



FIRST HALF-YEAR
2024
INTERIM REPORT

PCI Biotech - First half-year 2024 Interim Report

Presentation August 28, 2024

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- ▶ Morten Luhr, BD Manager

PCI Biotech

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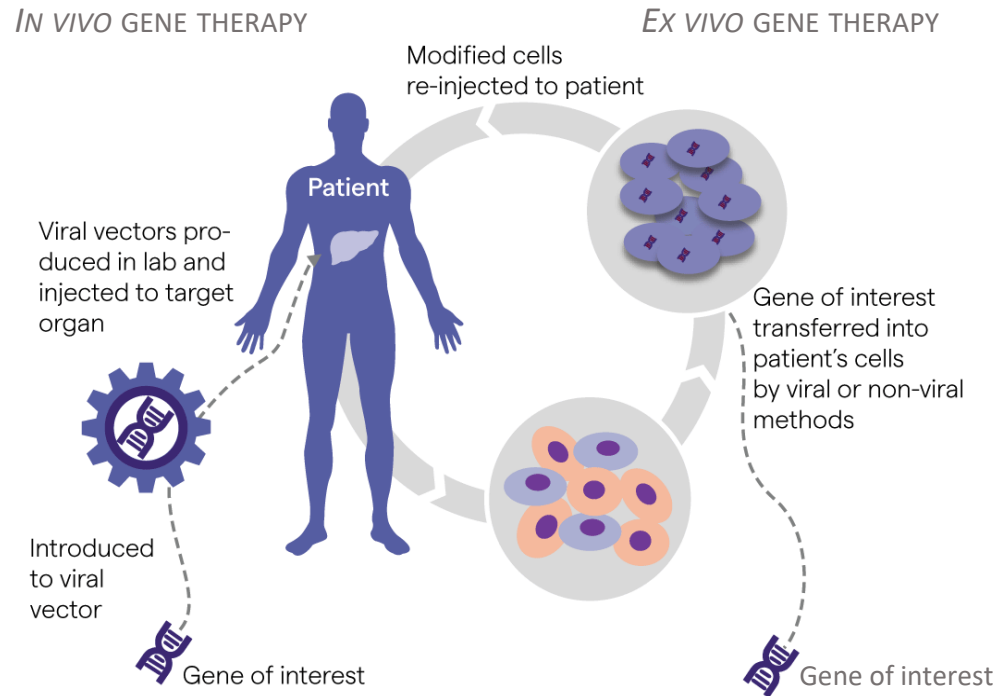


1H 2024

Bioprocessing



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^{1,2}
- ▶ *In vivo* gene therapies utilise viruses (“viral vectors”) to deliver genetic medicines
- ▶ Improved manufacturing is needed to make gene therapies more available

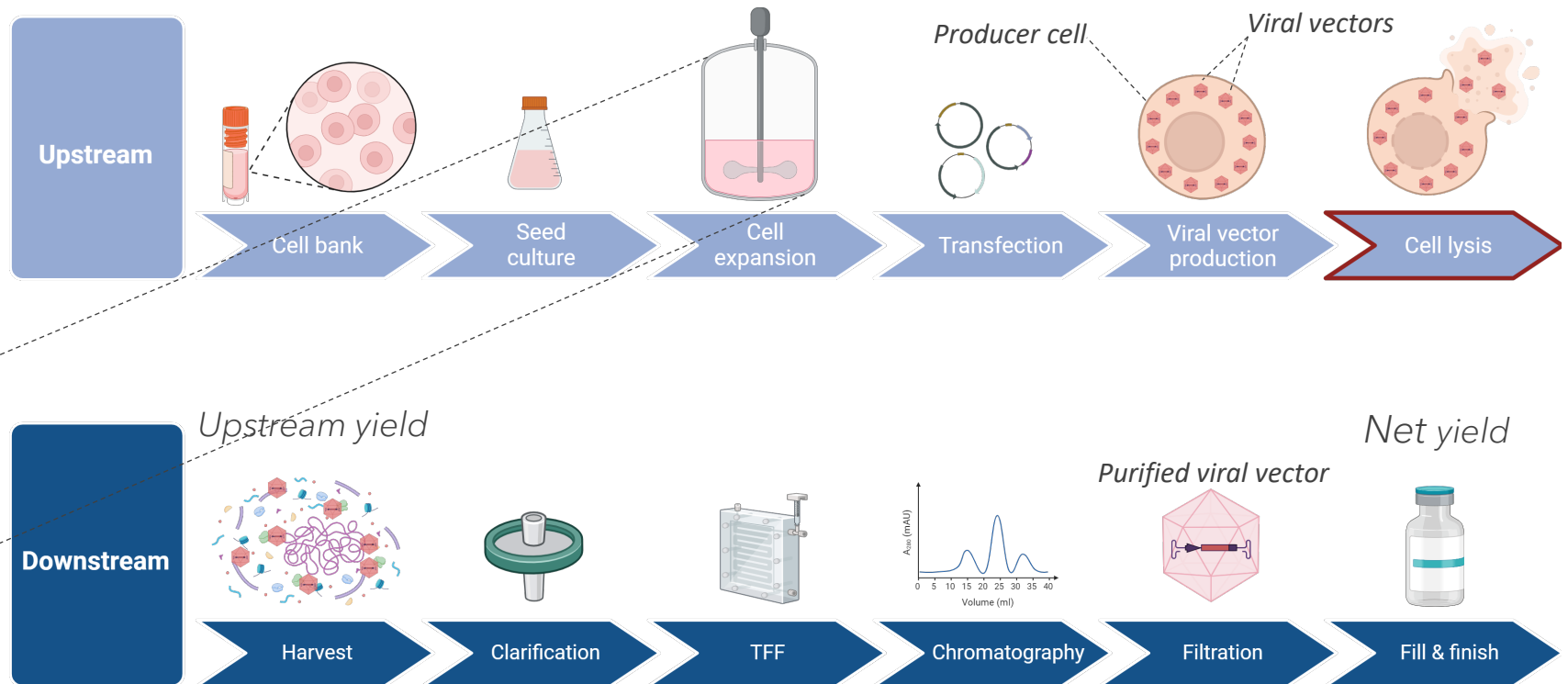
1. Mendell *et al.* 2017, NEJM, 377(18):1713-1722
2. Mendell *et al.* 2021, JAMA Neurology, 78(7):834-841

