



PRELIMINARY
2024
INTERIM REPORT

PCI Biotech - Preliminary full-year 2024 Interim Report

Presentation February 27, 2025

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- ▶ Morten Luhr, CSO

PCI Biotech

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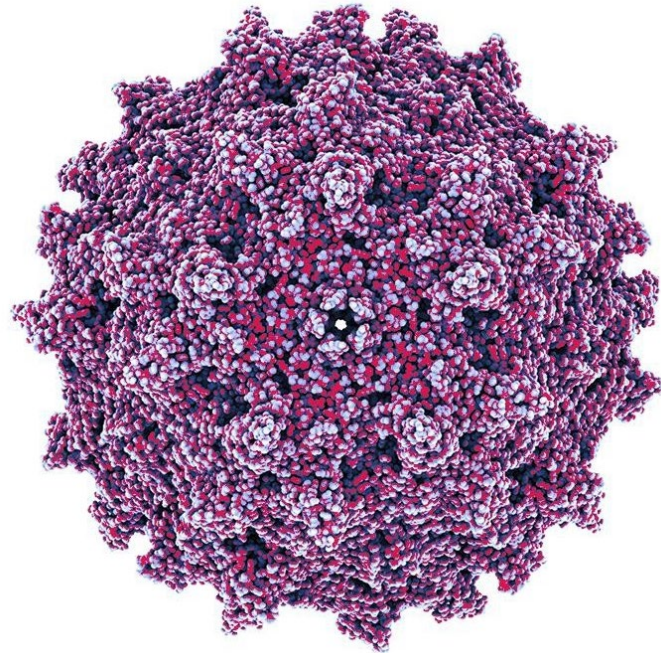


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Bioprocessing



GENE THERAPY – ADVANCED MEDICINAL PRODUCTS WITH GROUNDBREAKING POTENTIAL



Improving manufacturing productivity to make AAV gene therapy more accessible

2024

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GENE THERAPY – ADVANCED MEDICINAL PRODUCTS WITH GROUNDBREAKING POTENTIAL

Luxturna

(inherited retinal dystrophy)



Image: Charles Njuguna

Cause	Mutation in the RPE65 gene
Symptoms	Severe vision loss from young age, most become blind by age 20
Treatment effect	Luxturna improves vision
Patient population	Small (rare disease)

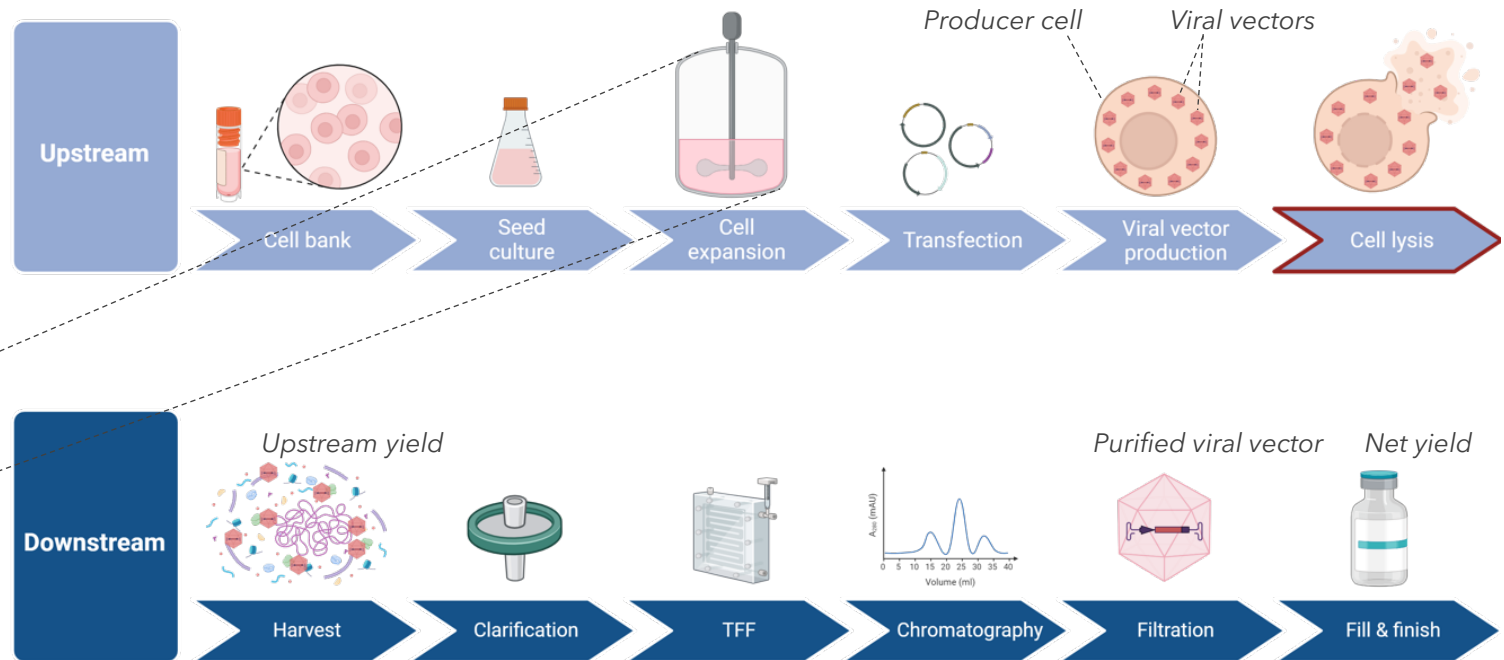
More efficient manufacturing is needed to make AAV gene therapies available to larger patient populations

