NovaHep

Tissue-Engineered Vessels For Life

Pitch Presentation

NovaHep AB

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The Company

To Deliver Readily Available

Personalized Tissue-Engineered Products

That Cure Severe Diseases

NovaHep in 5 years

We will have achieved this:

- 2-3 products on a multi BUSD market
- Marketing and sales established
- Proprietary manufacturing in EU and USA
- Out licencing in ROW
- Strategic collaborations to develop future products
- Well filled pipeline to continue to deliver state of the art innovative products for regenerative medicine
- Strong IP situation in all important markets
- Profitable and cash positive, building significant value for our investors

NovaHep – frontier in personalised regenerative medicine

- Founded as a university spin-off at **Karolinska Institute** in Stockholm
- Head quarter and operations in Biotech Centre in **Gothenburg**, Sweden
- **Privately funded** company
- **Highly experienced management team**; entrepreneurship, stem cell technologies and industrial regenerative medicine
- Commercialisation of **tissue engineering** and advanced **regenerative medicine**
- Current focus on **individualised blood vessels** and especially veins with competent valves

Technology

Transplantation of organs and tissues

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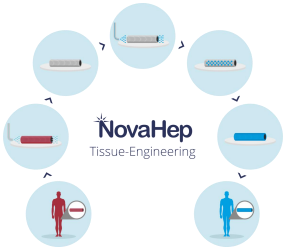
ORGAN DONATION
A GIFT FOR LIFE

Heart and liver transplantation is common today

The big challenges in transplantation:

- **Chronic lack of transplantable organs**
- **Transplantation requires life-long immunosuppression with severe side-effects (e.g. cancer)**

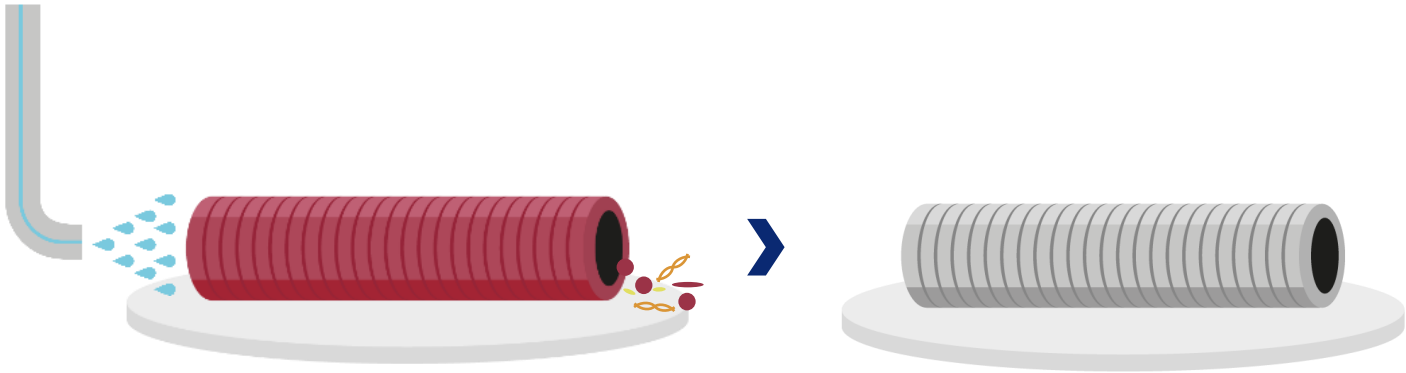
In many cases this is TOO MUCH RISK



NovaHep develops a solution to these problems

Personalization of transplants by de- and recellularization
No immunosuppression required!

