

ENGINEERING PHARMACEUTICAL INNOVATION

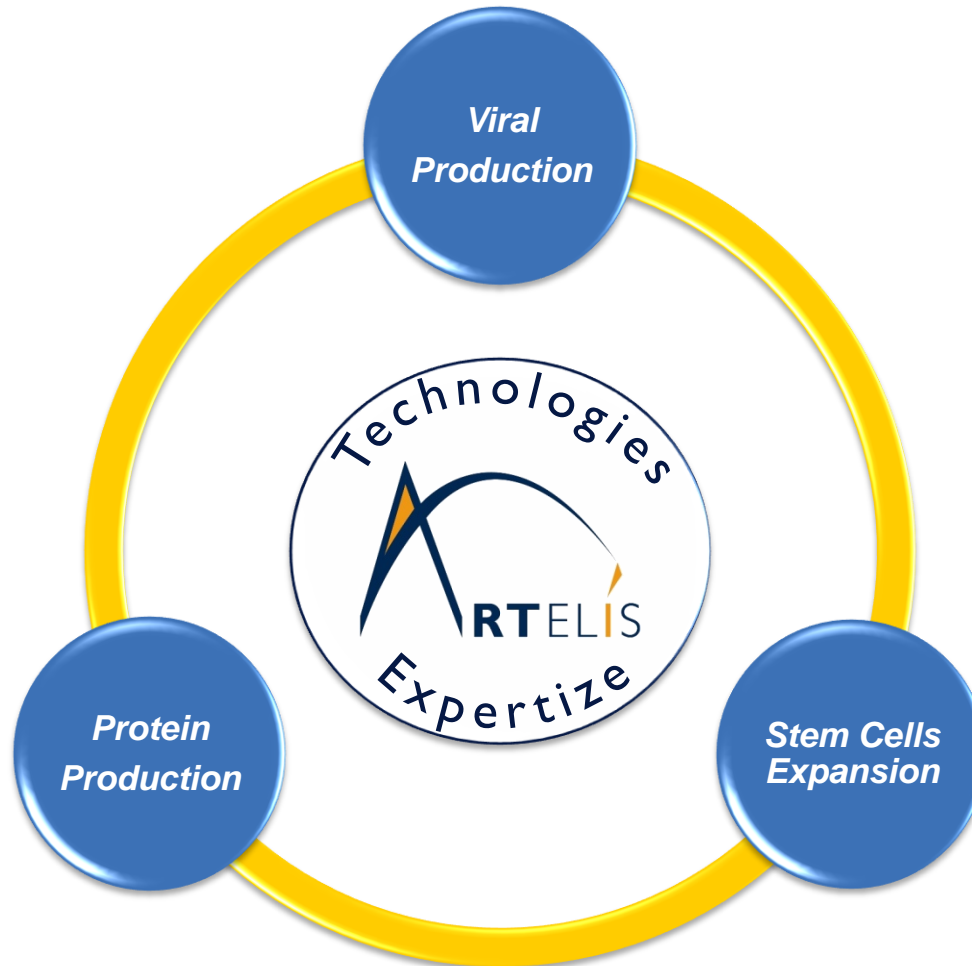


iCELLis™ Economical Impact on Investment and Production Costs

Case Study: CoGs model to compare iCELLis™ with traditional stainless steel bioreactors used for Mabs production

Artelis' mission

Artelis' next generation single-use technologies and expert supports provide efficient solutions for cell culture.