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AAV MANUFACTURING: RESOURCE-DEMANDING AND INEFFICIENT



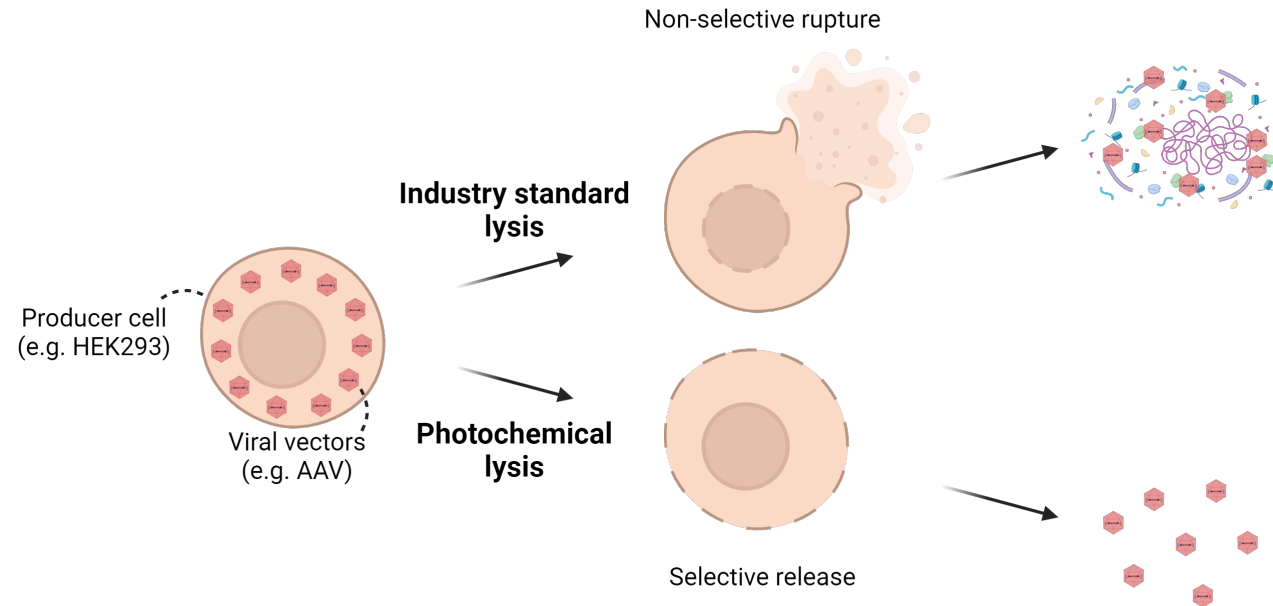
Manufacturing challenges for viral vectors include **host-cell impurities** and **low viral vector yield** from cell lysis, and up to **>70% loss of AAV material** in downstream

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PHOTOCHEMICAL LYSIS (PCL) - NEXT GENERATION VIRAL VECTOR EXTRACTION (LYSIS)



