PCI Biotech

Improving manufacturing productivity to make AAV gene therapy more accessible

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April 2025

PCI Biotech

Agenda

- PCI Biotech in brief
- Challenge
- Solution
- Market
- Business model & Go-to-market
- Landscape
- Roadmap

PCI Biotech (OSE:PCIB)

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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			

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

Morten Luhr, PhD, CSO

- Chief Scientific Officer since 2025 (Business Development Manager 2021-2024)
- Previously Senior Scientist in Thermo Fisher Scientific, developing bioprocessing technologies

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

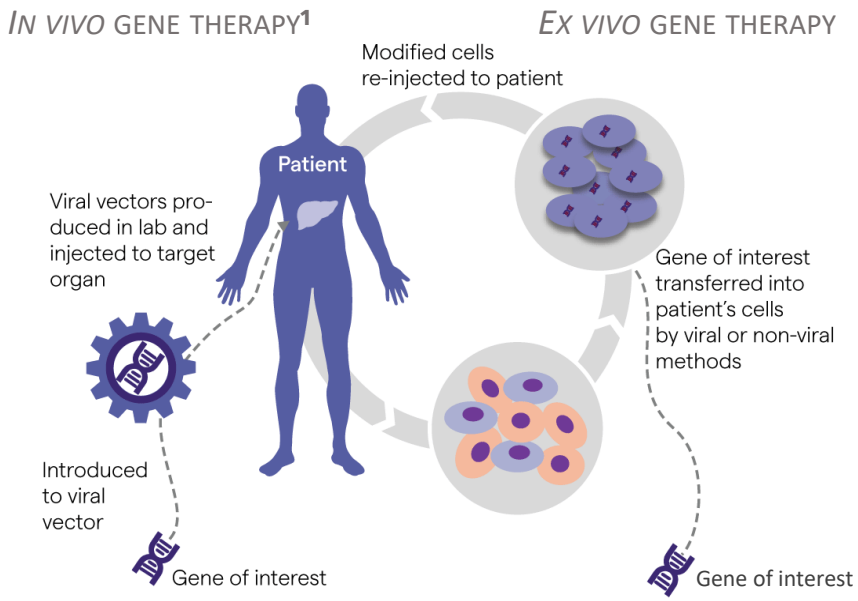
- 35+ years international experience from sales, marketing, strategy and management in pharma and biotech industry
- Most recently European Head of Rare Diseases for Sanofi Genzyme
- Board member of Bio-Me, Sedana Medical, Herantis, and Pluvia Biotech

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

Gene therapy

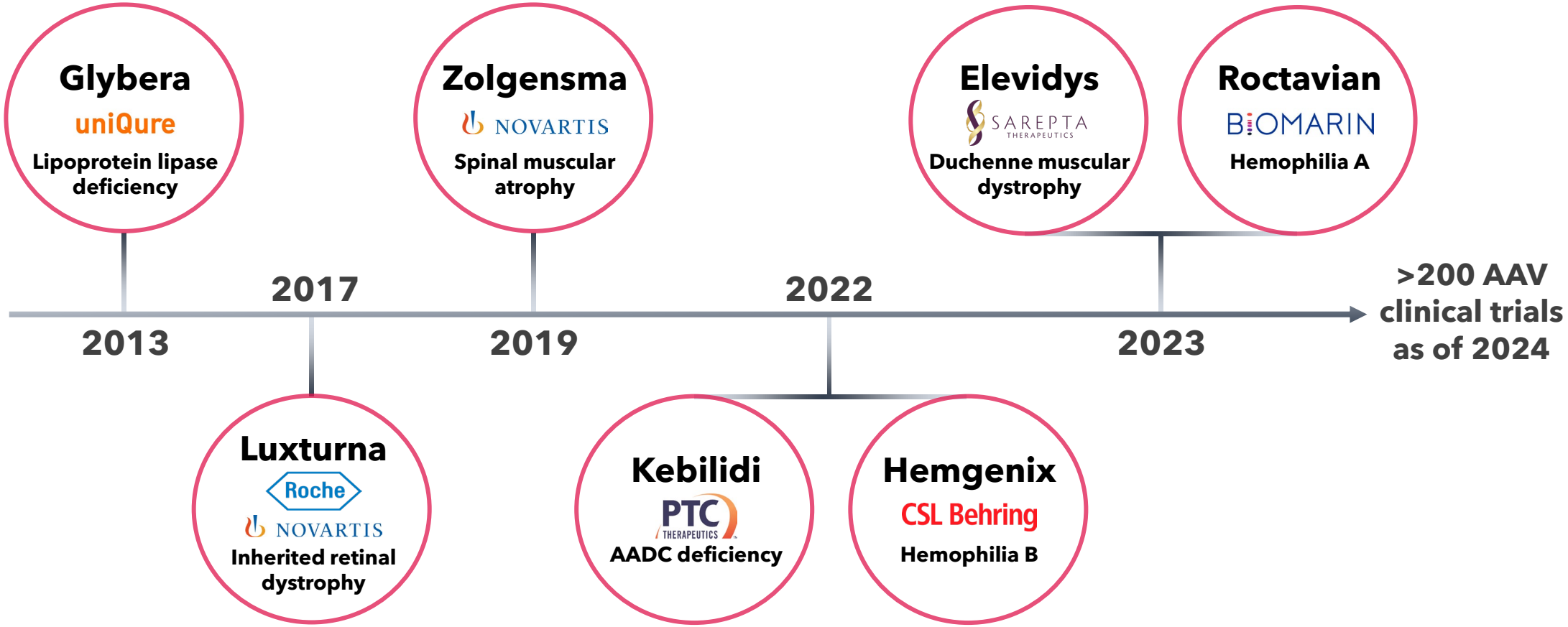
Advanced medicinal products with groundbreaking potential



