical trials launch for FDA purposes

2029-2030

2031-

Mitral and tricuspid valve replacement devices development

2024-2027

FiM clinical trials & medical device certification preparation

> 2027-2029



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IP RIGHTS

IP RIGHTS PROTECTION – INTERNATIONAL PATENTS

WO2020022914



Biological, low-profile, balloon-expanded prosthetic heart valve, percutaneously implanted, and the method of its manufacturing

WO2020022914



Artificial, low-profile, balloon-expanded specialized heart valve, percutaneously implanted

WO2020022915



System for introducing implants used in structural heart diseases using a minimally invasive method

WO2020022916

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Method of forming prefabricated units used in produce systems of prosthetic aortic valve transcatheter impleand prosthetic aortic valve prefabricated unit



	APPROVAL DATE [date of patent grant]	PATENT OWNERSHIP	PROTECTION RANGE
aortic thod	PL 2020 USA 2024	I4HV 100%	* * * * * * *
aortic	PL 2020 EU 2023 USA 2024	I4HV 100%	* * * * * * * *
	PL 2021	I4HV 100%	* * * * * * * *
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