1. Process Intensification Satisfies Key Business Drivers

- Low Capex Investment: < 50%
- Faster Buildout Time: < 2 years
- Flexible Smaller Footprint: 50-70%
- Higher Productivity: > 30%
- Lower COGS: Source: Data derived from Biosolve modelling

2. Upstream Process Intensification Strategies

Requirements include robust cell line and media suitable for long culture durations & high VCDs of perfusion, scalable performance from clone screening to manufacturing along with recipes & PAT sensors for process control

3. Clone Selection to Process Development

- Save Time, Run More Experiments and Obtain Useful Data Using High Throughput, Multi-Parallel Ambr® Systems

4. Process Development & Characterization

- Ambr® 250 Perfusion is Efficient & Cost Effective Compared to Traditional Benchtop Perfusion

5. Ambr® 250 Perfusion: Good Match to 5 L for VCD & Titer

- Blood product
- Higher titer, lower COGS
- 5L and 50L
- N-1 perfusion enables high inoculation of production bioreactor
- Reduce culture length of production bioreactor (-40%) - 17 seed train days (26-29 total USD days)

6. Flexible Seed Train Options

- Intensifying N-1 Seed Train is the easiest to implement with minimum change to the Fed-Batch process
- It results in up to 2× higher titer, up to 50% increase in throughput & lower COGS compared to Fed-Batch

7. Intensified N-1 Seed Train: 10× Productivity Increase

- Traditional Batch (Top) Versus Perfusion (Below) Seed Train Cell Culture Process Workflow at Intas
- Reduced seed train from 5.5 to 3 steps saving time and cost
- N-1 perfusion increased cell culture productivity 10× with a smaller manufacturing footprint
- Showed comparable growth kinetics and yields with a control process at 50 L scale
- Target VCD reached within 9 days culture viability in 6-8 days of fed-batch culture

8. Process Scale-up & Summary

- Sartorius Upstream Process Intensification Platform PD to Manufacturing

Summary

- Process Intensification maximizes productivity and flexibility and can be implemented step-wise or end-to-end
- High throughput Ambr® systems fast-track biopharm perfusion processes development saving time and money
- N-1 perfusion results in up to 2× higher titer, lower COGS and is the easiest to implement in an existing facility
- PAT sensors enable culture monitoring, automated inoculation of subsequent cultures & better process control