- 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

Approved AAV (*in vivo*) gene therapies[1]



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

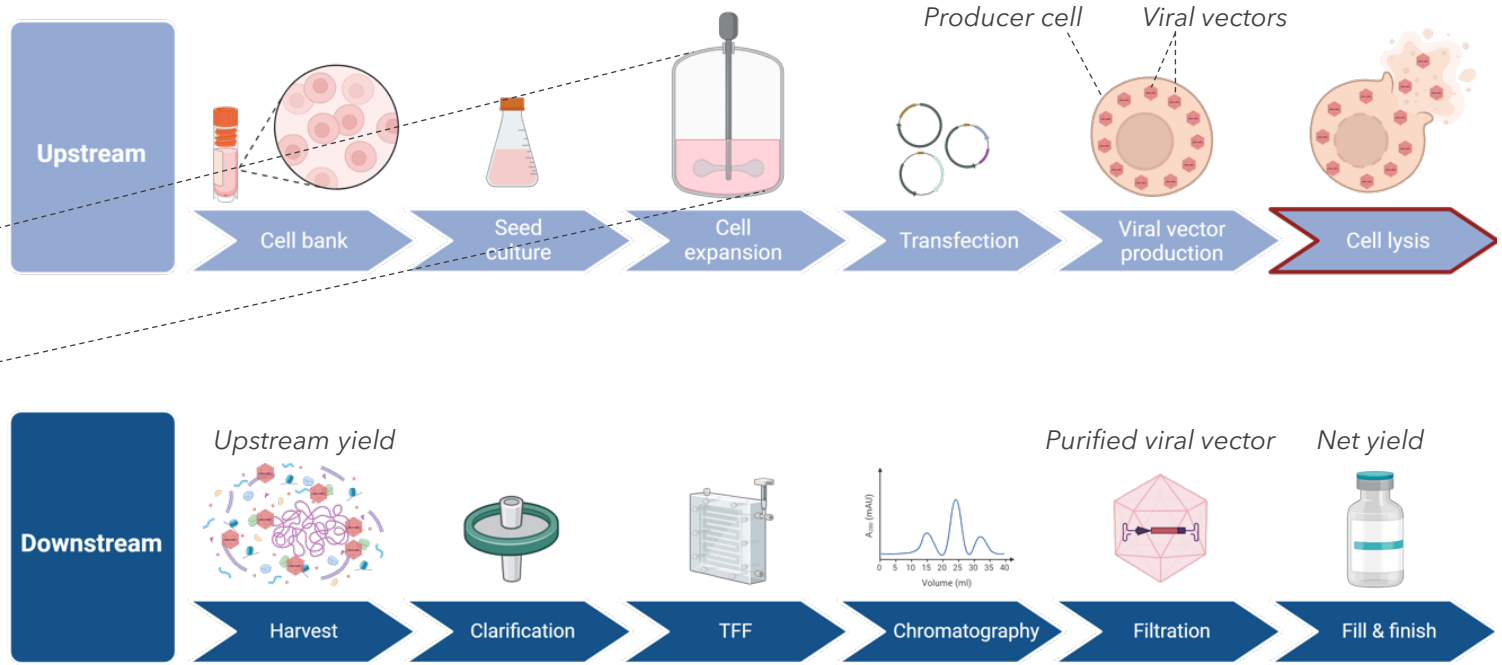
Approved AAV (*in vivo*) gene therapies

	Zolgensma (spinal muscular atrophy)	Luxturna (inherited retinal dystrophy)
	 1	 2
Cause	Mutation in the SMN1 gene	Mutation in the RPE65 gene
Symptoms	Severe motor disability, patients with SMA type 1 have life expectancy of <2 years unless on breathing support	Severe vision loss from young age, most become blind by age 20
Treatment effect	Improves motor abilities, prolongs survival	Luxturna improves vision
Patient population	Small (rare disease)	Small (rare disease)

More efficient manufacturing is needed to make AAV gene therapies available to larger patient populations

1. Charles Njuguna, 2. Spark Therapeutics/Roche