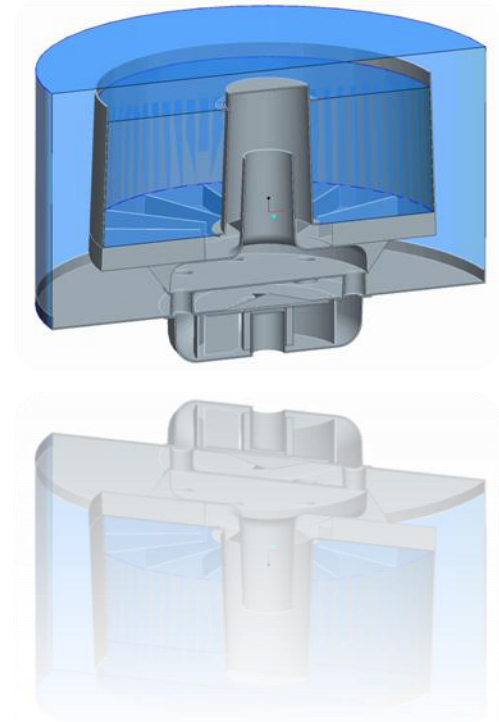


Artelis' solution

Artelis' solution for protein and viral production: iCELLis™ high-cell-density disposable bioreactor technology

iCELLis™ enables process intensification:

- Volumetric productivity is increased by 20-to 100-fold compared to traditional cell culture technologies
- Manufacturing scales are dramatically reduced
- Investment and operating costs are dramatically reduced
- Production process is simplified



iCELLis™

iCELLis™ is a complete solution: high-cell density, fully disposable, scalable and monitored.

Single-use components

- USP Class VI material
- Disposable probes integrated (pH, T, pO₂, biomass)
- Robust design

Fully disposable

Fixed-bed cells

- Adherent cells
- Macrocarriers fixed-bed
- Adaptable to suspension cells

High-cell density

Working volume

- A large range of working volumes suitable for every step of process development



Scalable

Hardware

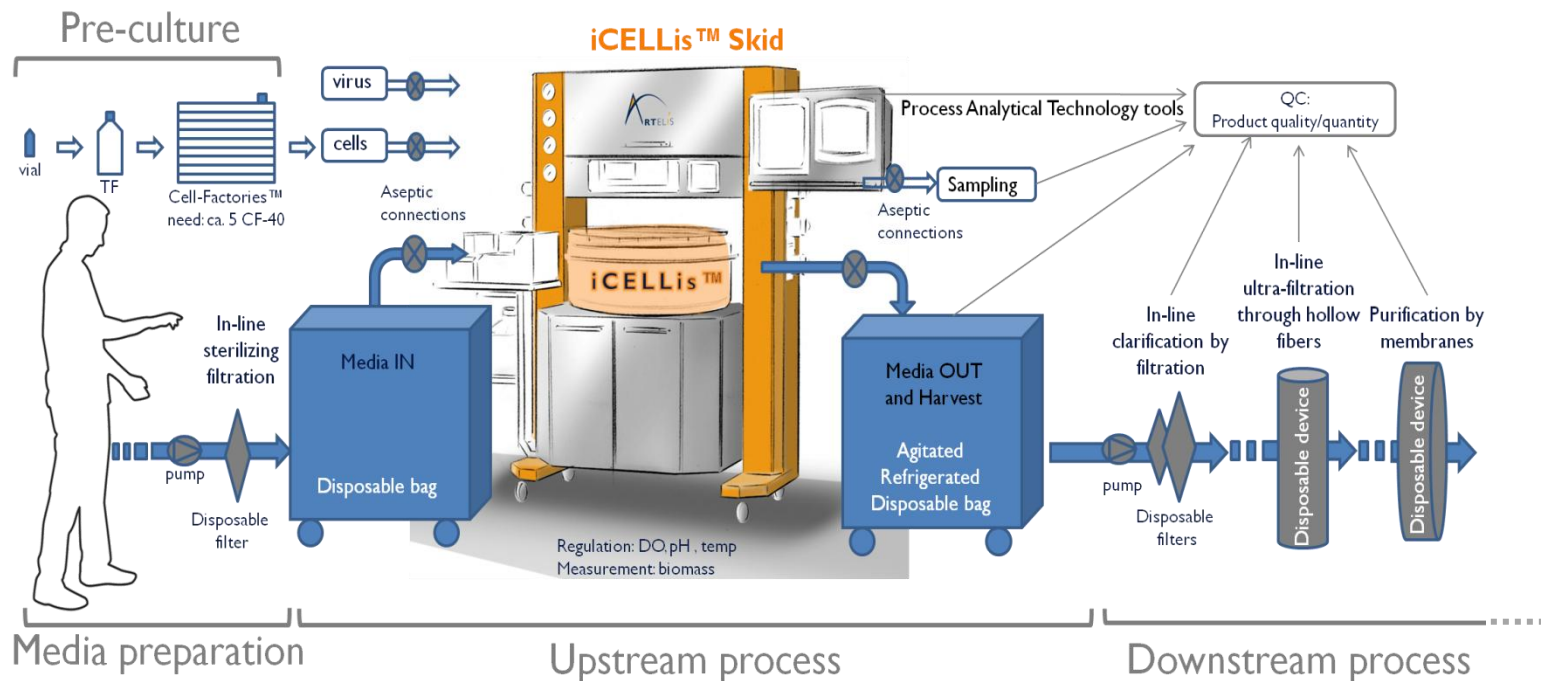
- Custom monitoring system developed in-house
- Client-oriented bespoke system

