# Disrupting Gene Therapy Manufacturing with Photochemical Lysis (PCL)

## PCI Biotech

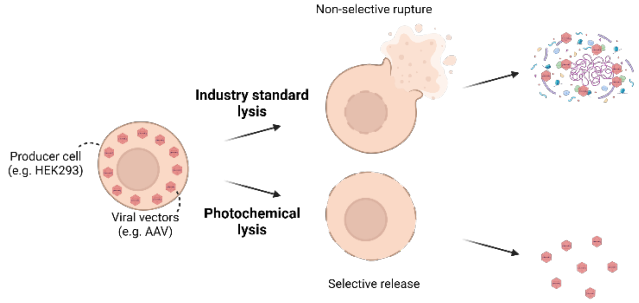
PCI Biotech is a small-cap biotechnology company listed on the Oslo Stock Exchange (OSE:PCIB). The company develops novel technologies that enable improved *manufacturing* of advanced therapies.

## The challenge

Virus (AAV) enabled gene therapy is one of the most exciting advancements in modern medicine, offering potential to cure genetic diseases. These transformative treatments remain prohibitively expensive, often exceeding $2 M per treatment. A major challenge lies in inefficient and costly manufacturing processes. Up to 70% of AAV gene therapy material is lost during production, generating a manufacturing capacity shortage we aim to address. A critical manufacturing step is AAV extraction from producer cells ("cell lysis"), needed to separate the gene therapy material from the cells that produce them. The industry standard for cell lysis is to use chemicals (e.g., polysorbate 20) to break open producer cells and release AAV, but these approaches are *non-selective* and release impurities that complicate the process. The result? Lower yields and restricted patient access.

## The solution

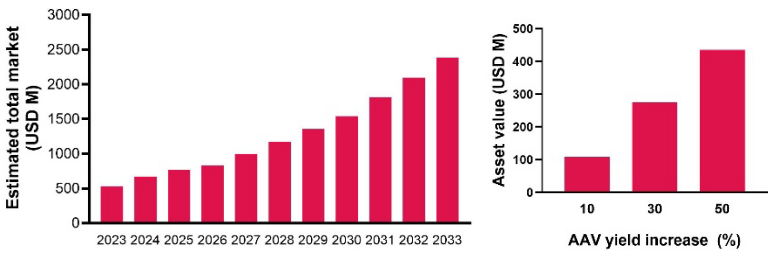
PCI Biotech has developed a novel cell lysis technology: photochemical lysis (PCL). By employing a light-activated photosensitiser, PCL *selectively* breaks open cell membranes and extracts viral vectors with strongly reduced impurities. This precise lysis method increases efficiency, reduces waste, and simplifies downstream processing. The result? Increased productivity and lower manufacturing costs.




| 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 |

## Market size

>200 clinical AAV trials are ongoing as of 2024, with an annual expected growth rate of 15%. The estimated *manufacturing* market for AAV is shown below (left figure). The PCL value proposition is increased batch yield, reducing manufacturing cost per dose. Initial data indicate that a 10-50% AAV yield increase is feasible with PCL. The increased productivity addresses the manufacturing capacity shortage and creates significant asset value potential for PCL, exemplified below for 2028.




## Business model

Licensing PCL to AAV manufacturers, generating revenue through access fees and R&D services. By targeting AAV manufacturers as market hubs, the model ensures flexibility while securing long-term value and strong market positioning.

## Milestones

PCL has been adapted to the predominant cell type (HEK293 3D culture) used in commercial AAV manufacturing, has successfully gone through early-stage field testing, and is currently being scaled to small bioreactors (250 mL volume). These bioreactors are representative of large-scale (commercial) manufacturing. Three important recent milestones from small bioreactors are the successful removal of the photosensitiser without adding complexity to the process, preservation of viral vector functionality after exposure to photosensitiser, and matching or improving *upstream* yield with reduced host-cell impurities compared with industry standard cell lysis.

## Development plans

The PCL technology introduces the requirement for in-process illumination. We aim to enable this through repurposing off-the-shelf bioreactors with integrated LEDs.

The next upcoming milestone is demonstration of increased *net* AAV yield after PCL and *downstream* processing, targeted for 2025. This would mark PCL's readiness for the R&D market.

The 2026 objective is to demonstrate PCL in a 50 L LED bioreactor to be ready for commercial manufacturing by 2027. PCI Biotech's current financial runway is into Q4 2025.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