

PRELIMINARY
2023
INTERIM REPORT



PCI Biotech - Preliminary full year 2023 Interim Report

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PCI Biotech

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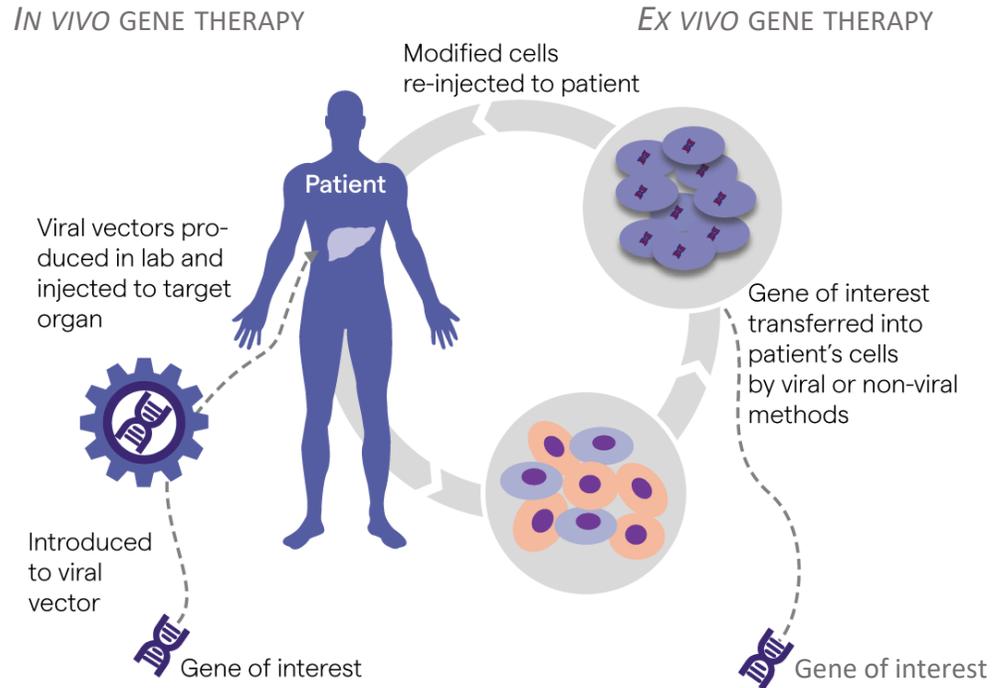
Highlights

GENE THERAPY – ADVANCED MEDICINAL PRODUCTS WITH GROUNDBREAKING POTENTIAL

2H 2023

fimaNAC

Bioprocessing



- ▶ 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

Highlights

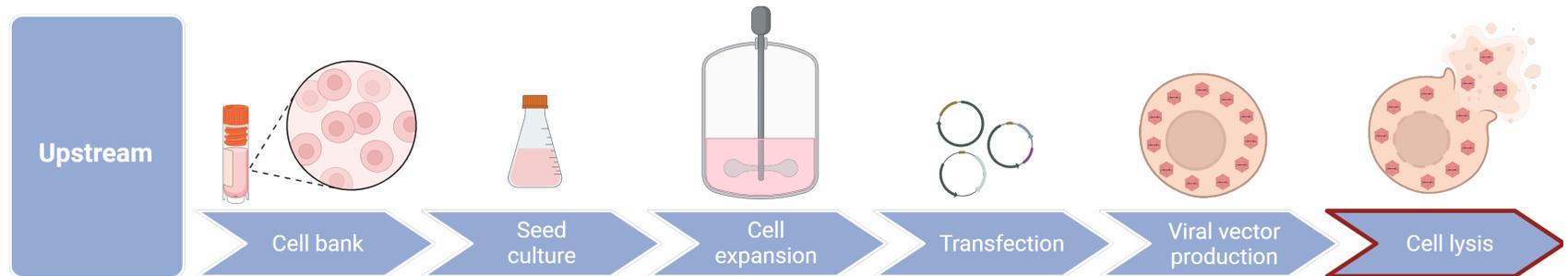
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VIRAL VECTOR MANUFACTURING - UTILISING CELLS AS “GENE THERAPY FACTORIES”