Complete solution



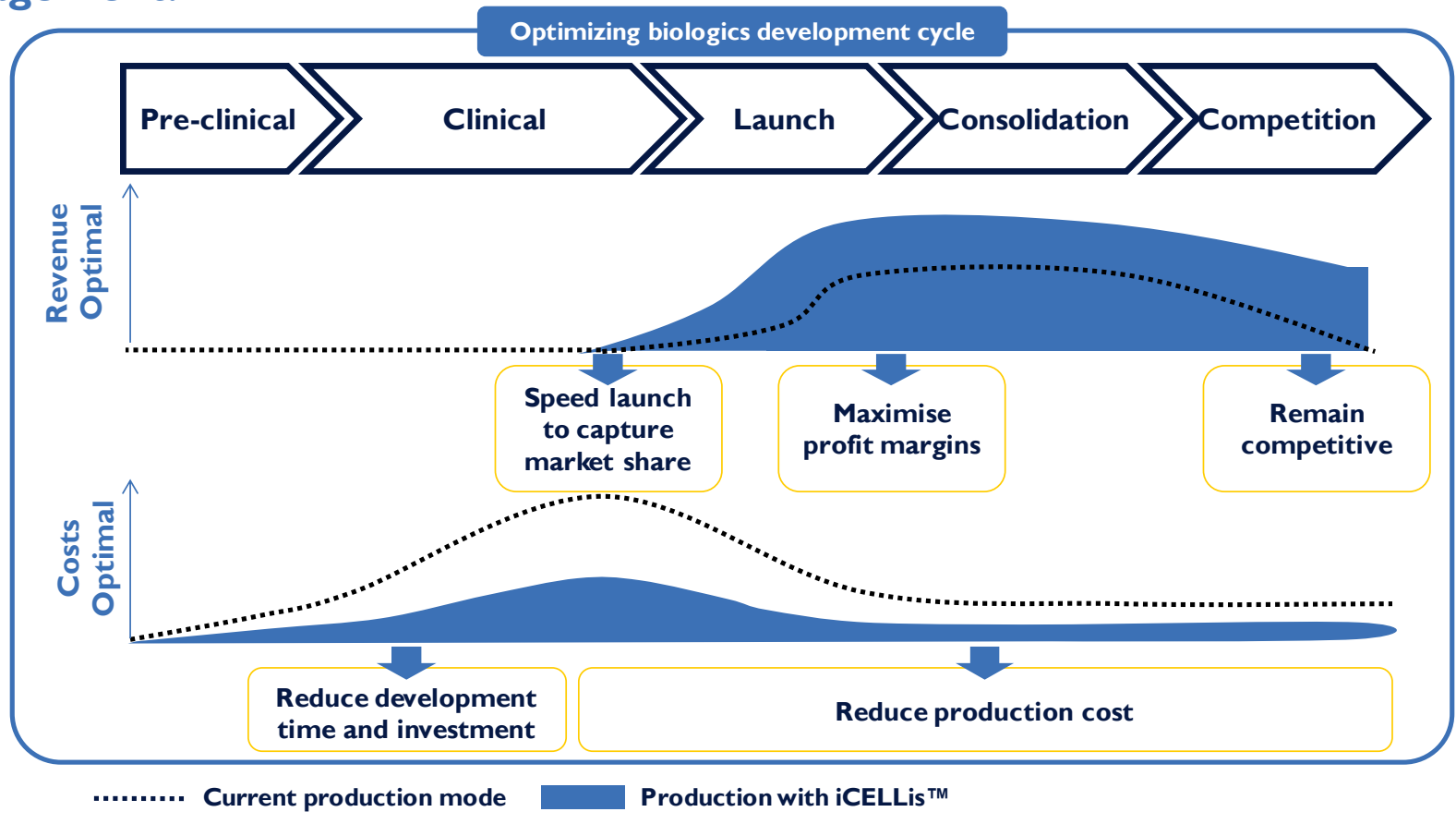
iCELLis™

iCELLis™ is specifically designed to integrate and simplify your process.



iCELLis™ - Advantages

Developing and commercializing a biologic is a long and expensive process that can be improved by quicker market access and better cost management.



Why a third-party cost model ?

Thus to demonstrate the reduction in **COGS** and in **Investments** we have used a well known third-party model

In order to demonstrate the economics evidence of using iCELLis™, we are using a “cost of goods” model carried out by Biopharm Services (BS).

Biopharm Services aims at “Process Modelling, Benchmarking, Validation Services and Consultancy for the Biopharmaceutical Industry”.



COST MODEL – CASE STUDY



Objectifs

Demonstrating how the iCELLis™ technology implies in COGs reduction and in investments on the MABs market.

This document demonstrates, for the case of a biological manufacturing how Artelis' high-cell-density disposable bioreactor dramatically impacts:

- ➔ on capital investment
- ➔ on operational costs



The Scenarios

We have run 6 scenarios to demonstrate that manufacturing capacity can be increased (X 5) or investment divided (\div 2) and COGs reduced by 20%