Blood vessels - Decellularisation

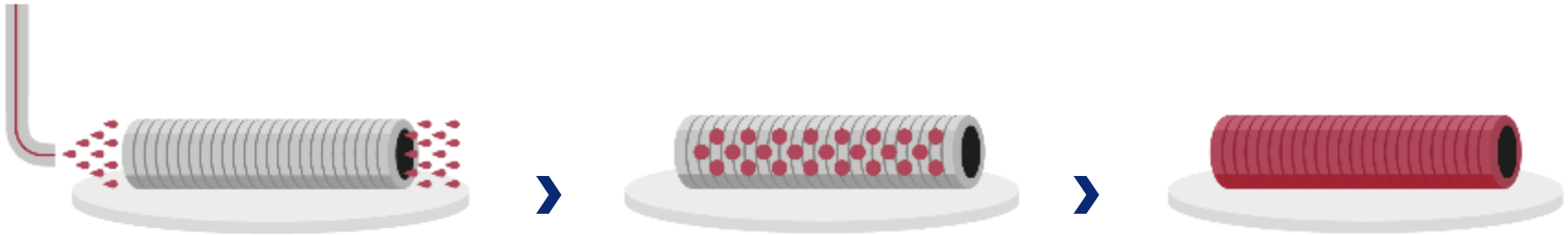


1. Removal of red blood cells
2. Removal of endothelial and smooth muscle cells
3. Removal of DNA
4. Cold storage of scaffold after sterilization

NO EXPANSION OF CELLS

READY TO USE BY SURGEONS IN 1 WEEK

SIMPLICITY IS KEY TO THE PROCESS

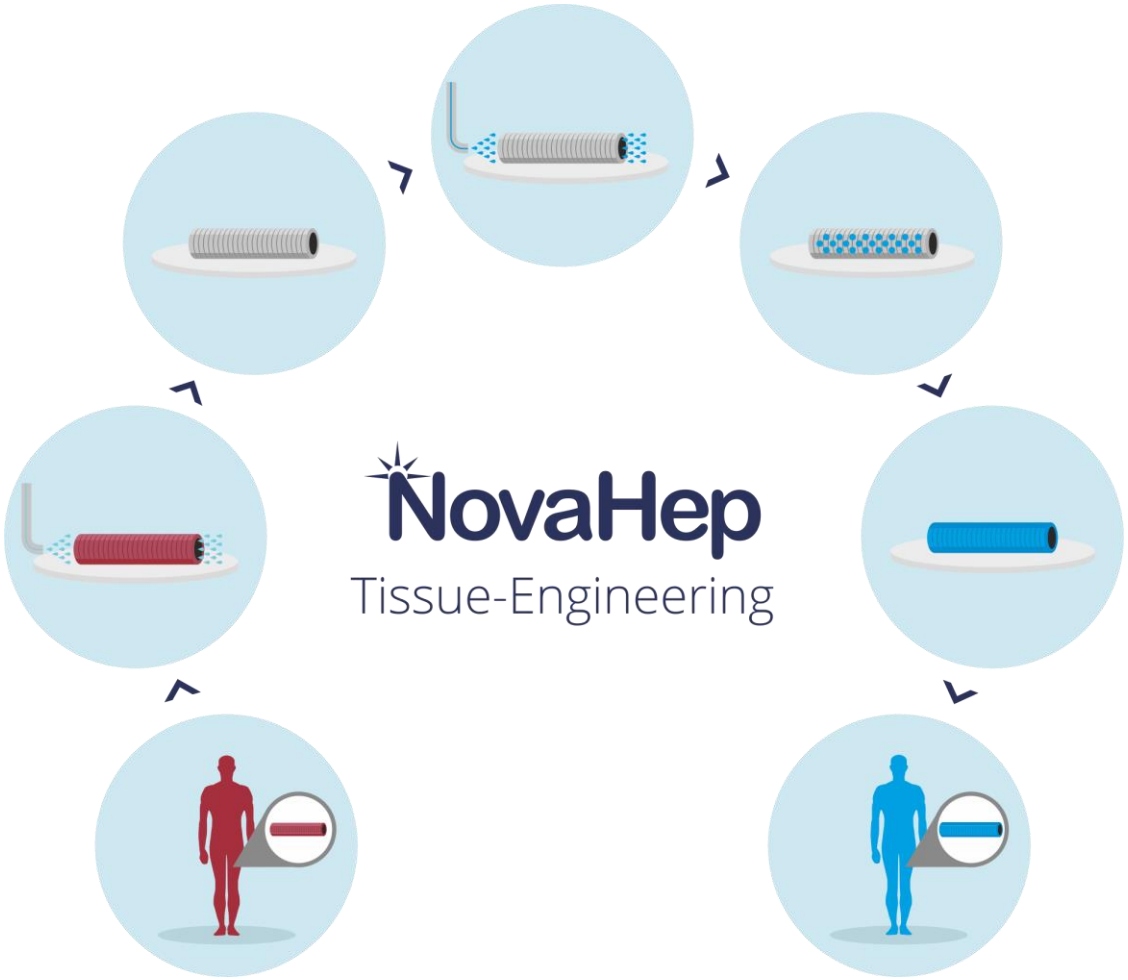


Perfusion of decellularised blood vessel with patient's blood

Binding of circulating vascular cells to scaffold

Personalized blood vessel in **one week**

Personalized by de- and recellularization



Engineering of individualized blood vessels for transplantation to avoid life-long immunosuppression