AAV manufacturing: resource-demanding and inefficient



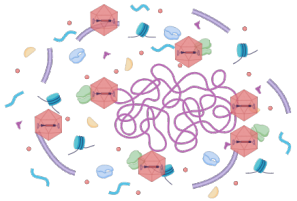
Manufacturing challenges for viral vectors include **host-cell impurities** and **low viral vector yield** from cell lysis, and up to **>70% loss of AAV material** in downstream

Voice of customer: What are “Midstream” pain points in AAV manufacturing?

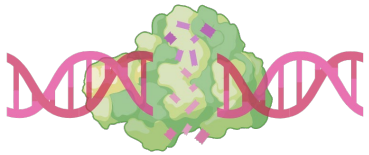
- We interviewed Pharma, CDMOs, and technology providers to understand pain points in AAV manufacturing
- The focus was on “Midstream”, as we consider this an overlooked area for innovation

Here are our key findings:

Ineffective cell lysis is a cause of low USP yield



Host-cell impurities contribute to poor DSP recovery

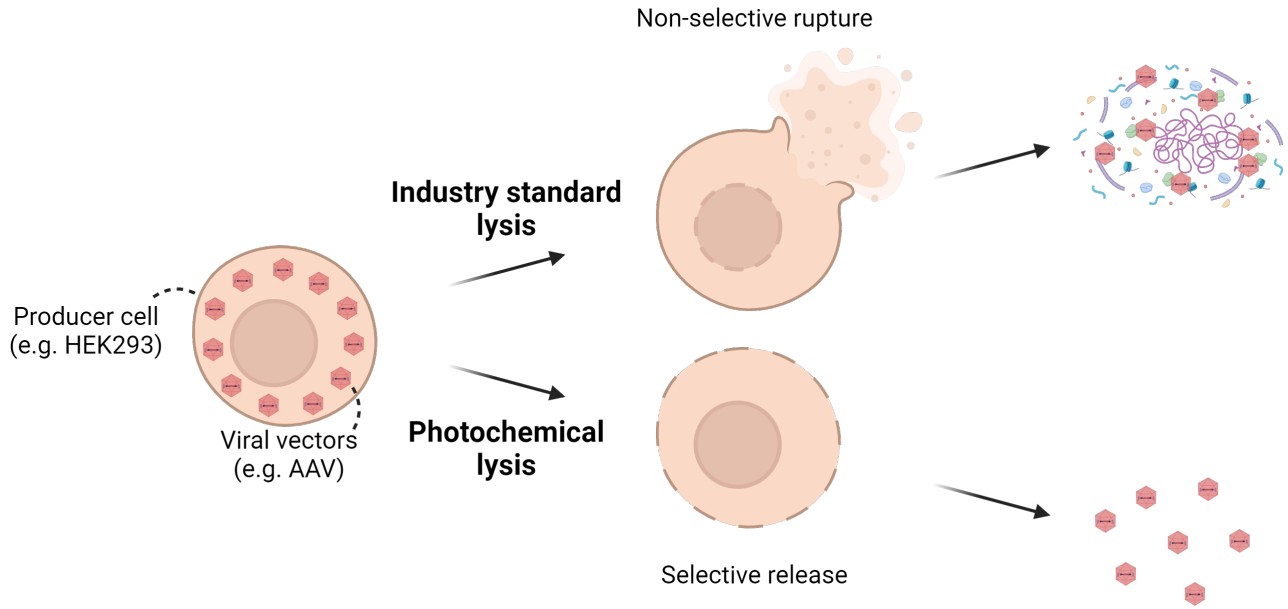


DNase for host-cell DNA removal is expensive

Takehome message:

- All agree that increased batch yields and reduction in host-cell impurities is positive
- New technologies should enable 10-50% batch yield improvements to be attractive
- New reagents must be GMP quality, be removed in DSP, have a QC assay, and not reduce AAV potency

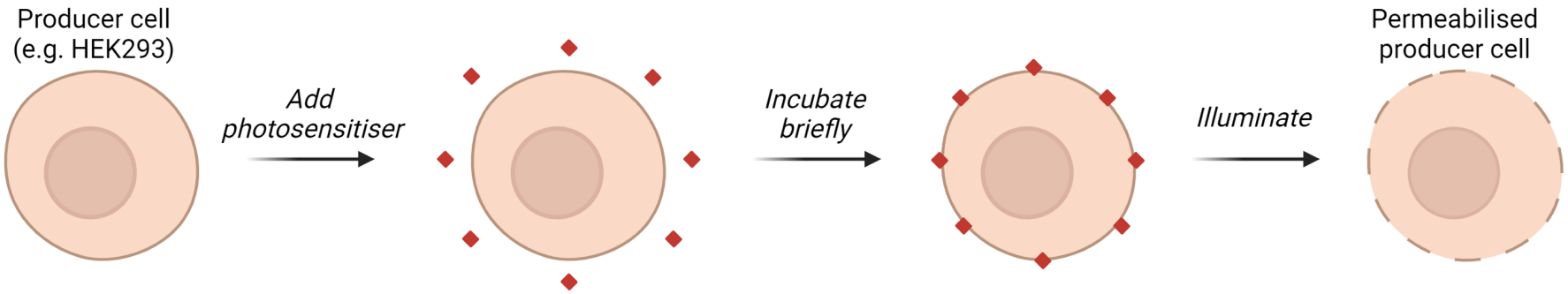
Photochemical lysis (PCL) - next generation viral vector extraction (lysis)



PCL **selectively and potently releases viral vectors from producer cells** with reduced host-cell impurities compared with the industry standard

This novel technology, developed by PCI Biotech, has the potential to **increase AAV batch yields,** thereby **improving manufacturing** productivity

Mechanism of action



PCL procedure*

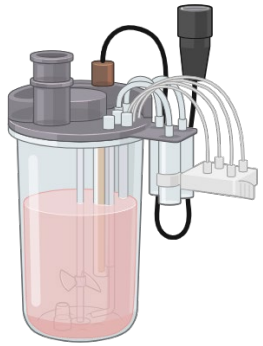
1. The amphiphilic photosensitiser is added to the cell culture (e.g. HEK293 suspension cells at the end of AAV production)
2. Following a brief incubation, the photosensitiser is localised to the plasma membrane
3. Upon illumination, a photochemical reaction is triggered, which disrupts the plasma membrane

When performed at the end of AAV production, PCL can be utilised to potently release AAV from producer cells

***PCI Biotech has a broad patent pending for use of PCL in viral vector manufacturing

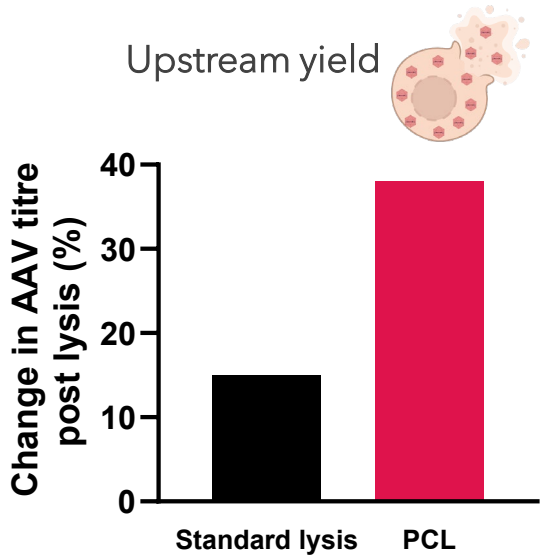
R&D milestones: outperforming industry standard on upstream yield and host-cell impurities

