PCI Biotech

Company presentation

October 2024

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PCI Biotech

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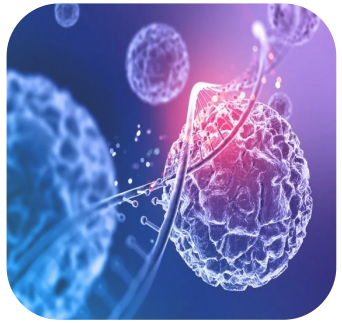
PCI Biotech in brief

PCI Biotech is a listed (PCIB:NO) company with an **innovation-driven pipeline**

Our vision is to **develop and commercialise novel therapeutic solutions** to address unmet medical needs for patients

Photochemical-based platform for two different areas: photochemical lysis (PCL) and photochemical internalisation (PCI)



Bioprocessing - There is a **great need** for novel technologies that **enable more effective** manufacturing. Our novel technology, PCL, is under development for increasing yield and reducing impurities in viral vector manufacturing

- **PCL extracts viral vectors** from producer cells while **reducing host-cell impurities**, by selective disruption of producer cell membranes during the cell lysis process

Drug delivery - Several novel classes of **drugs need access to the inside of their target cells** to be effective. Our novel technology, PCI, enables drugs to reach intracellular therapeutic targets by providing intracellular delivery

- **PCI** unlocks the potential of novel medicinal products, by **modifying intracellular trafficking** in target cells **leading to enhanced biological effects**

PCI Biotech board of directors

Hans Peter Bøhn, MD, Chair

- Chairman since 2016
- 12 years' experience from various management positions with Nycomed Imaging
- Other experience includes being a financial analyst, covering life science companies

Hilde Furberg, Director

- 35+ years international experience from sales, marketing, strategy and management in pharma and biotech industry
- Most recently European Head of Rare Diseases for Sanofi Genzyme
- Board member of Bio-Me, Sedana Medical, Herantis, and Pluvia Biotech

Lars Viksmoen, MD, Director

- 25+ years international experience from pharma, biotech and medtech industry
- Worked 10 years as a surgeon prior to his executive career
- Previous experience includes Merck & Co. Inc. and GN ReSound

PCI Biotech management team

Ronny Skuggedal, CEO and CFO

- Chief Executive Officer since June 2022
- Chief Financial Officer since 2013
- State Authorised Public Accountant Norway
- 12 years' experience from auditing and advisory services, PwC

Anders Høgset, PhD, CSO

- Chief Scientific Officer since 2001 (deputy CEO 2004-2008)
- Previously Senior Scientist at Radiumhospitalet developing the PCI technology

Leveraging the photochemical technology platform within bioprocessing, immunotherapy, and nucleic acid therapeutics

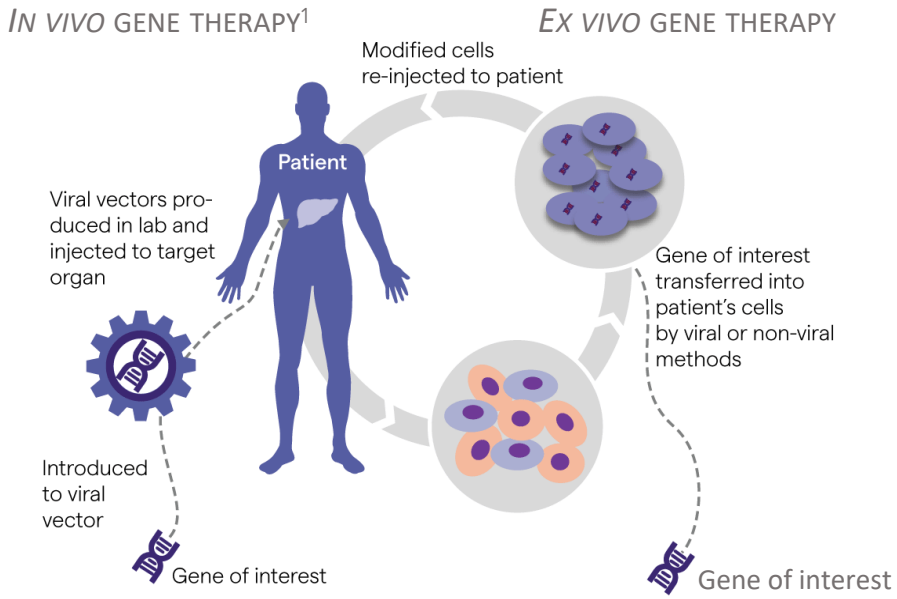
Bioprocessing (PCL)	Feasibility	Prototype	Commercial
Viral vector manufacturing			

