process solutions

Transforming the path from treatments to cures

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Head of Process Solutions

1st Virtual CMD of Merck KGaA, Darmstadt, Germany,
September 16, 2020

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Today's Call
Speakers in Process Solutions deep dive

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Head of Actives &
Formulation

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Modalities

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Agenda

01 Manufacturing is continuing to diversify

02 Innovate to accelerate

03 Executive summary

01

Manufacturing is continuing to diversify

Therapies are evolving *from treatments to cures*

Advancing traditional is critical as novel modalities develop

TRADITIONAL

- Uses small molecules, peptides, proteins
- Chronic, manages or treats
- Templated manufacturing

→ FORMULATED FOR THE MASSES

MODALITIES

HP-API

Plasma

mAbs

Vaccines

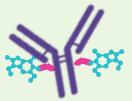
NOVEL

- Uses DNA, RNA, Cells
- Potentially curative
- Non-templated manufacturing

→ FORMULATED FOR an individual

MODALITIES

Gene & Viral



ADCs

Cell therapies

mRNA

Acronyms: HP-API = highly potent active pharmaceutical ingredient; mAbs = monoclonal antibodies; DNA = deoxyribonucleic acid; (m)RNA = (messenger) ribonucleic acid; ADC = antibody drug conjugate

COVID-19 demands align with our strengths but increase supply chain pressure

unit operations		PALL	ThermoFisher SCIENTIFIC	SARTORIUS
Cell culture media	●	●	●	●
Biopharm materials	●	●	●	●
Chromatography	●	●	●	●
Hardware	●	●	●	●
Single use	●	●	●	●
Sterile	●	●	●	●
Virus	●	●	●	●
Clarification	●	●	●	●
Tangential flow filtration	●	●	●	●

● = A leading player ● = Significant presence ● = No offering

Sources: press releases, company reports, and internal assessments

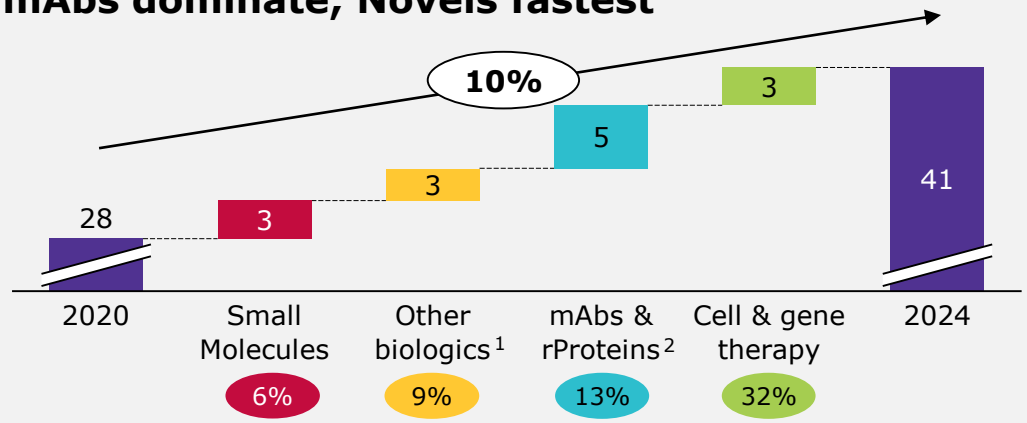
COVID-19 Outlook

Type	Implications
mAb **65** programs **Bind and block** virus from entering cells	• Universal templates • A leading position for 8 out of 9 unit ops
Vaccine **199** programs Protective **immune response**	• Multiple templates • Leveraging Single Use
Nucleic Acid **43** programs Leveraging **human factory**	• Emerging manufacturing processes • Lipids are critical

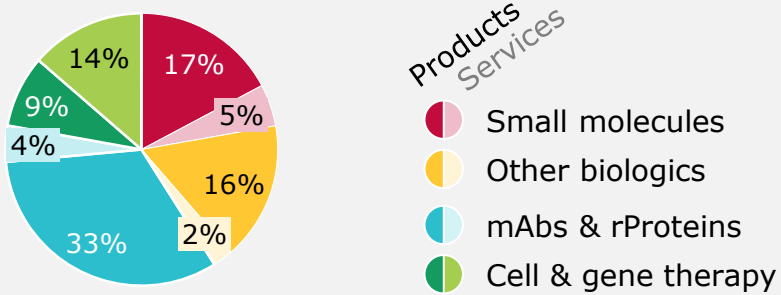
Opportunities in services to accelerate double-digit growth