AAV production vessel

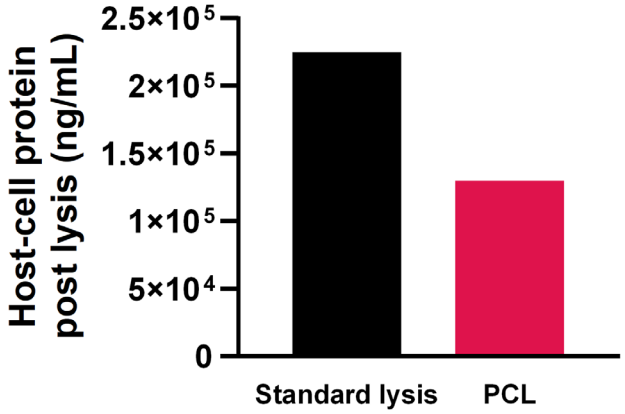


Mini benchtop bioreactor

Upstream yield



Upstream impurities



Run details: AAV was produced in mini benchtop bioreactor, followed by AAV extraction by industry standard lysis or PCL. The best PCL condition outperformed industry standard on both upstream AAV yield and host-cell impurities, exemplified by host-cell protein.

Based on these results, PCL is considered compatible with mini benchtop bioreactor, which are representative of large-scale (commercial) manufacturing

External feedback

PCL could be a market disruptive technology

Senior executive in an international bioprocessing group

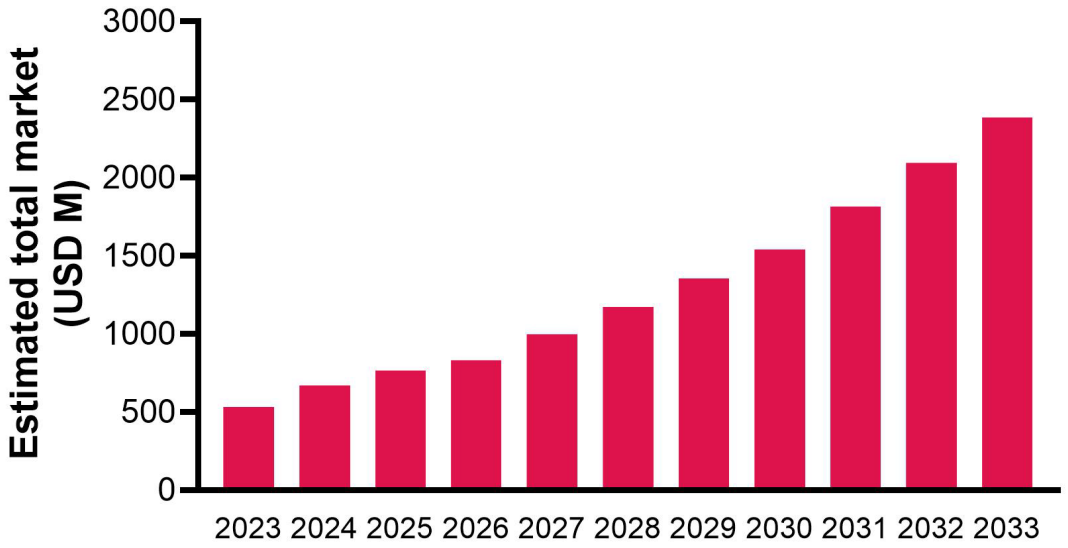
PCL is very exciting and unique

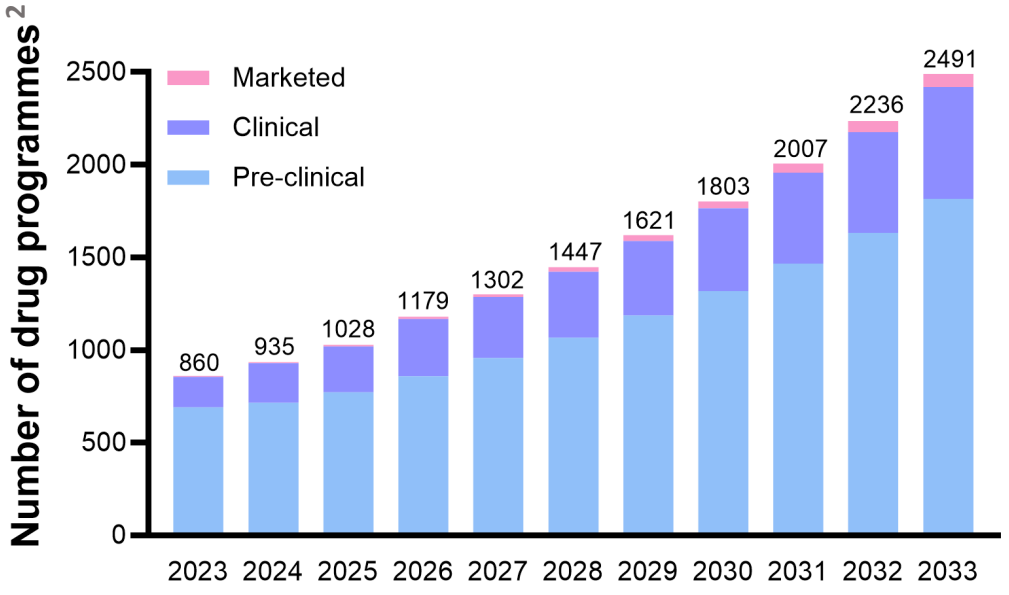
Leading bioprocess technology and service provider