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

Highlights

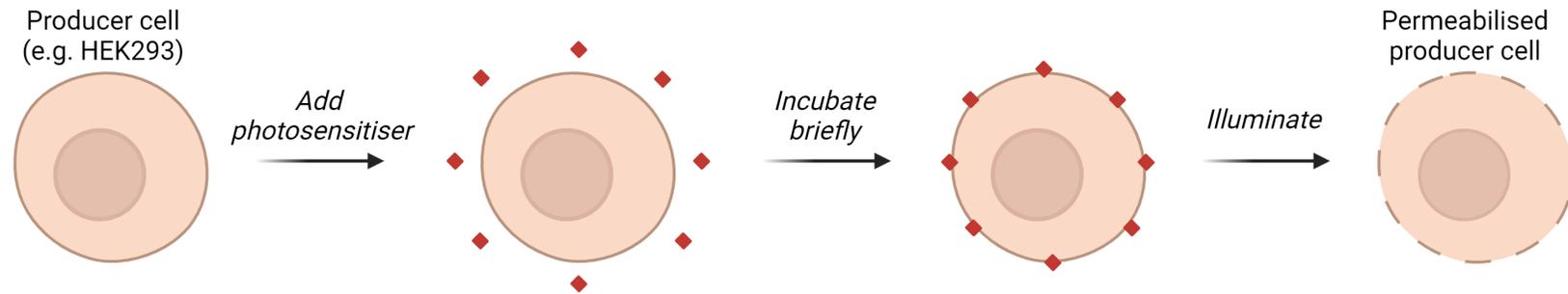
2H 2023

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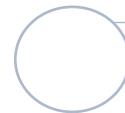
Bioprocessing



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

Highlights

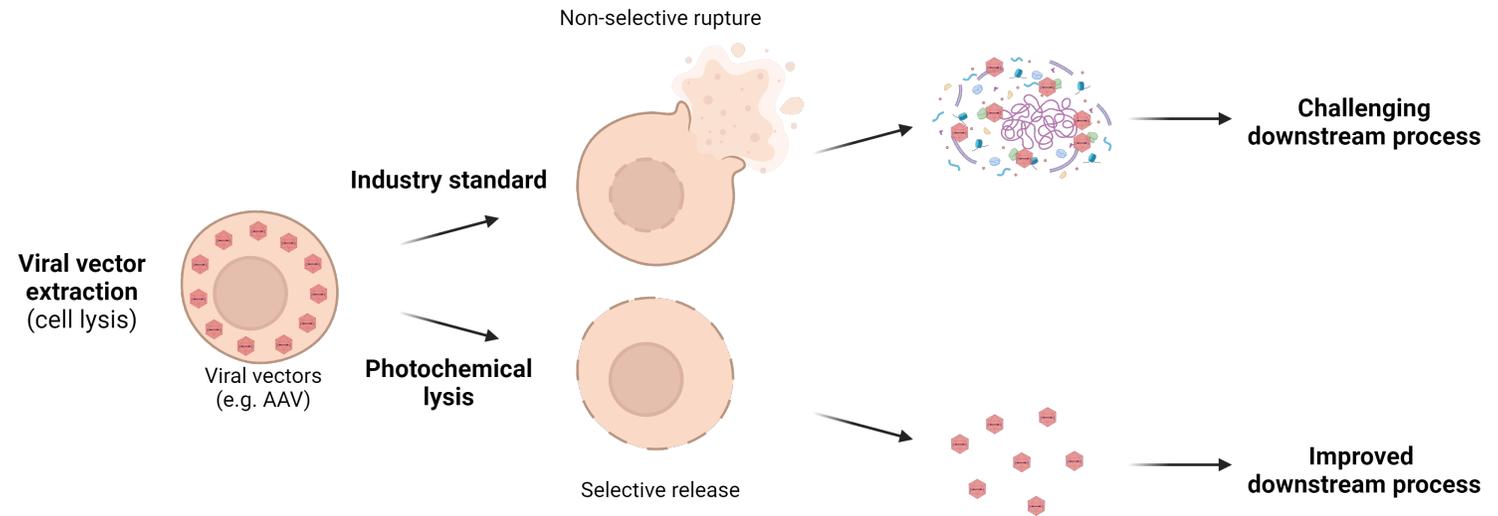
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PHOTOCHEMICAL LYSIS (PCL) - NEXT GENERATION VIRAL VECTOR EXTRACTION