Drug delivery (PCI)	Preclinical	Phase 1	Phase 2
Intratumoural immunotherapy			
Dermatology			

Bioprocessing

Viral vector manufacturing

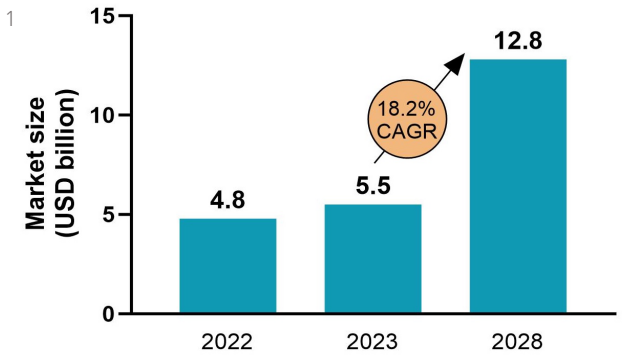
Gene therapy – Advanced medicinal products with groundbreaking potential

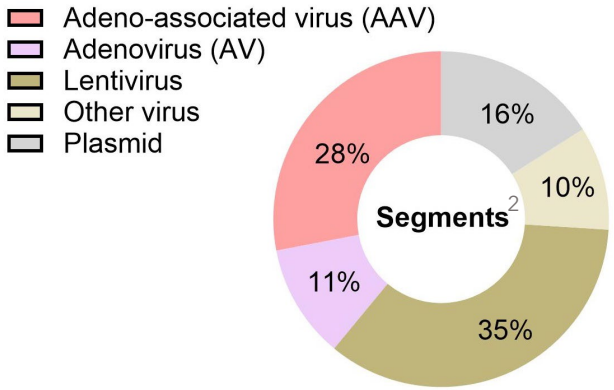


- Genetic disorders are caused by DNA mutations that may lead to severe disease
- Gene therapies are potentially life-saving treatments for genetic disorders in a single dose[2-3]
- *In vivo* gene therapies utilise viruses ("viral vectors") to deliver genetic medicines
- Improved manufacturing is needed to make gene therapies more available