PCL is a good substitute for industry standard lysis

PCL field tester

AAV manufacturing market[1]

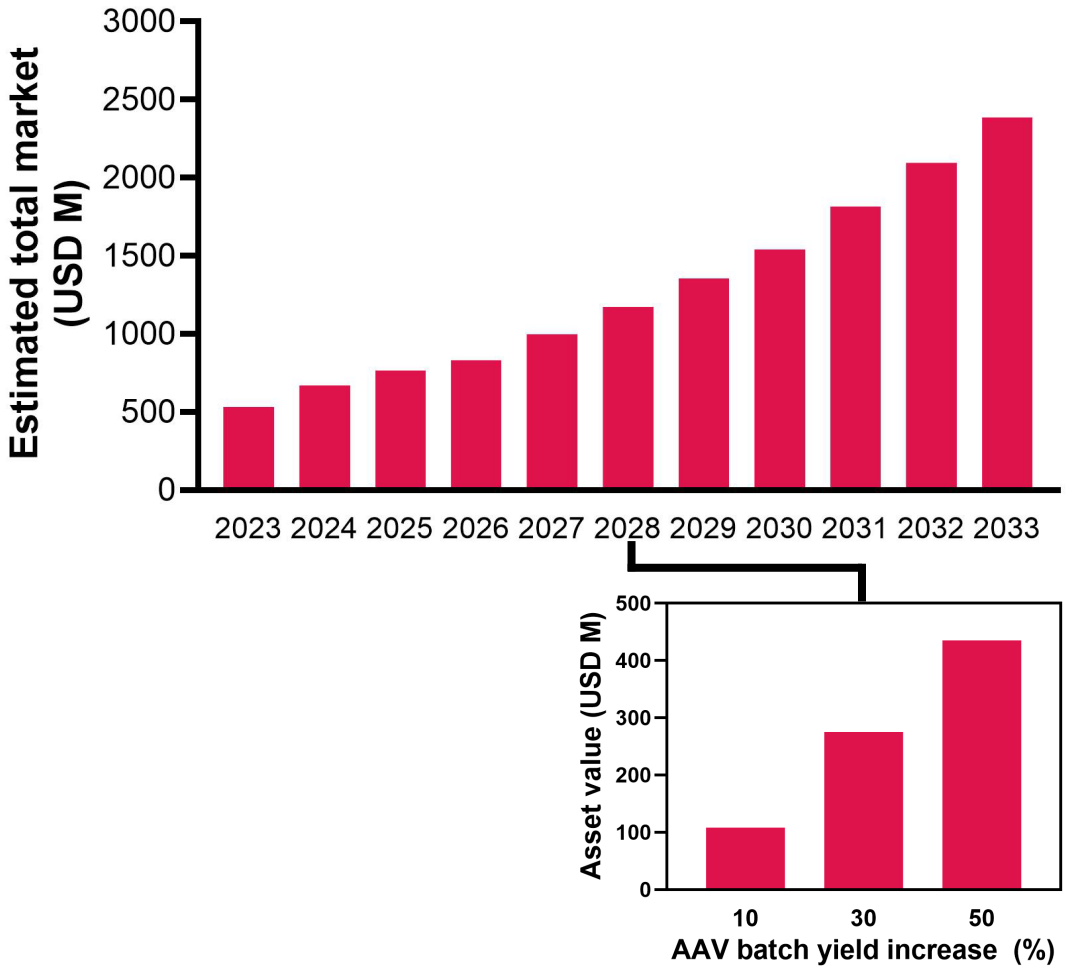




The manufacturing market is driven by development and success of AAV therapies

1. External market assessment
2. Source: GlobalData

Asset value potential[1]