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

Highlights

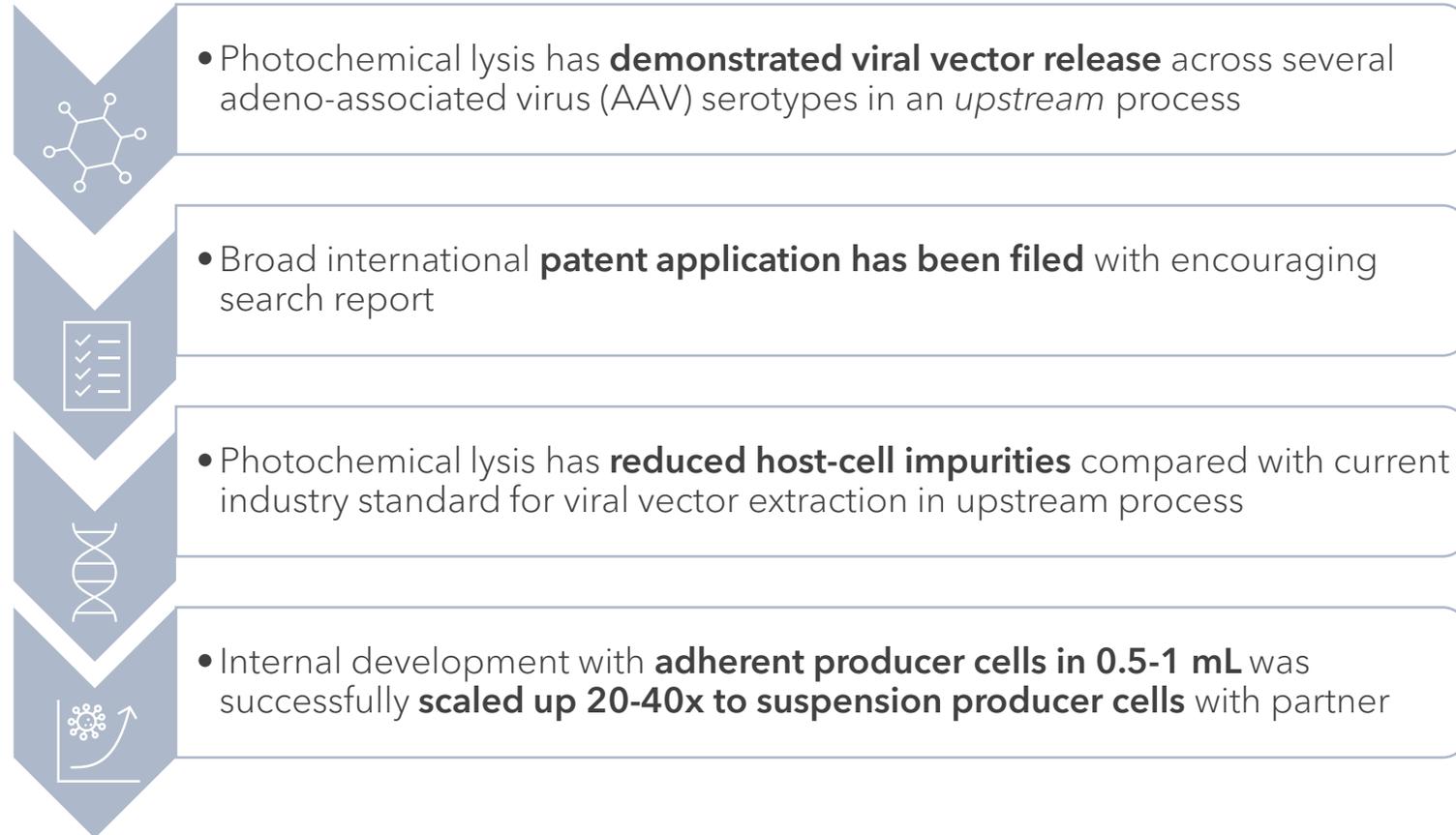
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IMPORTANT R&D MILESTONES



Highlights

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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

