Continuous Production of Monoclonal Antibodies for SARS-CoV-2

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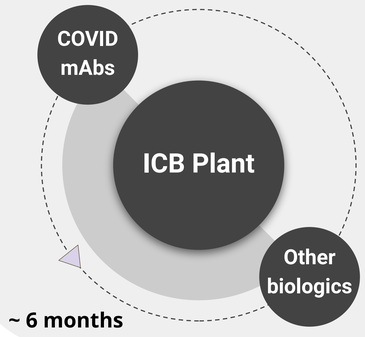
Project Background

Continuous production of SARS-CoV-2 treatment

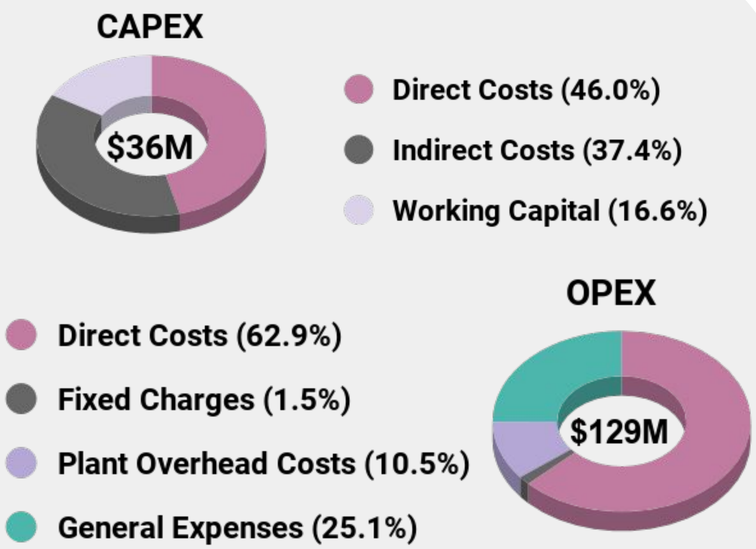
I C B **Integrated and continuous bioprocessing**
→ Reduces costs, speeds up production and development
→ Integrates single-use and stainless steel equipment



Production per year:
7,565 kg mAbs
2.7 million doses

mAbs per dose:
2,800 mg

Economic Assessment



MARR: 14.36%
Revenue: $27B
NPW: $26B
Plant life: 20 years

Sales price:
$1,563/dose

Production cost:
$57/dose

1. Perfusion Bioreactors

Growth of CHO cells and accumulation of monoclonal antibodies (mAbs) in a perfusion single-use bioreactor.

2. Protein A Capture

Separation of mAbs from media through specific and reversible binding of mAbs to the Protein A ligand

3. Viral Inactivation

Low pH inactivation for safety in compliance with FDA regulations of two viral clearance steps

4. Polishing Steps

Removal of aggregates, residual DNA, host cell proteins, and leached Protein A using anion & cation exchange chromatography

5. Viral Filtration

Removal of viruses using 20 nm pore size viral filters

6. Ultrafiltration/Diafiltration

Concentration of product and buffer exchange to ensure stability of biotherapeutic during storage