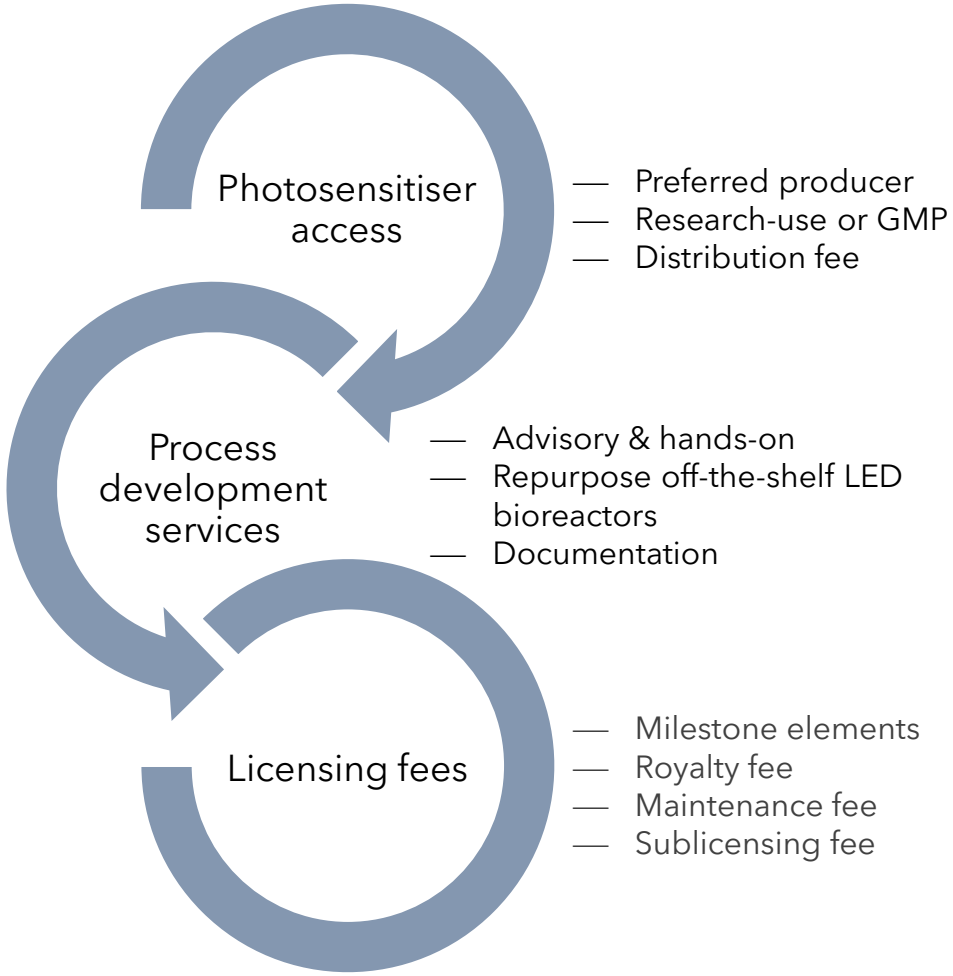
PCL may increase AAV batch yield

This improves manufacturing productivity, a highly sought-after feature

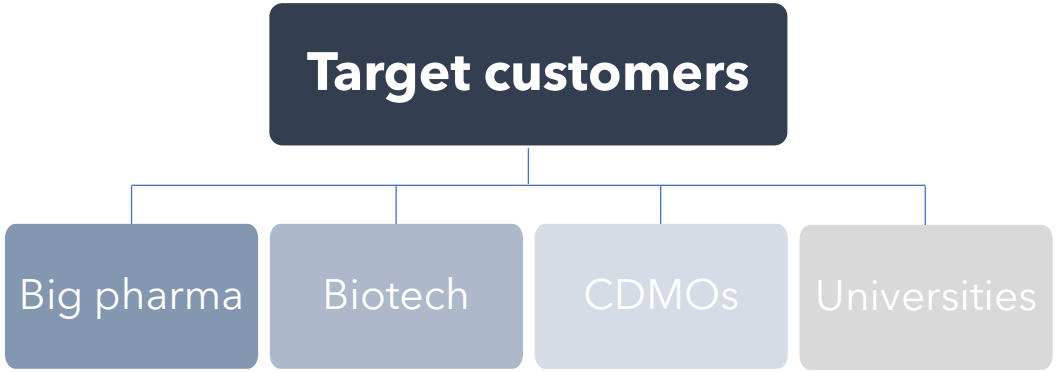
Improvement in batch yield's impact on PCL asset value is exemplified for 2028