PCI Biotech ultra scale-down AAV model

- Adherent producer cells
- 2D culture
- 0.5 - 1 mL volume

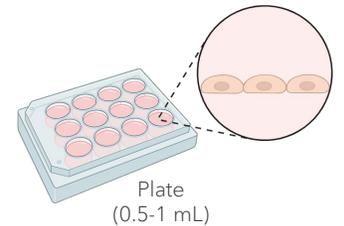
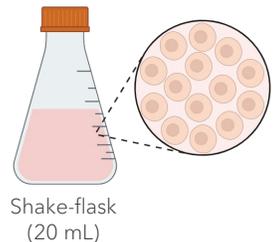


Plate
(0.5-1 mL)

Tester’s AAV upstream process

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



Shake-flask
(20 mL)

Highlights

2H 2023

THE PATH FROM FEASIBILITY TESTS TO COMMERCIAL MANUFACTURING

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Bioprocessing



Feasibility

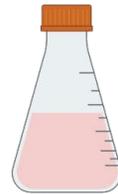
Prototype

Commercial



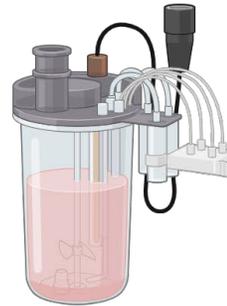
Plate
(0.5-1 mL)

2022
Proof of concept
adherent cells
(upstream)



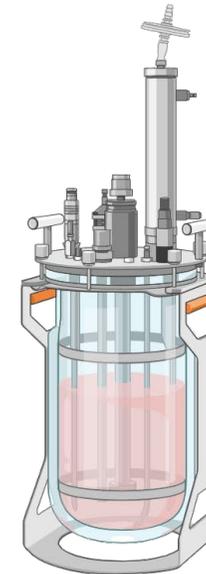
Shake-flask
(20 mL)

2023
Suspension cells and
scale-up (upstream)



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



Bioreactor
(50-500 L)

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

Highlights

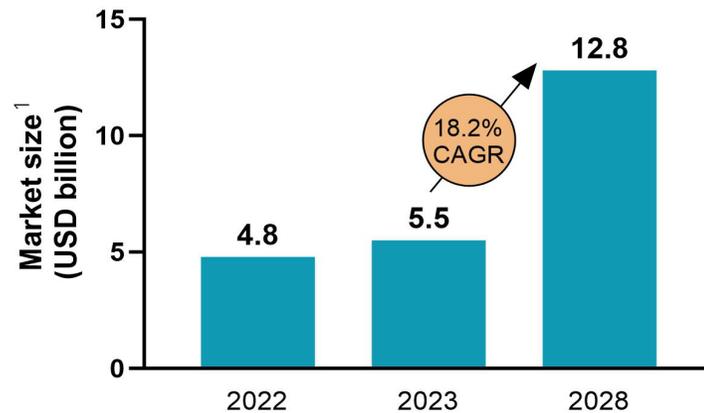
2H 2023

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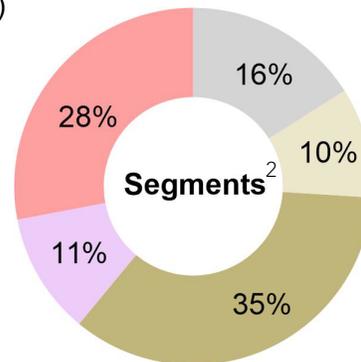
Bioprocessing



THE VIRAL VECTOR MANUFACTURING MARKET



- Adeno-associated virus (AAV)
- Adenovirus (AV)
- Lentivirus
- Other virus
- Plasmid



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
- ▶ **Photochemical lysis** primarily targets manufacturing of non-enveloped viral vectors, such as AAV and AV

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

Highlights

2H 2023

Corporate

- ▶ **Estimated financial runway**
 - Cash position of NOK 41 million supports operations into 2025, with current plans
 - Opportunity window to demonstrate commercial potential of the platform
 - Continue to explore financing and strategic opportunities
- ▶ **2024 focus areas**
 - Continue to advance **fimaNAc** as an enabling technology for gene therapy manufacturing
 - The dermatology opportunity pursued by collaborations
 - Exploration of innovative immunotherapy treatment combinations with **fimaVacc**