1H 2024

Bioprocessing



VIRAL VECTOR MANUFACTURING - UTILISING CELLS AS “GENE THERAPY FACTORIES”



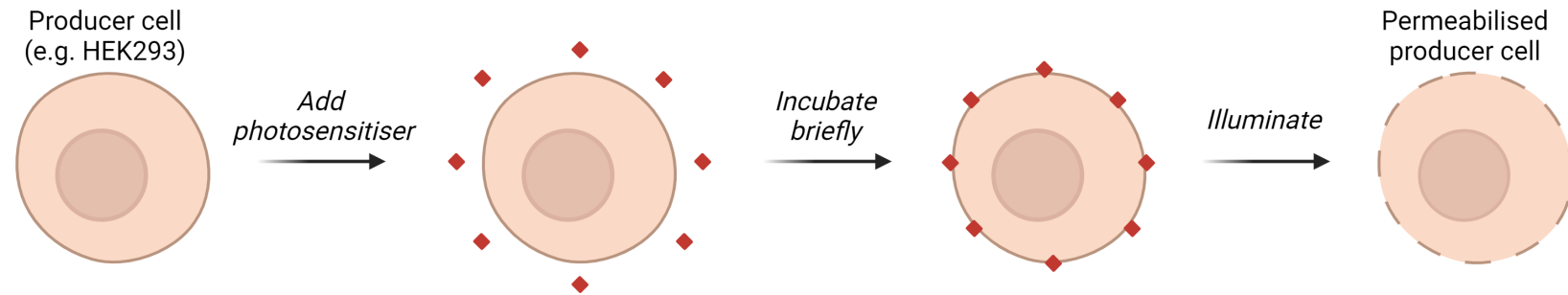
Manufacturing challenges for viral vectors include host-cell impurities (e.g. DNA and protein) and low viral vector yield from cell lysis