1. Figure adopted from Lonza
2. Mendell *et al*. 2017, NEJM
3. Mendell *et al*. 2021, JAMA Neurology

The viral vector manufacturing market



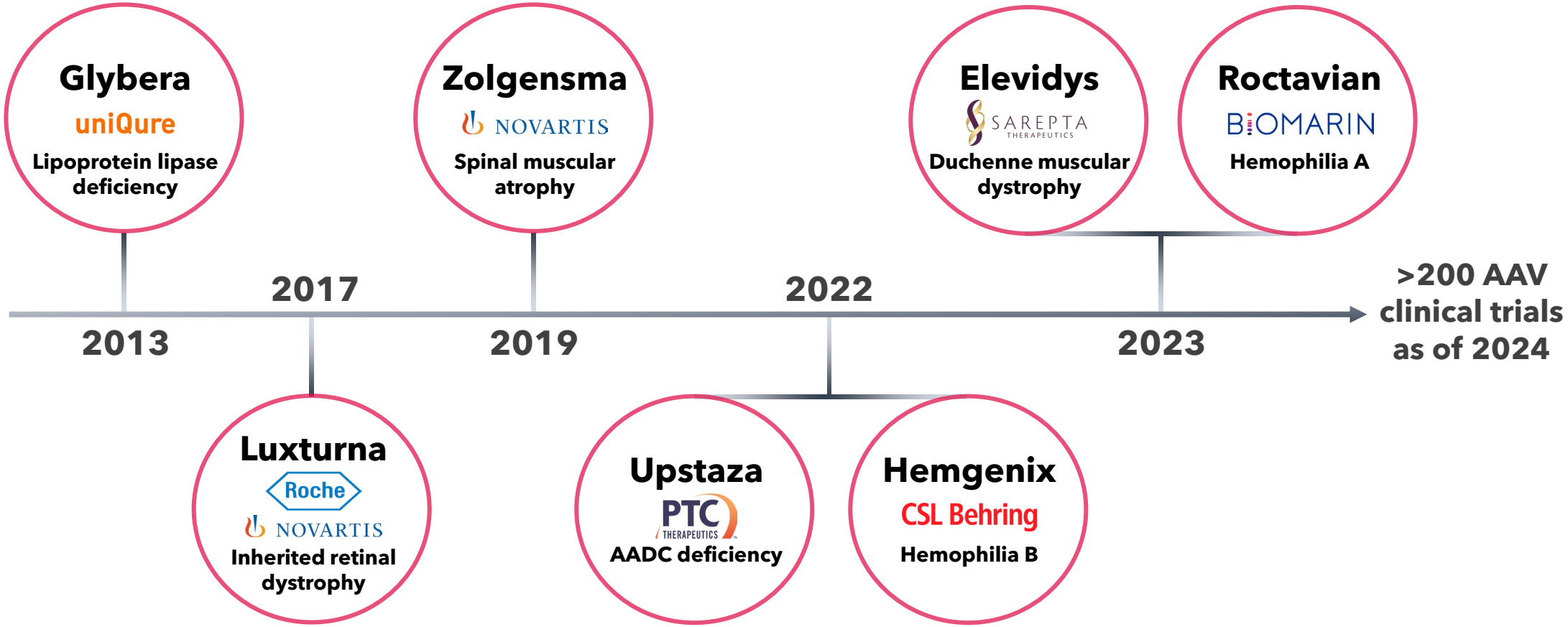


AAV gene therapy	Target indication	FDA approval	List price (per treatment)
Hemgenix	Hemophilia B	2022	$ 3.5 million
Zolgensma	Spinal muscular atrophy	2019	$ 2.1 million
Luxturna	Retinal dystrophy	2017	$ 825 000 (both eyes)

- Viral vector manufacturing is in high demand
- Manufacturers are mainly big pharma and CDMOs/CMOs
- Manufacturing cost constitute a significant part of a drug's list price
- **PCI Biotech** primarily targets manufacturing of non-enveloped viral vectors (e.g. AAV and AV), with an emphasis on AAV therapies

1. Markets and Markets 2023, "Viral Vector & Plasmid DNA Manufacturing Market"
2. Batavia Biosciences, "Solving challenges in manufacturing viral vector based atmps"

Approved AAV therapies[1]



1. Adopted from Wang *et al.* 2024, Signal Transduct Target Ther

Viral vector manufacturing - utilising cells as “gene therapy factories”

Unmet technical need

- Gene therapy utilises viruses (viral vectors) to deliver potentially life-saving genetic medicines to patients. There is a need for novel technologies enabling more effective viral vector manufacturing with higher yield as well as increased quality