Key financials

Outlook

Q&A

Finance

2H 2023

Key financial figures

- ▶ **Cash position estimated to support operations into 2025**
 - ▶ Year-end cash position at NOK 41 million
 - ▶ Net change in cash of NOK -15 million during 2023
 - ▶ Public grants reduced based on R&D cost reductions
 - ▶ The 2022 restructuring makes comparison of figures not relevant

<i>(figures in NOK 1 000)</i>	2H 2023	FY 2023	FY 2022
Other income (public grants)	2 573	2 990	4 750
Operating results	-9 536	-22 241	-56 447
Net financial result	1 026	1 926	1 352
Net profit/loss	-8 510	-20 315	-55 095

<i>(figures in NOK 1 000)</i>	2H 2023	FY 2023	FY 2022
Cash & cash equivalents	41 184	41 184	56 596
Cash flow from operating activities	-4 224	-15 072	-59 042

Outlook

Leveraging the technology platform within bioprocessing, dermatology, and immunotherapy

Milestones

Bioprocessing



2023 Achievements

- ✓ IP broadened for all programmes
- ✓ Data from ultra scale-down model attracted industry interest
- ✓ Initiated early-stage field testing with international partner

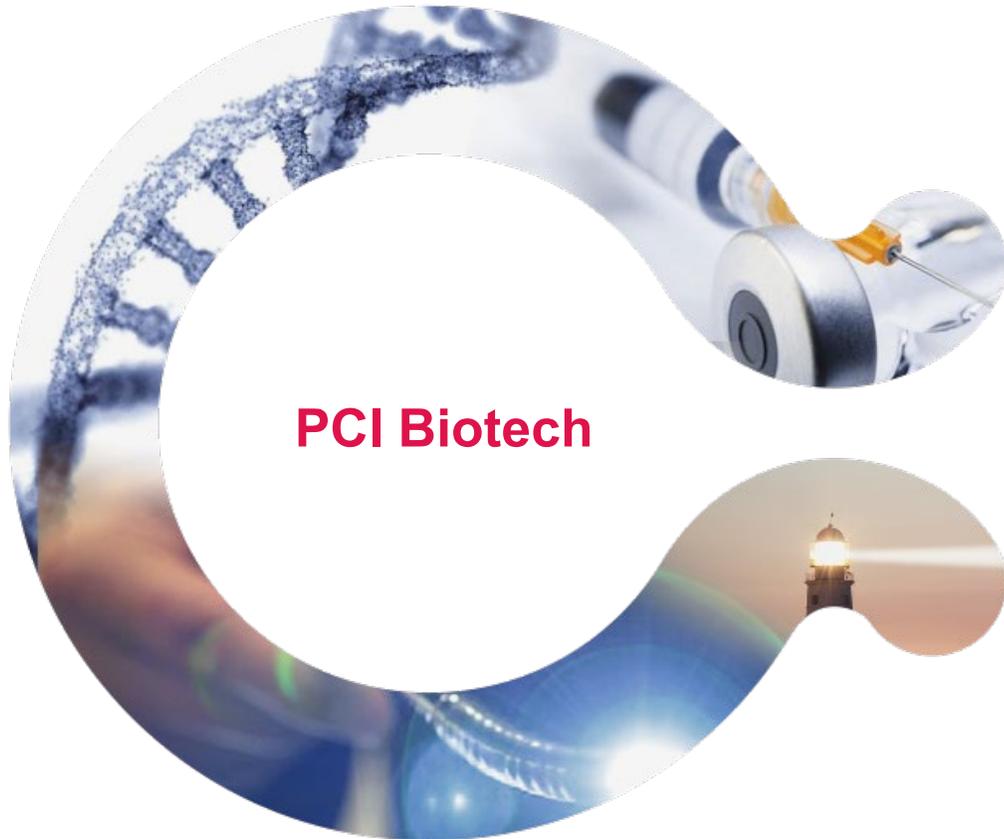
2024 Goals - Bioprocessing

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

Laying the ground for **partnership-driven development**

Pipeline

Programme	Description	Preclinical	Phase 1	Phase 2
fimaNAC	Dermatology			
fimaVacc	Intratumoural immunotherapy			
Programme	Application	Feasibility	Prototype	Commercial
fimaNAC	Viral vector manufacturing			



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