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

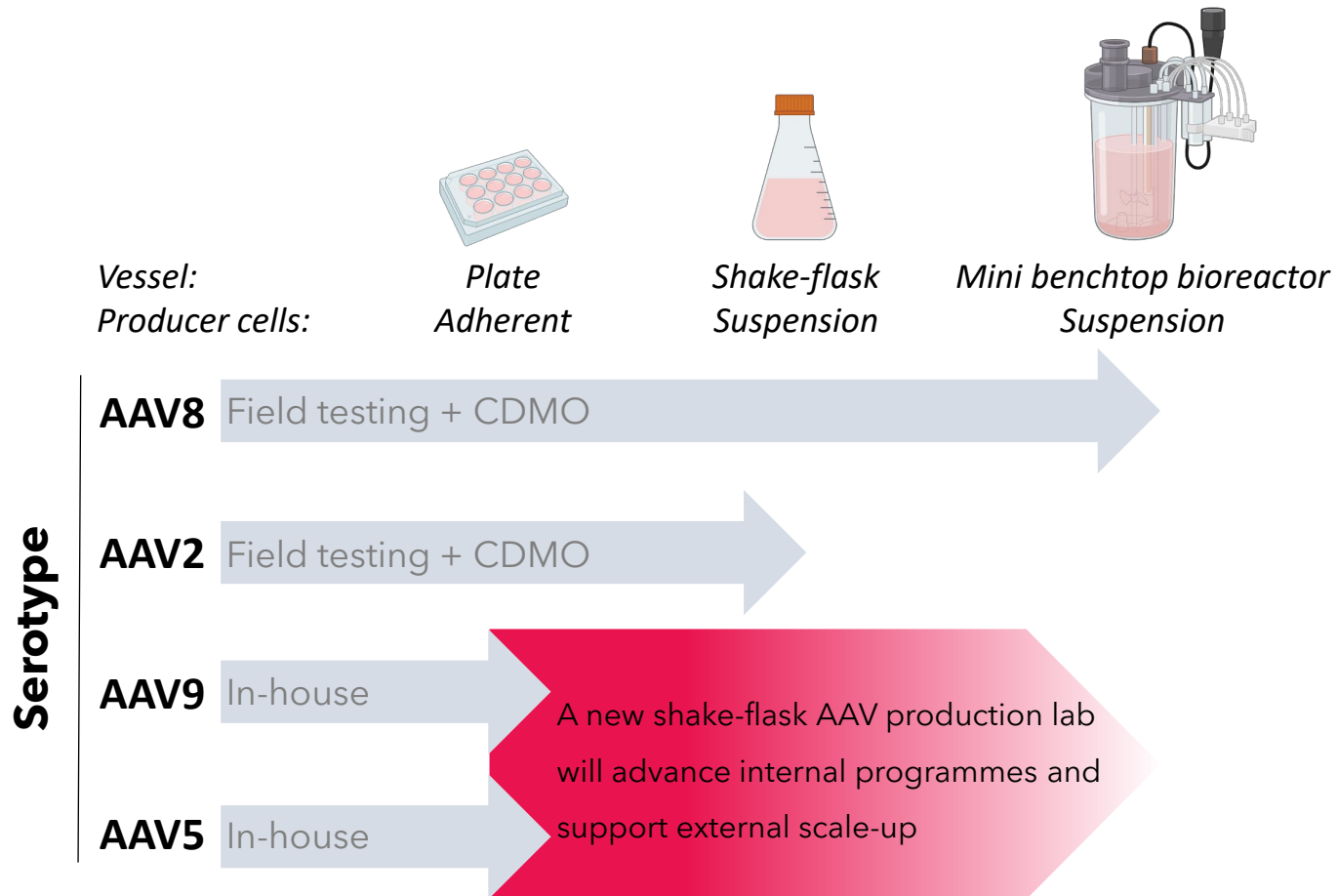
This novel technology, developed by PCI Biotech, has the potential to **increase AAV batch yields**, thereby **improving manufacturing** productivity

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DEVELOPING A BROADLY APPLICABLE TECHNOLOGY



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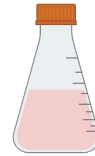


R&D MILESTONES

Vessel:
Producer cells:



Plate
Adherent



Shake-flask
Suspension



Mini benchtop bioreactor
Suspension

● Important progress has been made in mini benchtop bioreactor in 2024, with results indicating:

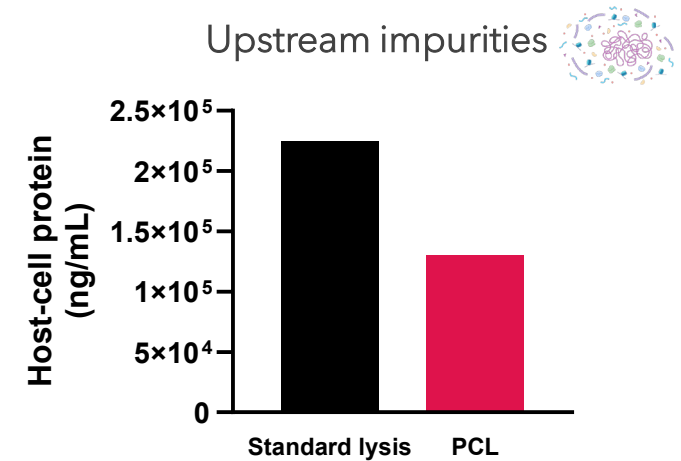
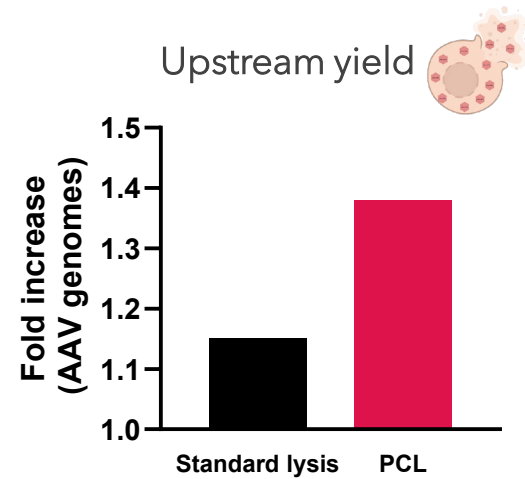
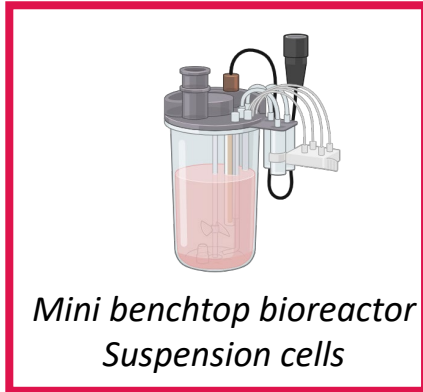
- ▷ Photosensitiser is cleared in downstream processing of AAV
- ▷ Photosensitiser has no negative impact on viral vector (AAV) functionality
- ▷ PCL matches or increases *upstream* yield with reduced host-cell impurities

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R&D MILESTONES



- PCL enhanced upstream yield compared with standard lysis, with reduced host-cell impurities
- PCL's scalability is considered demonstrated by these encouraging upstream results
- Net yield after initial downstream processing was inconclusive, attributed to variability and technical issues in downstream processing
- New bioreactor runs aim to reproduce the positive upstream results, and translate this into increased net yield by utilising a downstream process with lower variability
- This is expected to translate to increased net manufacturing yield after downstream processing, a highly sought-after feature by the industry