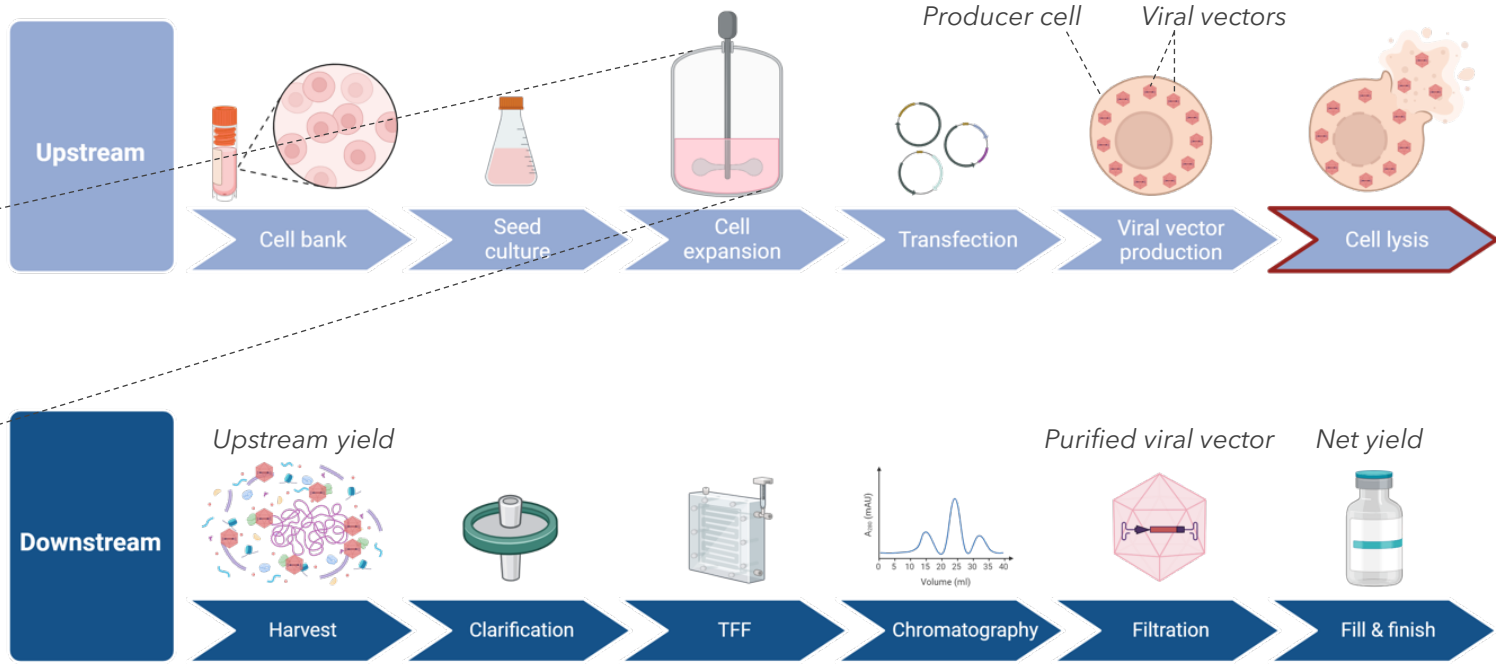
Manufacturing challenges

- Viral vectors are produced by living cells that act as “gene therapy factories”. The combination of living cells as “producers” and a complex output of “viruses” is what makes the manufacturing so challenging