Individualized blood vessels – Clinical POC

- Patented technology has been used in academic setting to treat patients
- Three patients transplanted with individualized tissue engineered veins
- No immunosuppressive drugs used
- Clinical proof-of-concept of safety and efficacy of the technology

In vivo application of tissue-engineered veins using autologous peripheral whole blood: A proof of concept study. Olausson M, Kuna VK, Travnikova G, Bäckdahl H, Patil PB, Saalman R, Borg H, Jeppsson A, Sumitran-Holgersson S. EBioMedicine. 2014 Sep 22;1(1):72-9. doi: 10.1016/j.ebiom.2014.09.001. eCollection 2014 Nov.

Transplantation of an allogeneic vein bioengineered with autologous stem cells: a proof-of-concept study. Olausson M, Patil PB, Kuna VK, Chougule P, Hernandez N, Methe K, Kullberg-Lindh C, Borg H, Ejnell H, Sumitran-Holgersson S. Lancet. 2012 Jul 21;380(9838):230-7. doi: 10.1016/S0140-6736(12)60633-3. Epub 2012 Jun 14.

First Product

Severe Chronic venous insufficiency – Medical need

1,5 M patients in US/EU alone

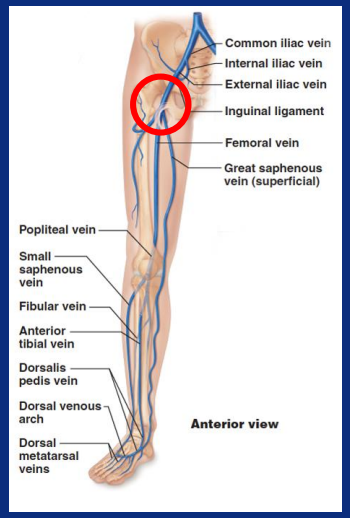
Enormous socio-economic burden

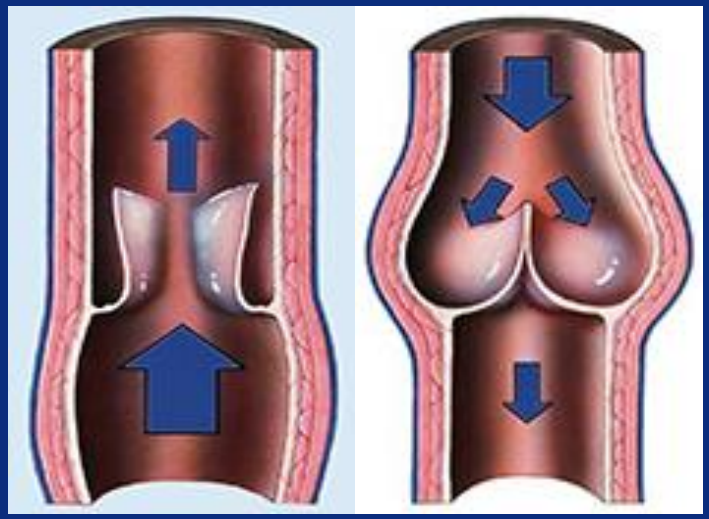
Severe chronic venous insufficiency (CVI)