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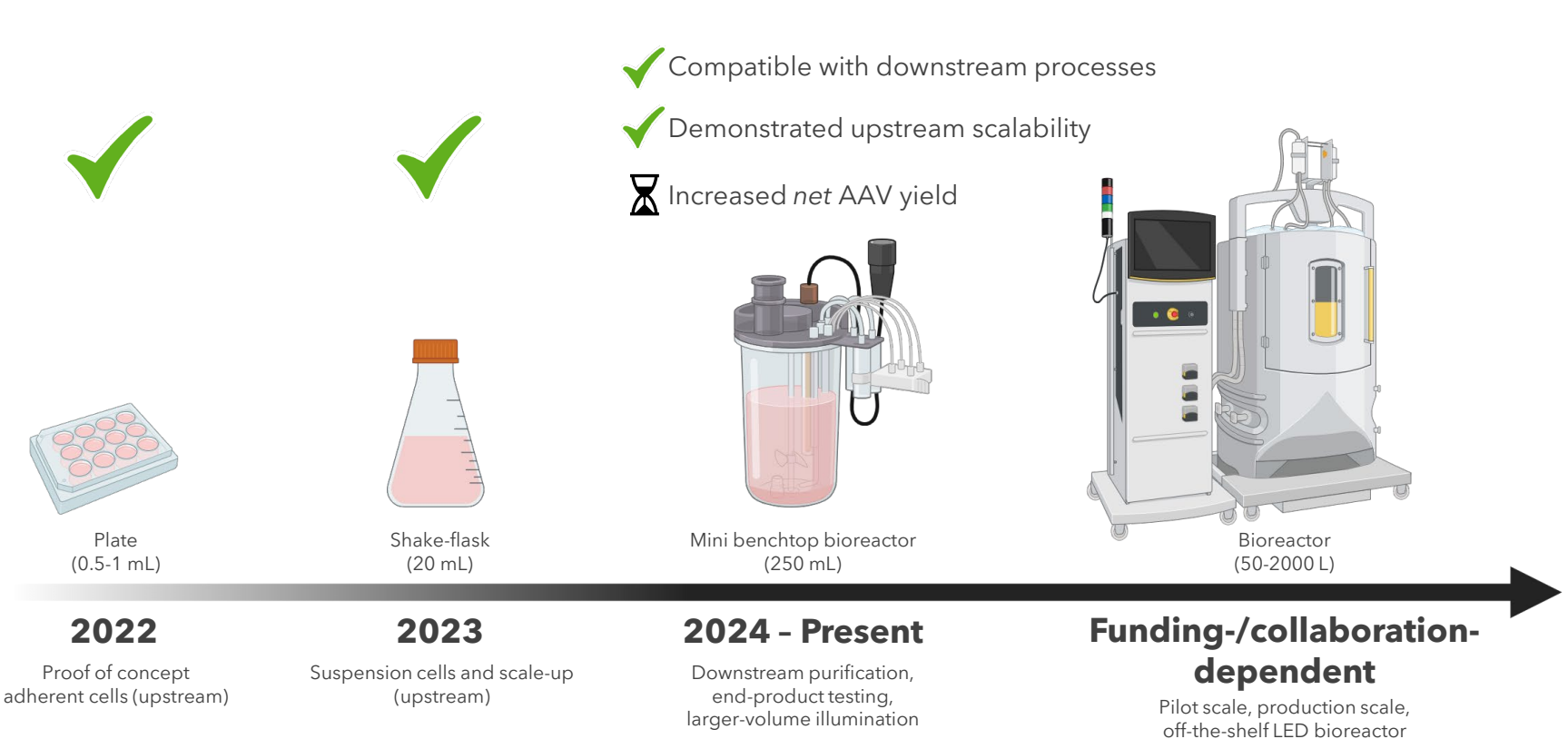


ROADMAP: ACCELERATING THE PATH TO COMMERCIAL MANUFACTURING

Feasibility

Prototype & Research-Use

Clinical & Commercial



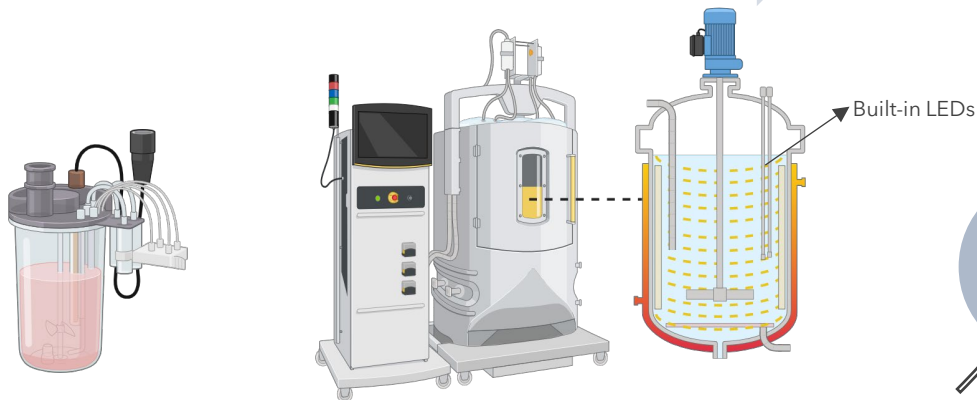
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ROADMAP: ACCELERATING THE PATH TO COMMERCIAL MANUFACTURING