Viral vector extraction

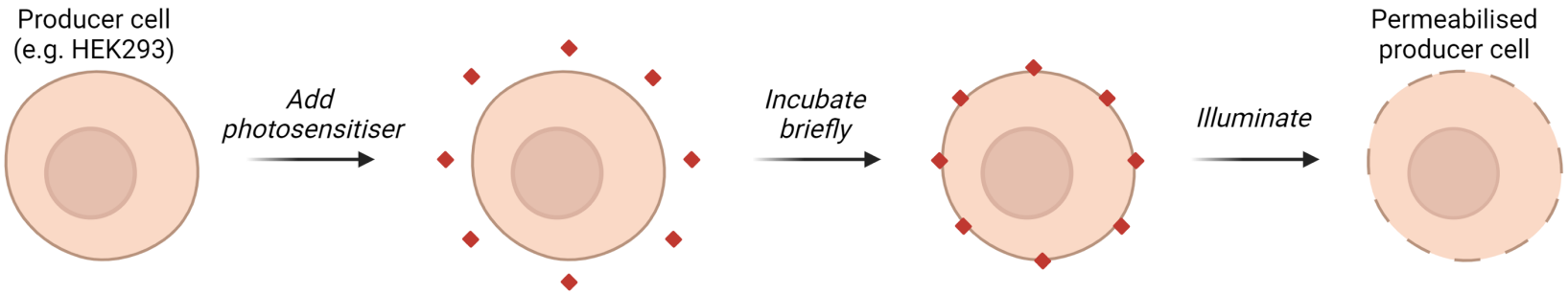
- Manufacturing includes intricate upstream and downstream processes. Cell lysis is the final upstream step where viral vectors (e.g. AAV) are extracted from the producer cells. In the subsequent downstream process, the viral vectors are separated from various producer cell debris (impurities) in sequential purification steps

Viral vector manufacturing - utilising cells as “gene therapy factories”



Manufacturing challenges for viral vectors include **host-cell impurities** (e.g. DNA and protein) and **low viral vector yield** from cell lysis

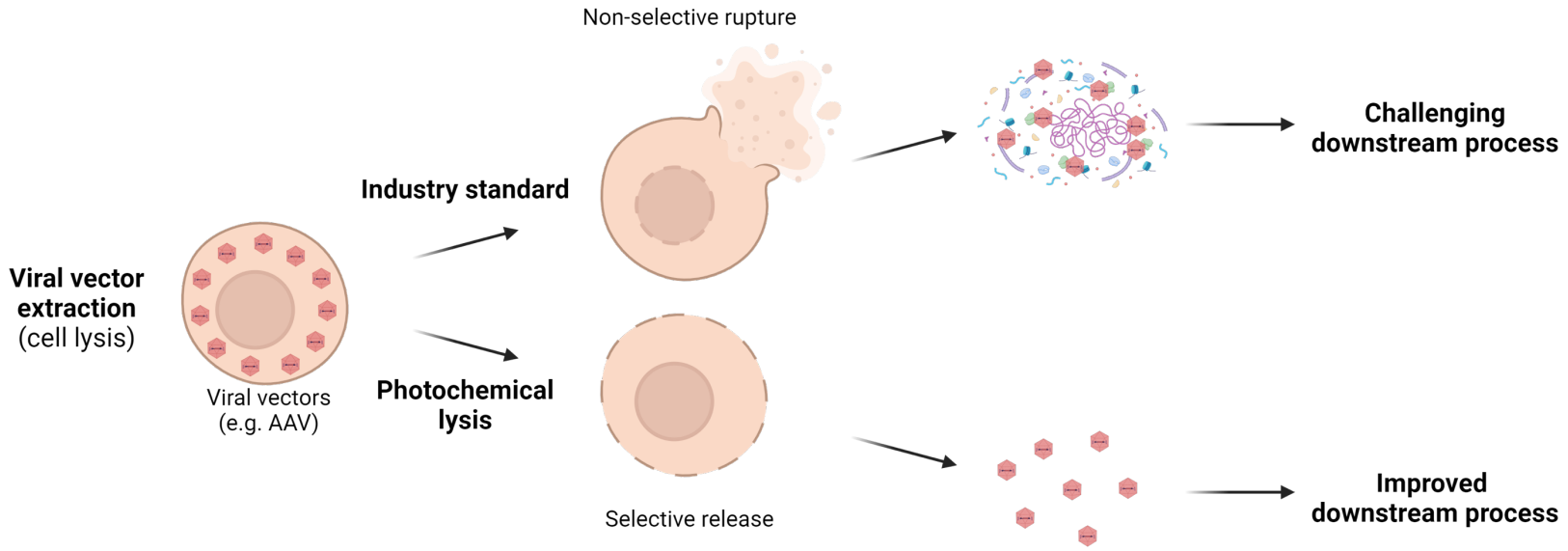
Photochemical lysis (PCL) - next generation viral vector extraction