1. External market assessment

Business model



Go-to-market



Key geographies are USA and Europe

Competitive landscape

- PCL may improve both upstream and downstream processing

Upstream processing

MERCK = MILLIPORE SIGMA

BASF We create chemistry

CRODA Pharma

PanReac AppliChem ITW Reagents

ArcticZymes Technologies

Downstream processing

ThermoFisher SCIENTIFIC

SARTORIUS

cytiva

MILLIPORE SIGMA

With no equivalent from competitors, PCL is positioned as a potentially disruptive technology

Roadmap: Accelerating the path to commercial manufacturing

Feasibility

Prototype & Research-Use

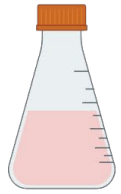
Clinical & Commercial

✓ Compatible with downstream processes

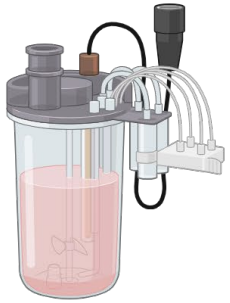
✓ Demonstrated upstream scalability

⧗ Increased *net* AAV yield

Plate
(0.5-1 mL)



Shake-flask
(20 mL)



Mini benchtop bioreactor
(250 mL)

Bioreactor
(50-2000 L)

2022

Proof of concept
adherent cells (upstream)

2023

Suspension cells and scale-up
(upstream)

2024 – Present

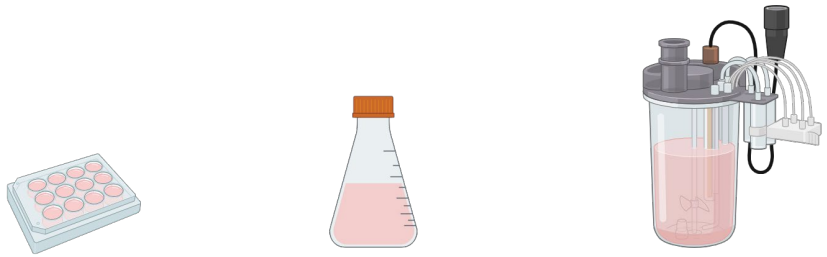
Downstream purification,
end-product testing,
larger-volume illumination

Funding-/collaboration-dependent

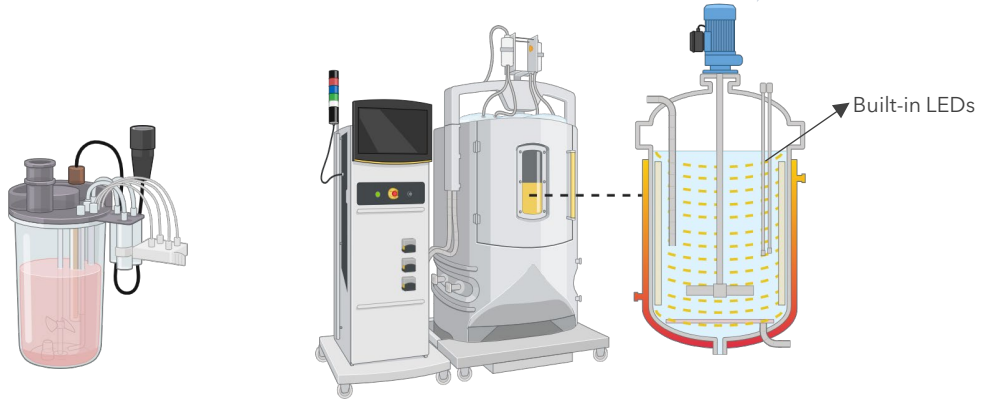
Pilot scale, production scale,
off-the-shelf LED bioreactor

Roadmap: Accelerating the path to commercial manufacturing

500x during 2022-2025



50x 2-year plan



- 500x scale-up of PCL and adaptation to suspension cells has been achieved
- There are 50 L (and larger) off-the-shelf LED bioreactors suitable for AAV manufacturing
- Scale-up to 50 L bioreactor would demonstrate compatibility with commercial equipment
- We aim to be ready for the research market in 2H 2025, followed by a 2-year plan to make PCL ready for commercial manufacturing

Investment Highlights

Compelling market	AAV gene therapy is a rapidly growing market in need of novel technologies
Disruptive technology	PCL shall increase productivity in AAV manufacturing, a highly sought-after feature
Compelling data	PCL has shown manufacturing benefits in AAV production and been scaled to small bioreactor, representative of large-scale manufacturing
Early market entry	PCL can be ready for the R&D market in <1 year and commercial AAV manufacturing in approximately 2 years
Lean organisation	A small organisation enables cost-effective and agile development

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