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



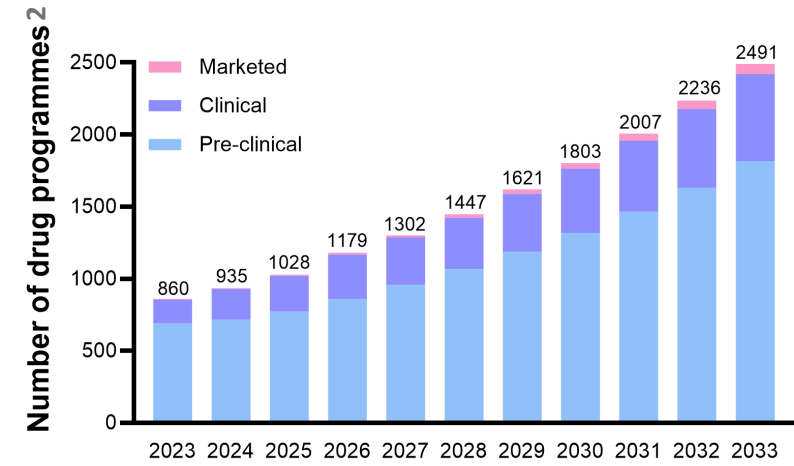
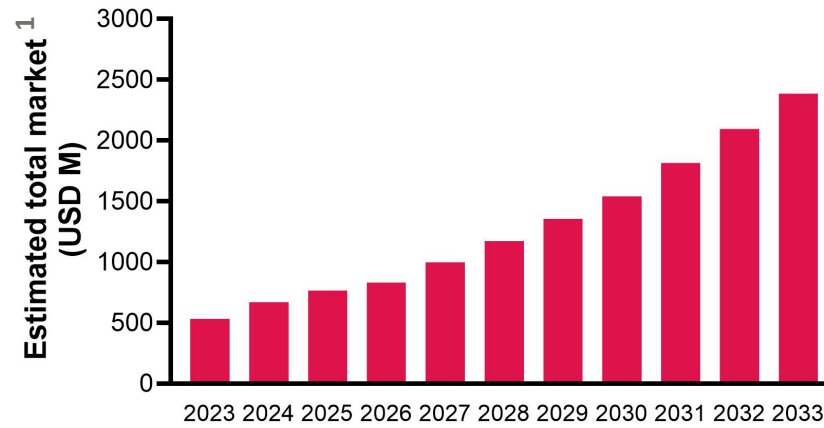
We aim to be ready for the research market in 2H 2025, followed by a 2-year plan to make PCL ready for commercial manufacturing

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THE AAV MANUFACTURING MARKET



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

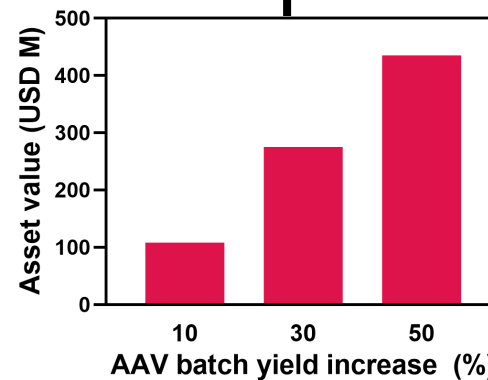
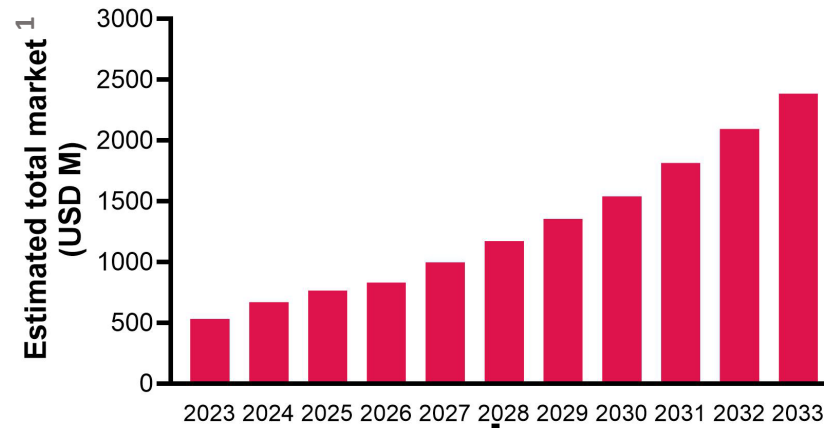
1. External market assessment
2. Source: GlobalData

