

Simplifying Progress

Capital Markets Tutorial Sartorius offering for cell and gene therapies

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Cell and gene therapies (CGT): an upcoming catalyst for growth

The evolution of biologics



Pillars of growth CAGRs 2022-2027¹

Pharma market	\longrightarrow	~3-6%
Biopharma market	\longrightarrow	~10%
Y Biosimilars	\longrightarrow	~15%
र्द्र CGT		~20%
Single-use	\rightarrow	~15%

1 Source: Company estimates based on EvaluatePharma 2023, IQVIA 2023, Global Data 2023, Roots Analysis 2021, Markets & Markets 2023



CGT is becoming an increasingly relevant market segment

~30% of biopharma pipeline is focusing on CGT¹



>6,000 CGT candidates in development¹

1 Source: GlobalData, October 2023 2 FDA

Number of commercial processes is expanding rapidly

~60 approved CGT globally¹

11 CGT approvals in 2022 and 2023 alone

~10-20

CGT approvals expected p.a. by 2025²



How do gene and gene-modified cell therapies work?





Need for innovation in CGT development and manufacturing



1 Cost per treatment in the USA 2 Cost per treatment in Europe



Manufacturing of new modalities has similarities with antibody production

mAbs	Cultivation	Harvest	Concentration	Purification	Formulation	Fill & Finish		
Plasmids	Fermentation	Harvest	Concentration	Purification	Formulation			
Viral vectors	Cultivation	Transfection	Harvest	Concentration	Purification	Formulation	Fill & Finish	In vivo
Cell therapy	Isolation & enrichment	Activation & modification	Expansion	Harvest	Formulation	Fill & Finish		Ex vivo
mRNA	In vitro transcription	Concentration	Purification	LNP-Based Formulation	Fill & Finish			



Sartorius offers scalable up- and downstream solutions for all CGT...



Source: Sartorius Group: The illustration shows only a small part of the relevant portfolio



...with differentiated separation technologies and analytics...

Purification of large molecules with CIMmultus monoliths



Higher drug quality, higher chance of clinical sucess

Automated centrifugation system Ksep



Single-use gentle cell washing for allogeneic cell therapies

At-line process analytics with PATfix



Fast analytics to optimize and control transfection process



... and a complementary offering of media and critical raw material





Strong core capabilities paired with media and raw materials create enhanced customer value

Combining Recombumin® with media



- Higher and more consistent quality profile
- Can be used in multiple process steps to improve cell growth and protect cells from physical stress, e.g. during separation or freezing

1 HSA = (standard) Human Serum Albumin

Filling media for autologous cell therapies using Linkit® AX



- Very accurate and quick in filling media for cell therapies
- Workflow simplification leads to efficiency gains and lower labor costs



Plasmids and viral vectors are vital for the functioning of most CGT





Plasmids are critical raw materials for the production of viral vectors



Acronym: AAV = Adeno Associated Virus, LV = Lentivirus, Other VV = Other viral vector, RV = Retrovirus, AV = Adenovirus, Non VV = Non viral vector; 1 GlobalData, 2023



Polyplus: Mission-critical reagents for gene therapies



Transfection

- First mover advantage with PElpro[®]
- Leading innovation with next generation transfection technology
- Strong market penetration with FectoVIR-AAV in next-gen suspension processes



Plasmid design and production

- Next-gen plasmid engineering technology
- High success rate
- GMP accreditation
- Fast turnaround time, proprietary manufacturing process, flexibility



Innovative gene-delivery reagents

- Emerging portfolio for DNA/RNA therapeutics
- Cationic lipids and transfection polymers which are a critical component in the formulation of LNPs



Industry-leading transfection reagents and plasmids deliver high performance and scalability

Up to 20-fold increase in functional viral titers with FectoVIR-AAV + Polyplus' optimized plasmids



- Highest viral vectors titers in suspension systems
- Improved full/empty capsids through optimization of plasmids, resulting in improved viral particle quality
- Adapted to large-scale production:
 - Long complex stability
 - Low complexation volume



Strong market position and unique set of expertise

Attractive business model - Upstream material spend by phase \notin in millions



- Integrated workflow solutions to speed up time-to-market and improve process economics
- Spec`d into significant portion of approved & pipeline CGT
- Deep application know-how in areas such as polymer synthesis and formulation, advanced biologics processes, molecular and cell biology as well as scientific and regulatory support



Excellently positioned for CGTs' uptake

- Large and growing pipeline of gene and gene modified cell therapies as well as DNA/RNA therapeutics in development
- Sartorius well positioned to benefit from above-average market growth
- Spec wins through best-in-class solutions, providing high productivity and low cost per dose
- Improve time-to-market through seamless scale-up support and best-in-class delivery and quality service levels
- Leveraging commercial, innovation and operations synergies













Disclaimer

This presentation contains statements concerning the future performance of the Sartorius Group. These statements are based on assumptions and estimates. Although we are convinced that these forward-looking statements are realistic, we cannot guarantee that they will actually materialize. This is because our assumptions harbor risks and uncertainties that could lead to actual results diverging substantially from the expected ones. It is not planned to update our forward-looking statements.

Throughout this presentation, differences may be apparent as a result of rounding during addition.