Scenario Bases

Mabs production

New facility

New facility

Stainless steel
bioreactors

VS

100L iCELLis™
bioreactors

Facility utilization = 80%

Product titre = 4g/L

Scenario 1

• 1 X 5000L stainless steel bioreactor

Scenario 2

• 2 X 5000L stainless steel bioreactors

Scenario 3

• 3 X 5000L stainless steel bioreactors

Scenario 4

• 4 X 5000L stainless steel bioreactors

Scenario 5

• 5 X 5000L stainless steel bioreactors

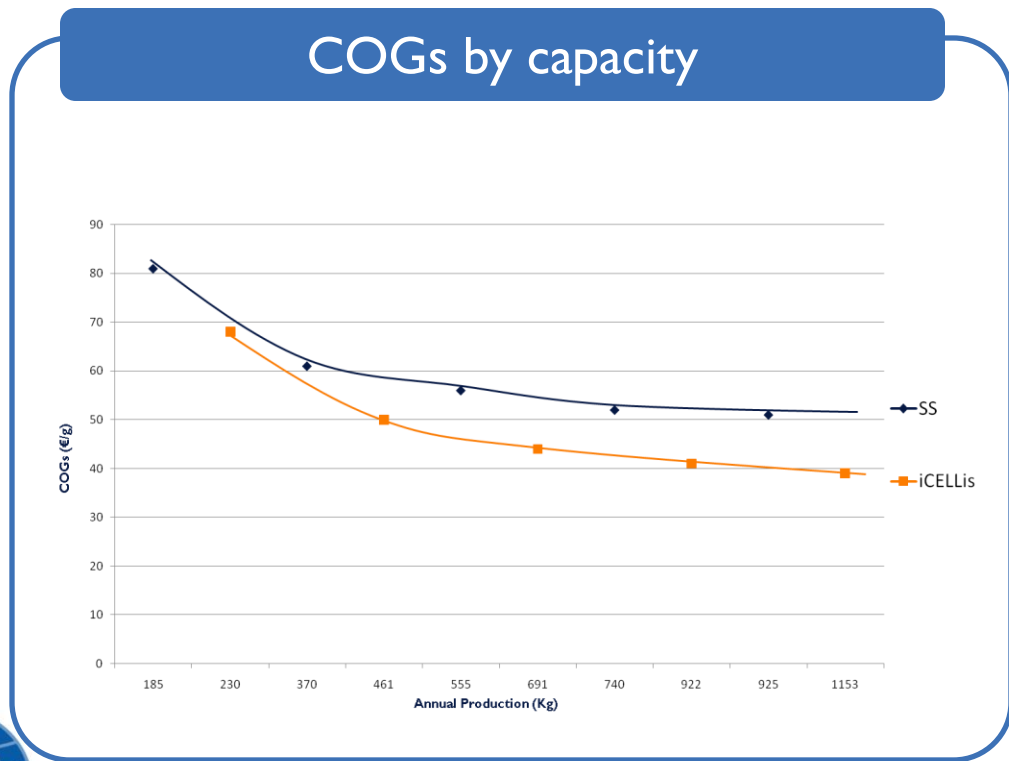