NO competition

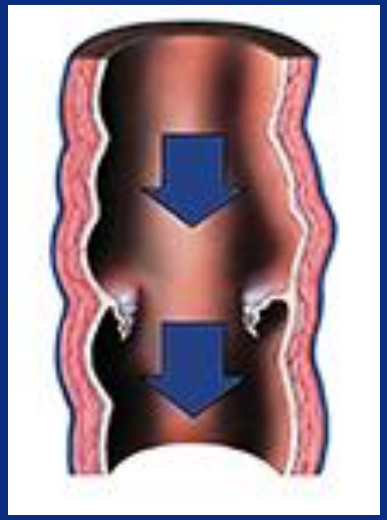
Virgin market of ≥ USD 2-3B

Deep veins with valves



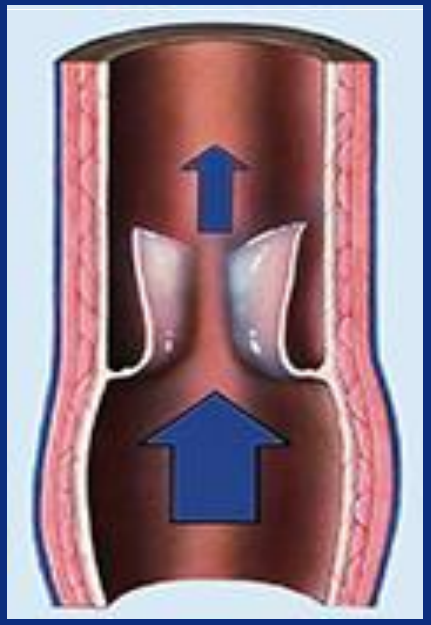


Normal Function



Insufficient Valve

P-TEV product



Personalized Tissue-Engineered Vein

P-TEV

- 4-6 cm long vein segment
- Contains one functional valve
- Grafting by simple end to end anastomosis

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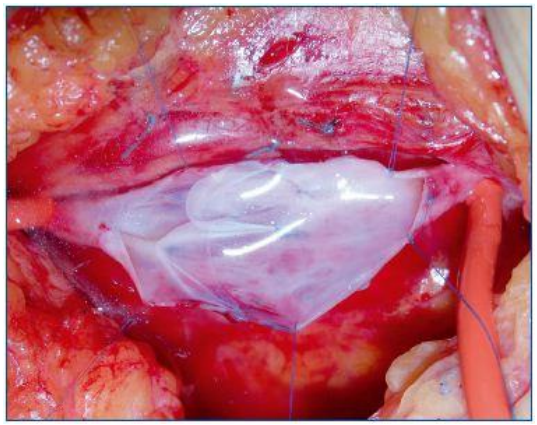
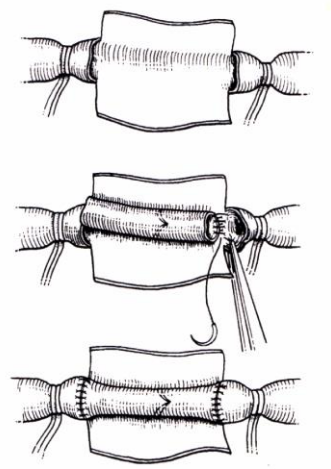
Phase I/II clinical trial at Oslo University Hospital, Norway



- 13 Patients with severe CVI
- Replacement surgery
- Open vein segment with incompetent valve
- Graft P-TEV with functional valve
- Safety endpoints evaluated after 4 weeks
- Safety and efficacy at 3, 6 and 12 months



First clinical trial of its kind worldwide

Oslo universitetssykehus

Severe CVI market and strategy

Severe CVI – EU28 and North America

1,5 million patients

Conventional symtomatic care costing USD 15,4B annually

Severe CVI:

- 1,5 million patients in EU28/North America alone
- Virgin market of USD 20B
- No competition and no other cure in development
- Calculating with 10-15% market penetration for P-TEV product
- NovaHep's market share of USD 2-3B
- Strong reimbursement model

NovaHep's Strategy:

- POC in Scandinavia
- Start of commercial distribution as an ATMP in 2019
- Scandinavian market enough for NovaHep to break even
- Secure EU market, expanding to USA, followed by ROW

Development Pipeline

NovaHep development programmes:

Three main programmes:

Personalized tissue-engineered veins (P-TEV)

Clinical POC, ready for Phase I/II trial targeting chronic venous insufficiency 2017

Personalized tissue-engineered arteries (P-TEA)

Preclinical development, target indications decided

Personalized tissue-engineered nerves (P-TEN)

Preclinical development

P-TEA and P-TEN are both addressing multi BUSD markets!