PCI Biotech develops a novel technology - photochemical lysis (PCL) - to **address technical needs** in viral vector manufacturing

Photochemical lysis **selectively releases viral vectors from producer cells** with reduced host-cell impurities compared with the industry standard

Selective disruption of the plasma membrane by PCL



Viral vector extraction	Mode of action	Host-cell impurities	Net viral vector yield
Industry standard	Non-selective	High	Moderate
Photochemical lysis *ambition*	Selective	Low	High

Early-stage field (“alpha”) testing with undisclosed partner

Test setup - upstream process

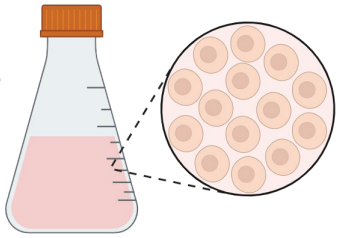
Photochemical lysis was tested in partner’s upstream AAV process development process with suspension HEK293 cells in shake flasks

Following harvest, samples were analysed for yield and host-cell impurities (DNA, protein)

Photochemical lysis matched industry standard lysis in terms of yield in *upstream* process, while strongly reducing host-cell impurities

Tester’s AAV upstream process

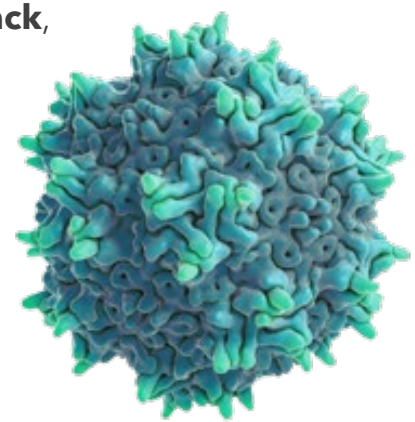
- Suspension producer cells
- 3D culture
- 20 mL volume



Shake-flask
(20 mL)

Recent R&D milestones within AAV manufacturing

- PCL has **demonstrated viral vector release across several** adeno-associated virus (AAV) **serotypes** in an upstream process
- Received **encouraging feedback** from the international search report on the PCL **patent application**
- **Alpha testing** with undisclosed partner completed Q1 2024 with **positive feedback**, supporting further development with an **emphasis on AAV gene therapy**
- To **accelerate development**, PCL was **successfully transferred** to a renowned service provider for scale-up to **mini benchtop bioreactor** during Q2 2024
- **Important progress** has been made in mini benchtop bioreactor, with **initial results Q3 2024** indicating:
  - **Photosensitiser** can be **cleared in downstream processing** of AAV
  - Photosensitiser has **no negative impact on viral vector** (AAV) functionality
- Further research is required to **demonstrate enhanced** viral vector **yield also in** mini benchtop **bioreactor**



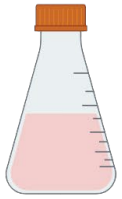
The path from feasibility tests to commercial manufacturing

Feasibility

Plate
(0.5-1 mL)

2022

Proof of concept
adherent cells (upstream)

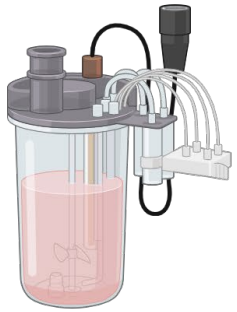


Shake-flask
(20 mL)

2023

Suspension cells and scale-up
(upstream)