1H 2024

Bioprocessing



PHOTOCHEMICAL LYSIS (PCL) - NEXT GENERATION VIRAL VECTOR EXTRACTION



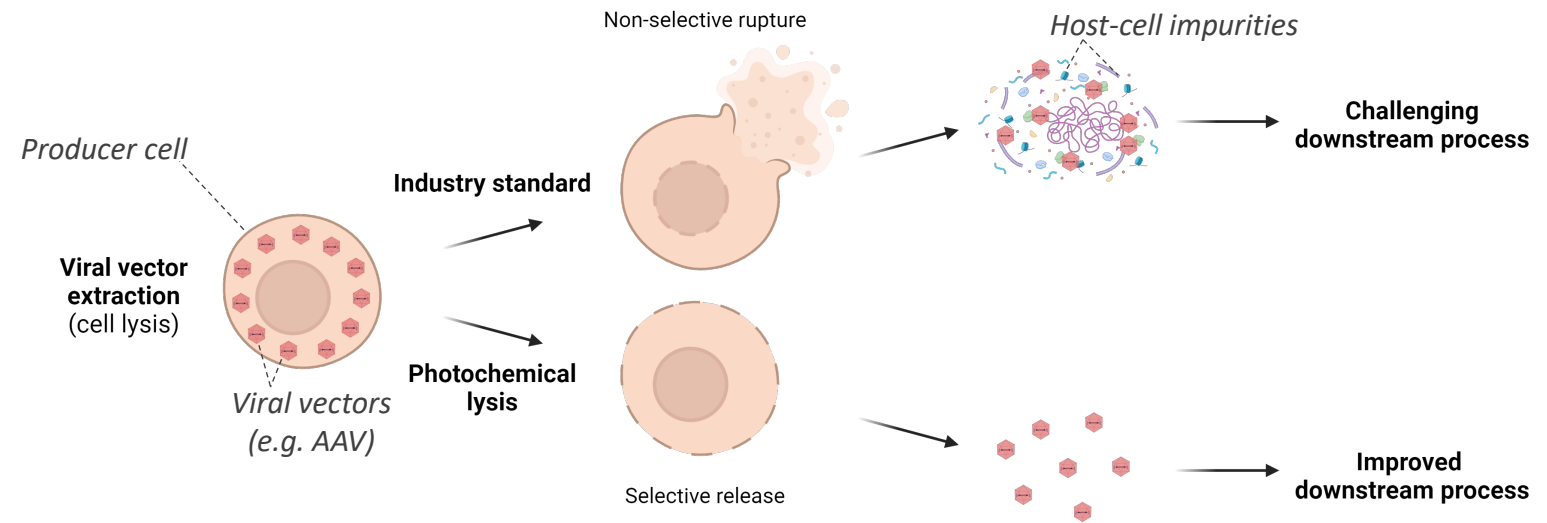
- PCI Biotech develops a novel technology - photochemical lysis (PCL) - to address technical needs in viral vector manufacturing
- Photochemical lysis **selectively releases viral vectors from producer cells** with reduced host-cell impurities compared with the industry standard

1H 2024

Bioprocessing



PHOTOCHEMICAL LYSIS (PCL) - NEXT GENERATION VIRAL VECTOR EXTRACTION



Viral vector extraction	Mode of action	Net viral vector yield	Host-cell impurities
Industry standard	Non-selective	Moderate	High
Photochemical lysis <i>potential</i>	Selective	High	Low

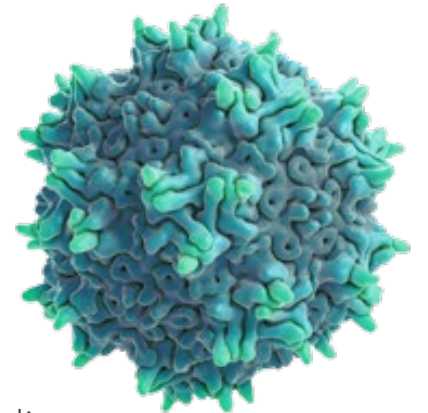
1H 2024

Bioprocessing



R&D MILESTONES

- Received encouraging feedback from the international search report on the PCL patent application
- Alpha testing with undisclosed partner was completed with positive feedback, supporting further development of the PCL technology 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
- Important progress has been made in mini benchtop bioreactor, with initial results 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 in mini benchtop bioreactor



1H 2024

Bioprocessing



THE PATH FROM FEASIBILITY TESTS TO COMMERCIAL MANUFACTURING

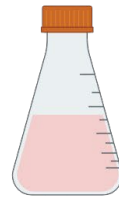
Feasibility

Prototype

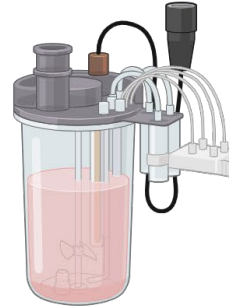
Commercial



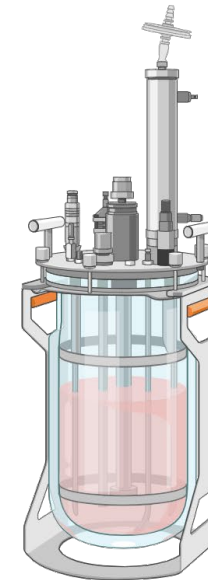
Plate
(0.5-1 mL)



Shake-flask
(20 mL)



Mini benchtop bioreactor
(250 mL)



Benchtop bioreactor
(1-10 L)



Bioreactor
(50-500 L)

2022

Proof of concept
adherent cells
(upstream)

2023

Suspension cells and
scale-up (upstream)

2024

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

Partner-dependent

Further scale-up,
process development

Partner-dependent

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

Key financials

Outlook

Q&A

Finance

1H 2024

Key financial figures

- ▶ Cash position estimated to support operations into 2H 2025
 - ▶ Cash position per end June 2024 at NOK 30 million
 - ▶ Net change in cash of NOK -15 million in last twelve months and for calendar year 2023
 - ▶ New public grant for 2024, up to NOK 3.5 m by Innovation Norway for bioprocess