Case Study Simulation

• Selling a new biosimilar Mabs for a 5 year period



Scenario 1-5 : COGS

Regardless of annual production quantity, the iCELLis™ technology enables an average 20% COGs reduction



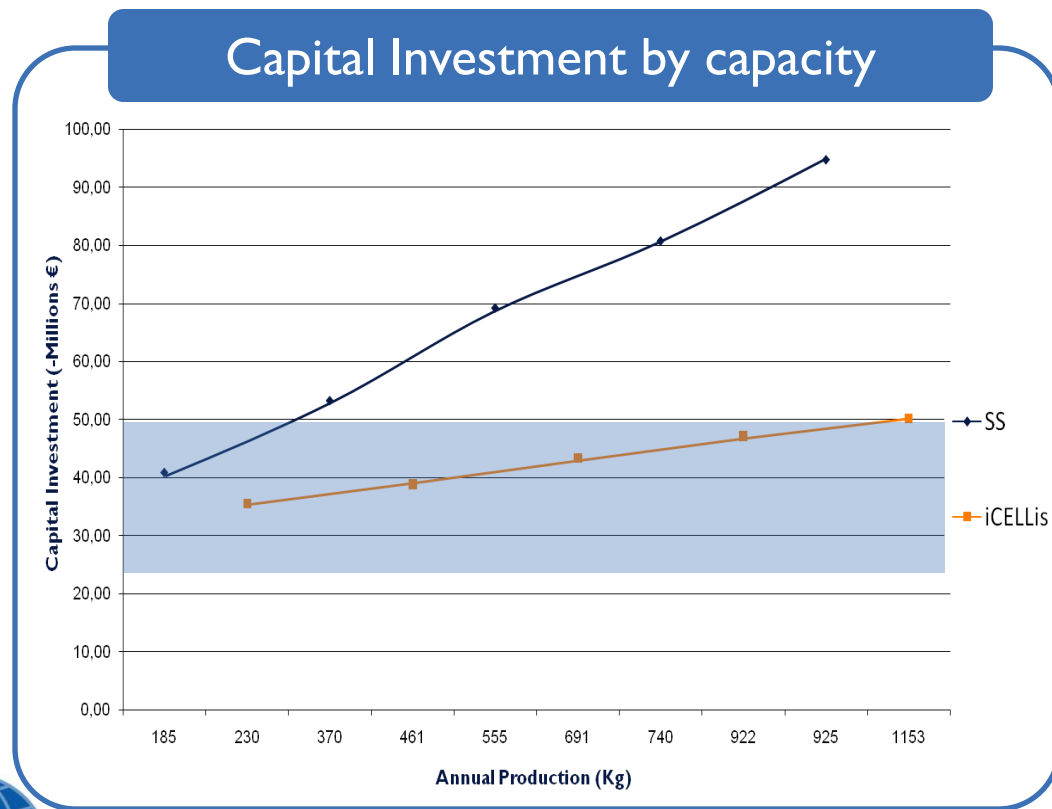
20% COGs reduction

COGs reduction with capacity increase



Scenario 1-5 : Investments

The iCELLis™ technology enables dramatic reduction in investment while increasing the capacity (X 5)