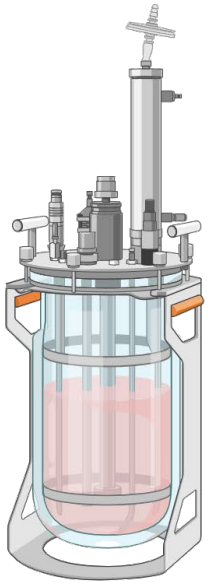
Prototype



Mini benchtop bioreactor
(250 mL)

2024

Downstream purification,
end-product testing,
larger-volume illumination

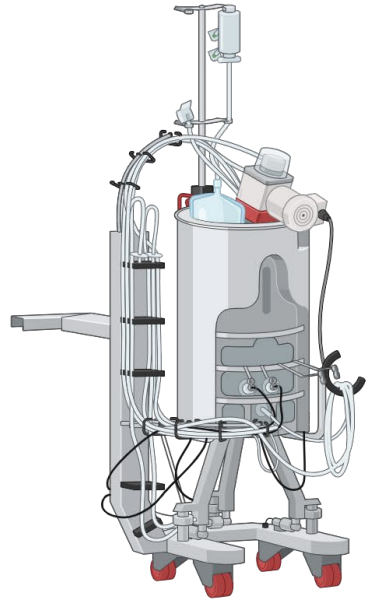


Benchtop bioreactor
(1-10 L)

Partner-dependent

Further scale-up,
process development

Commercial



Bioreactor
(50-500 L)