<i>(figures in NOK 1 000)</i>	1H 2024	1H 2023	FY 2023
Other income (public grants)	3 426	417	2 990
Operating results	-8 259	-12 705	-22 241
Net financial result	857	900	1 926
Net profit/loss	-7 402	-11 805	-20 315

<i>(figures in NOK 1 000)</i>	1H 2024	1H 2023	FY 2023
Cash & cash equivalents	30 536	45 578	41 184
Cash flow from operating activities	-10 470	-10 848	-14 970

Outlook

Bioprocessing

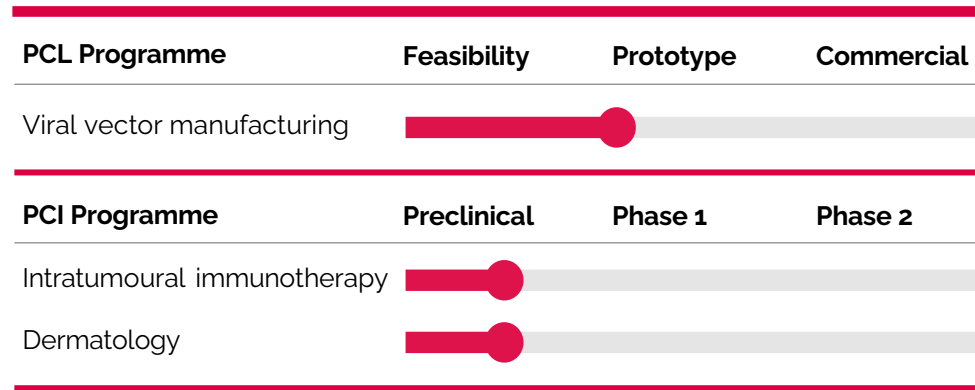


Advancing manufacturing of gene therapies

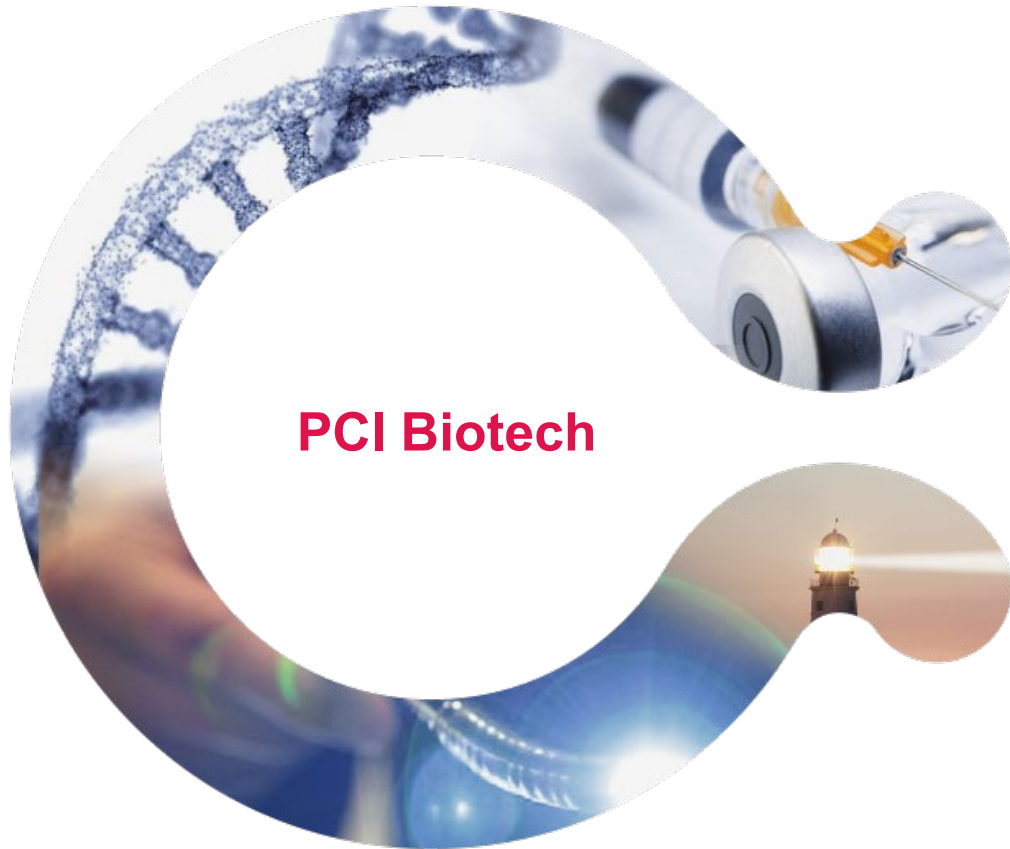
2024 Goals

- Complete early-stage field testing ✓
- Demonstrate technology in commercially representative model ⌚
- Ready for late-stage field testing in 2025

Pipeline



Laying the ground for partnership-driven development



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