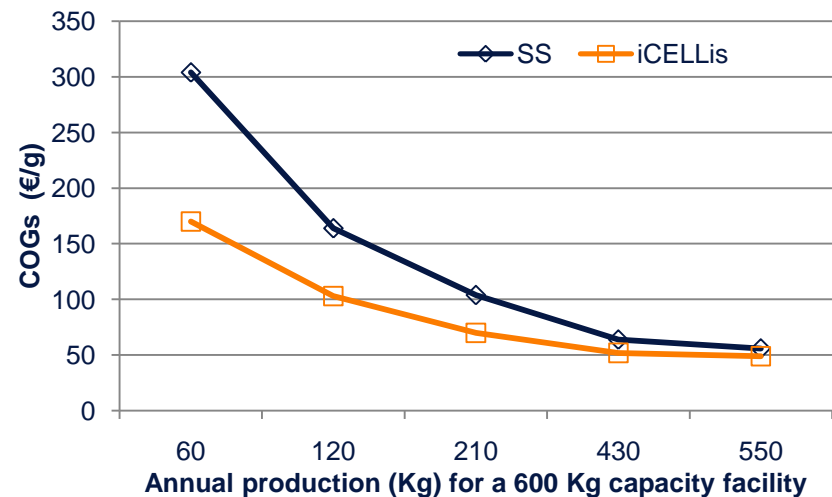
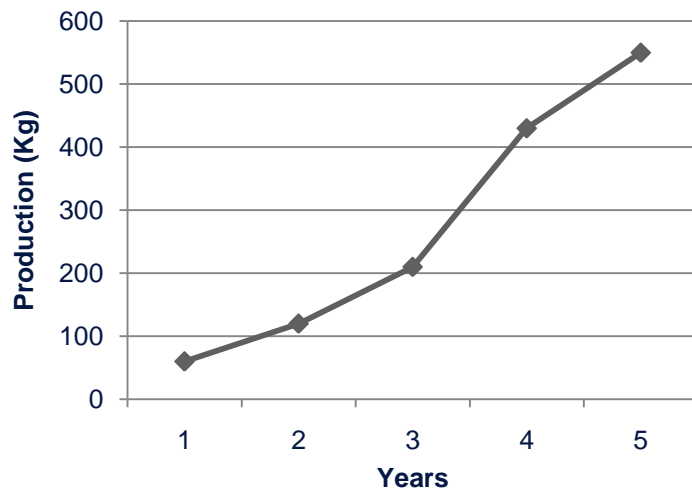
Up to 42% reduction in terms of investment

For the same budget :
X 5 capacity



Case : COGS and Investments

The iCELLis™ technology implies production flexibility, which enables to meet the market demand while reducing COGs and investment.