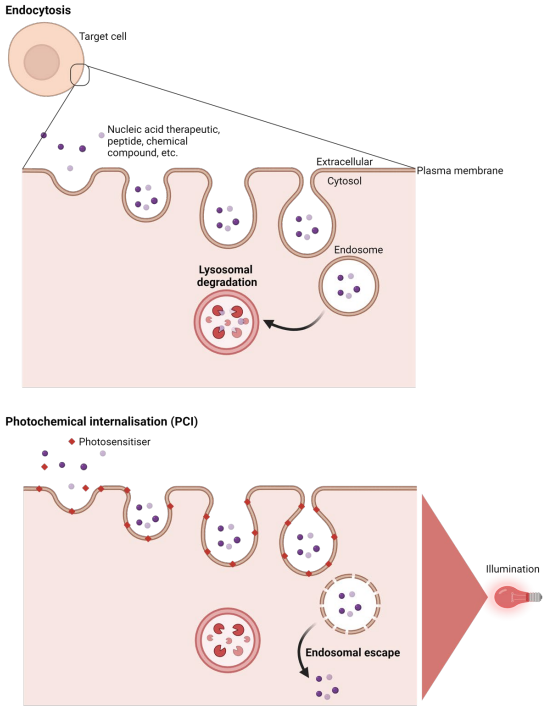
Partner-dependent

Pilot scale, production scale,
fit-for-purpose illumination

Drug delivery

PCI: Enabling intracellular delivery by a unique mode of action

Triggered endosomal release

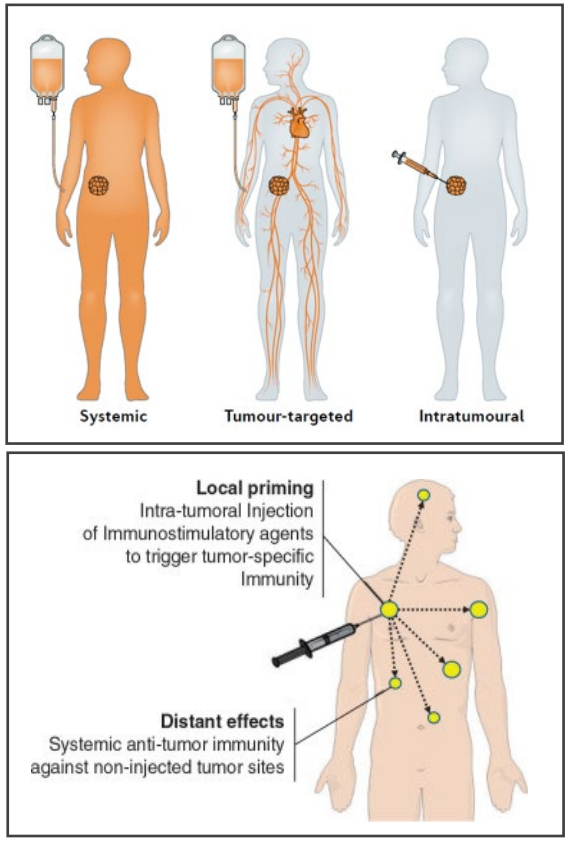


Demonstrated with a wide range of therapeutic modalities

Type of Molecules	Examples
Plasmids	
mRNA	
Oligonucleotides	siRNA, antisense oligos, peptide nucleic acids
Proteins	Toxins, immunotoxins, antibodies, antigens
Peptides	Antigens
Small molecules	Cancer drugs like bleomycin, gemcitabine, docetaxel, erlotinib
Viral gene therapy vectors	AAV, adenovirus

- **PCI unlocks the potential** of novel medicinal products, by modifying intracellular trafficking in target cells, leading to enhanced biological effects
- PCI triggers **endosomal escape** in response to illumination
- Fimaporfin is triggered by blue and red light, with different tissue penetration
- Improved cytosolic delivery may **enhance the therapeutic effect** of a **wide range of modalities**

Leveraging intratumoural immunotherapy to achieve a systemic anti-tumour immune response



Melero *et al.* 2021, Nat Rev Clin
Marabelle *et al.* 2017, Ann Oncol

Local enhancement technology

- PCI is a technology designed for local enhancement of therapeutic effects and is well-suited for delivery of immune stimulants to tumour sites

Intratumoural immunotherapy – excellent technological fit

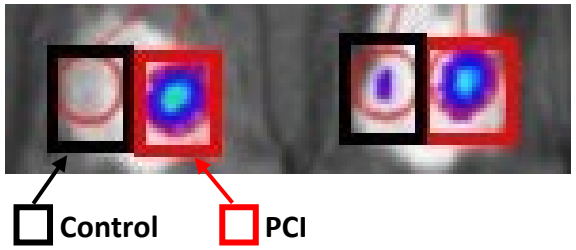
- Intratumoural treatment aims at exploiting patient's own tumour as a patient-specific therapeutic "cancer vaccine" and the treatment may include both immunostimulants and components that target immunosuppressive mechanisms. Treatment of one tumour lesion can induce specific immune response targeting other tumour lesions

Identifying novel treatment combinations

- PCI Biotech is exploring intratumoural immunotherapy by an industry PhD candidate grant supported by the Research Council of Norway (2023-2025), aiming at identifying novel treatment combinations to overcome resistance to immune-checkpoint inhibitors

Excellent technological fit with dermatological diseases

In vivo data



Skin imaging after intradermal injection of luciferase mRNA alone or with PCI

Unlocking the potential of innovative medicine

- Nucleic acid therapeutics have the potential to improve treatment of dermatological diseases

Local enhancement technology

- Delivery to skin remains an obstacle. This is a challenge PCI is uniquely positioned to solve, by achieving site-directed intracellular nucleic acid delivery
- *In vivo* data show that PCI can strongly enhance nucleic acid delivery in the skin

Collaborative approach

- Development is pursued by collaborations.

Investment Highlights

Broad innovation platform	Proprietary platform technology targeting rapidly growing markets
Pipeline opportunities	PCL solves challenges in viral vector manufacturing, in particular AAV PCI represents early-stage opportunities for local drug delivery
Compelling data	PCL has shown manufacturing benefits in AAV production PCI has been demonstrated with a broad range of drug modalities and tissue
Collaborative development strategy	A partnership-driven approach is pursued to leverage synergies with other technologies, as well as seek out-licensing opportunities
Strong leadership	Experienced team in drug discovery and product development

PCI Biotech

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