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THE AAV MANUFACTURING MARKET



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

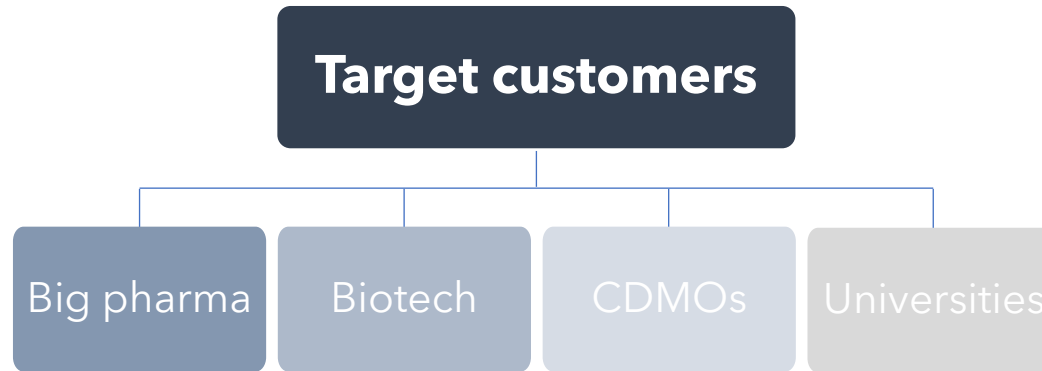
1. External market assessment

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TARGET CUSTOMERS AND COLLABORATORS



Key geographies are USA and Europe

Upcoming meetings



1. External market assessment

Key financials

Outlook

Q&A

Finance

FY 2024

Key financial figures

- ▶ **Focus on securing financing for continued development**
 - ▶ Cash position estimated to support operations into Q4 2025
 - ▶ Opportunity window to demonstrate the commercial potential in mini benchtop bioreactor
- ▶ **Key figures 2024**
 - ▶ Cash at NOK 27m per year-end
 - ▶ Increased public grant level

<i>(figures in NOK 1 000)</i>	FY 2024	FY 2023
Other income (public grants)	6 735	2 990
Operating results	-17 955	-22 241
Net financial result	1 538	1 926
Net profit/loss	-16 417	-20 315

<i>(figures in NOK 1 000)</i>	FY 2024	FY 2023
Cash & cash equivalents	27 069	41 184
Cash flow from operating activities	-13 758	-14 970

Outlook

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Goals

Advancing manufacturing of gene therapies

- Complete early-stage field testing ✓
- Demonstrate technology in commercially representative model: *Upstream* ✓
- Ready for late-stage field testing in 2H 2025 ⌚

IR

New investor presentation and “one-pager” will be available online

Agenda

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

Disrupting Gene Therapy Manufacturing with Photochemical Lysis (PCL)

PCI Biotech is a small cap biotechnology company based on the Cellxion and Cytocine 2024 CDMO. The company focuses on developing and manufacturing of advanced therapies.

The challenge
The AAV enabled gene therapy is one of the most exciting advances in medical medicine, offering potential to cure genetic diseases. These manufacturing challenges, among production efficiency, lower cost, and shorter timelines, are a major obstacle to the widespread use of gene therapy. A major challenge is the low productivity of the current manufacturing processes. The 20% of total gene therapy material is lost during production, leaving only 80% available for the cells that produce them. The industry is looking for solutions to increase the productivity of the manufacturing process, to reduce the cost of production and increase the number of patients that can be treated. The result is lower costs, higher yields, and shorter patient wait times.

The solution
PCI Biotech has developed a novel cell-free manufacturing process, PCL, that uses a light-activated photochemical reaction to produce AAVs. This process is highly efficient, scalable, and easy to implement. It offers a significant improvement in productivity, reducing waste and simplifying downstream processing. The result is higher yields and lower manufacturing costs.

Market size
The global gene therapy market is projected to reach \$1.5 billion by 2025, with a CAGR of 15%. The market is currently dominated by AAV gene therapy, which accounts for 80% of the total market. The market is expected to grow significantly over the next five years, driven by the increasing number of gene therapy products in development and the growing awareness of the benefits of gene therapy.

Improving manufacturing productivity to make AAV gene therapy more accessible



**Enabling
advanced
therapies**

PCI Biotech

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