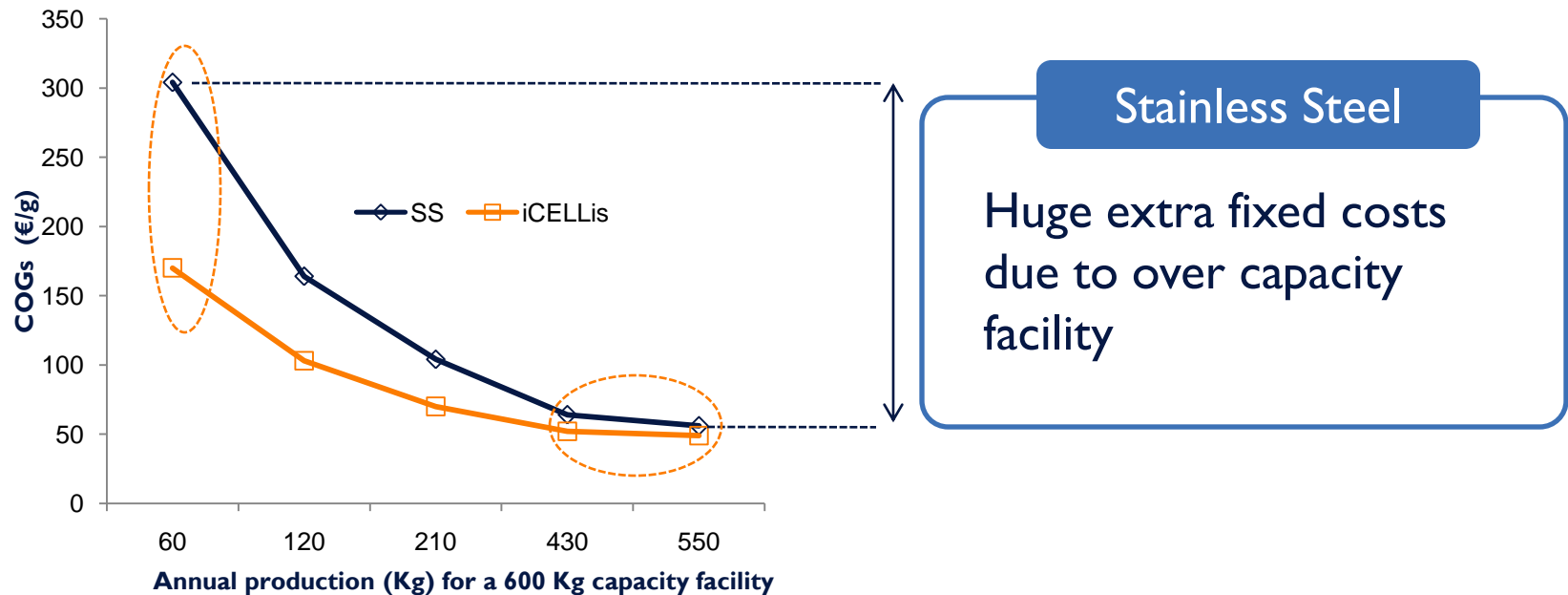
Technologie	Investment (€)	COGs Years 1 (€)	COGs Years 2 (€)	COGs Years 3 (€)	COGs Years 4 (€)	COGs Years 5 (€)
Stainless Stell (3 X 5000L)	67.299.152	18.240.000	19.680.000	21.840.000	27.520.000	30.800.000
iCELLis (100L)	39.630.120	10.200.000	12.360.000	14.700.000	22.360.000	26.950.000
REDUCTION	27.669.032	8.040.000	7.320.000	7.140.000	5.160.000	3.850.000

Inv. ÷ 2

Total COGS reduction during the 5 y = € 30 M

Case :from Fixed to Variable Costs

The iCELLis™ technology enables to move Fixed costs into Variable costs.



iCELLis™

iCELLis™, a single-use technology enables flexible production, which allows dramatic decrease in fixed costs without increasing variable costs



Cost modeling conclusions

Implementing iCELLis technology has impacts on:

Time-to-market

- A large scale pilot suite is not needed for scaling-up
- Complexity of manufacturing facility: decreases risk of delay in facility setup
- Competitive advantage to catch market shares

Investment & COGS

- Dramatic decrease of the investment
- Financial risk management – no risk of high depreciations if finally product does not succeed
- Dramatic decrease in CoG per dose

Flexibility

- Easier to face rapid increase of market demand
- Easier to export “ready-to-use” facility with a “ready-to-use” process to developing countries

Implementing iCELLis technology enable



Timeline reduction

Capital reduction

COGS reduction

**Think process
intensification...**

Choose iCELLis™