NovaHep products in pipeline:

Personalized tissue-engineered arteries (P-TEA)

Arterio Venous (AV) grafting

Arterial Bypass in the extremities (e.g. below the knee)

Coronary Artery Bypass Grafting (CABG)

Already mature billion USD markets for existing products

Personalized grafts offer big advantages over existing products

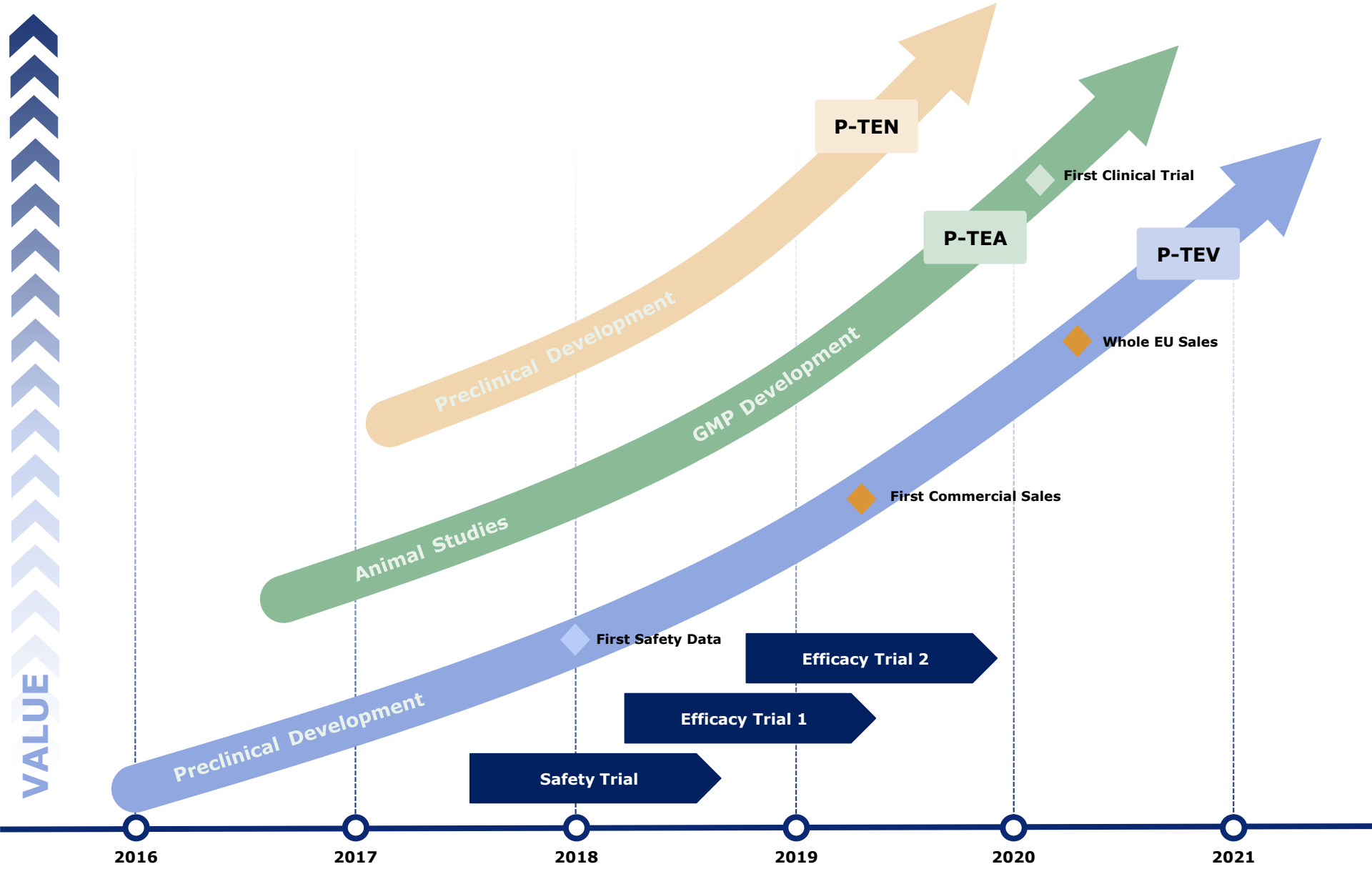
Personalized tissue-engineered nerves (P-TEN)

Nerve grafts for peripheral nerve gap repair

Civil and military applications

Already a billion USD market

Trajectories 2017 forward



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IP

Intellectual property

- NovaHep is in possession of six patent families
- Two of the patent families cover de- and recellularisation of blood vessels (patent "503 and 504")
- Patent family 503 covers use of peripheral blood for recellularisation
  - Granted in the US and EPO
  - Late process in most other countries including Europe, China, Japan etc.
- Patent family 504 covers specifically valve-bearing blood vessels
  - National filing in countries like China, Japan and South Korea
- In addition Trade Secrets are used to strengthen protection of the company´s industrial excellence
- Additional IP in the areas of kidney, liver and skin is secured
- ***The above described IP is expected to give NovaHep a strong competitive advantage for the future product portfolio***

Investment Opportunity

Investment summary Q1, 2017:

Capital to be raised: USD 6M

Timelines: Q3/Q4 2017

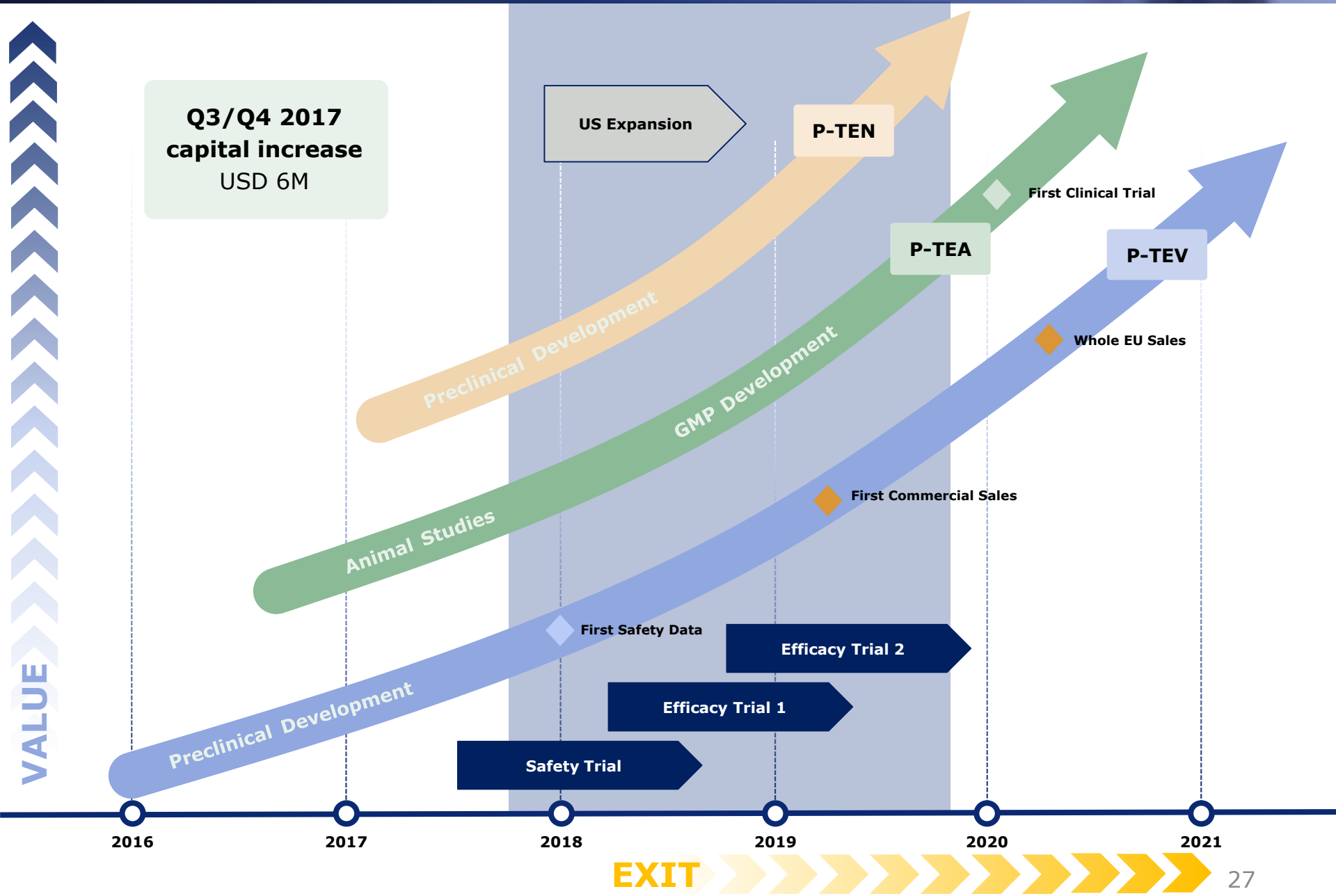
Use of funds:

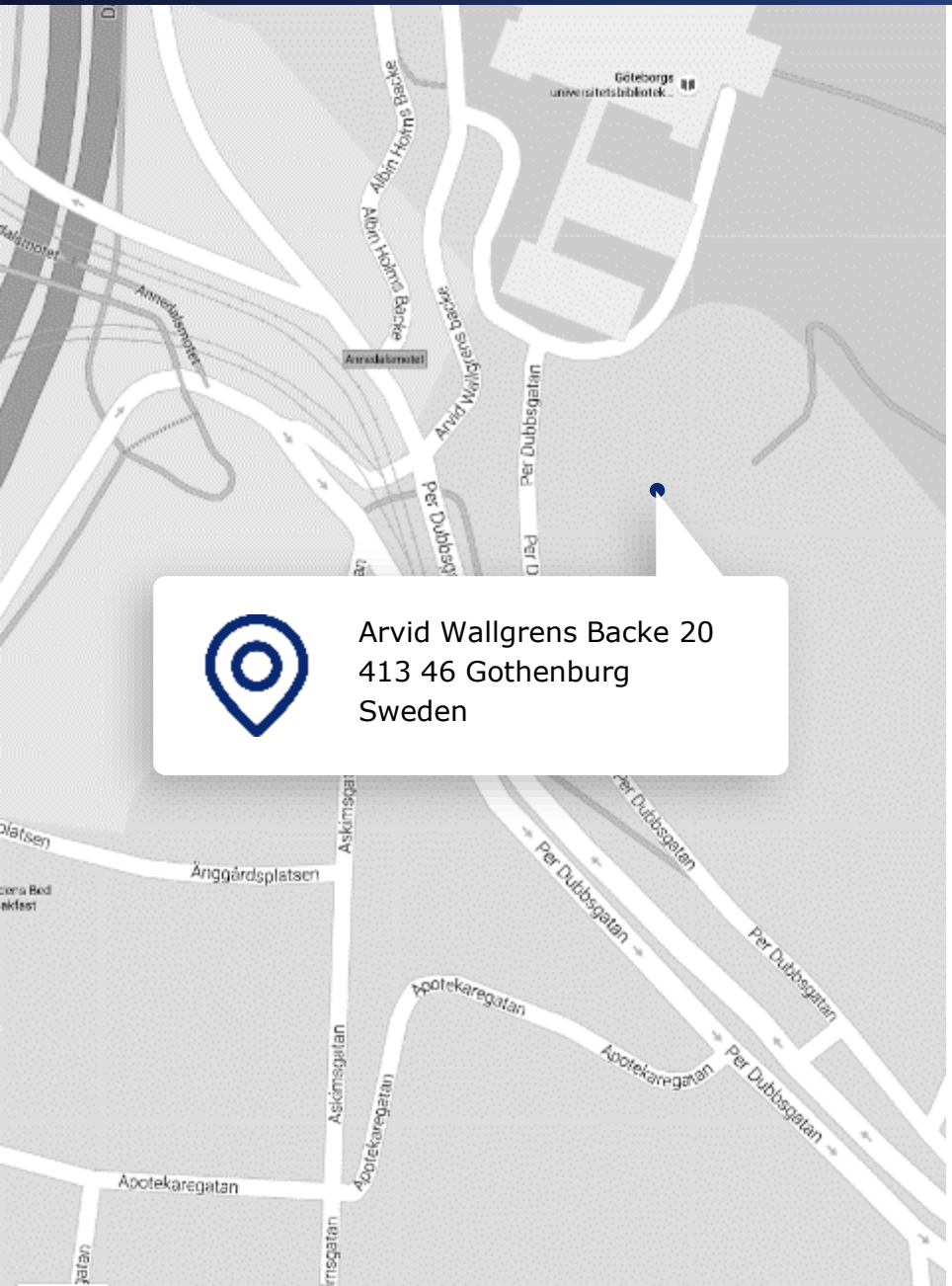
- Personalised tissue-engineered veins (P-TEV) - Clinical POC (Phase I/II)
- P-TEV efficacy trial 1
- P-TEV efficacy trial 2
- Marketing & Sales organisation
- Reach first commercial sales and increase manufacturing scale accordingly
- Personalised tissue-engineered arteries (P-TEA) - Preclinical development
- Personalised tissue-engineered nerves (P-TEN) - Preclinical development
- Initiation of NovaHep US operations

Valuation: TBD (latest valuation USD 8,3M, Euro 7,7M, SEK 73M)

Exit: IPO or trade sale in 2-4 years

Capital increase, use of funds and exit





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