Accessible Market (€ bn)

mAbs dominate; Novels fastest

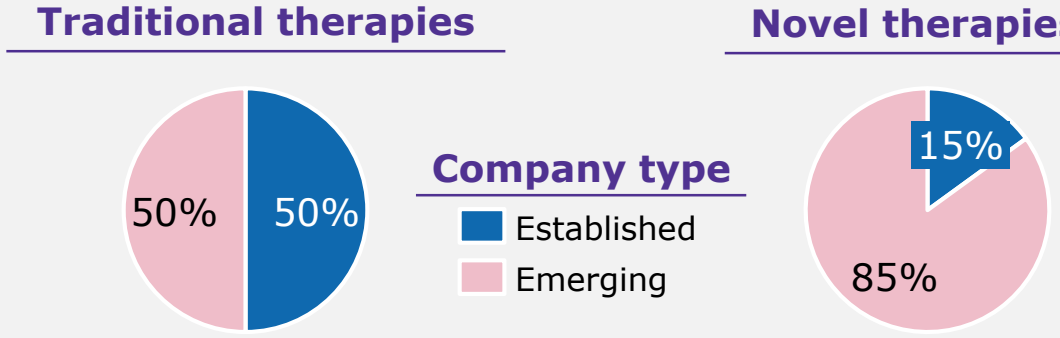


Service importance varies by modality

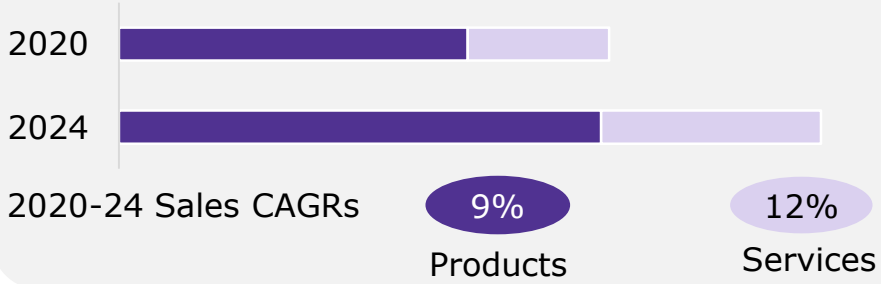


Origins of biologics pipeline

Emerging biotechs drive novels

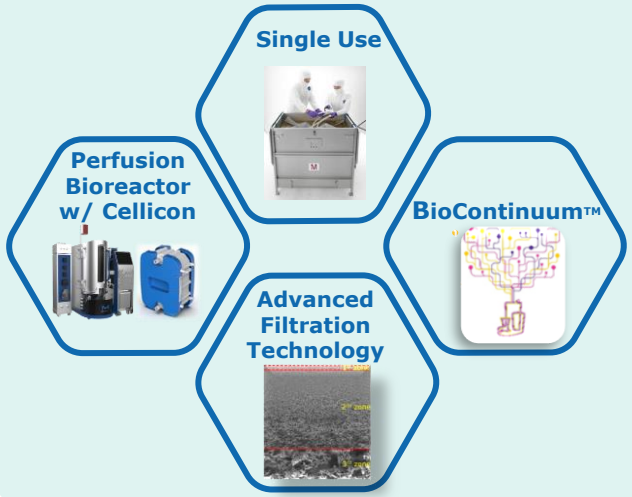
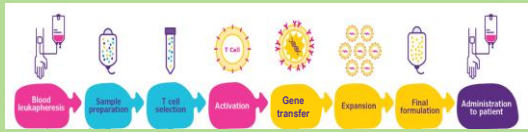


Services see faster growth in coming years



Sources: Evaluate Pharma, internal market models, CSR sales data; [1] Other biologics include plasma, vaccines, insulin, microbial and non-mAb biosimilars; [2] mAbs include ADCs here;
Additional acronym: rProteins = recombinant proteins

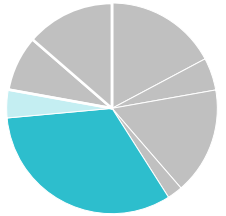
Strategic direction – innovate and invest today to continue above market growth in the future

	TRADITIONAL	ALL	NOVEL
Modality			
Revenue driver	Near term	Mid term	Long term
Offering	Products	Services	Products
Portfolio		 ✓ Contract development & manufacturing organization ✓ Contract testing organization ✓ Product characterization	Manufacturing novel therapies  ✓ Templated viral manufacturing consumables and reagents ✓ Autologous manufacturing system

02

innovate to accelerate

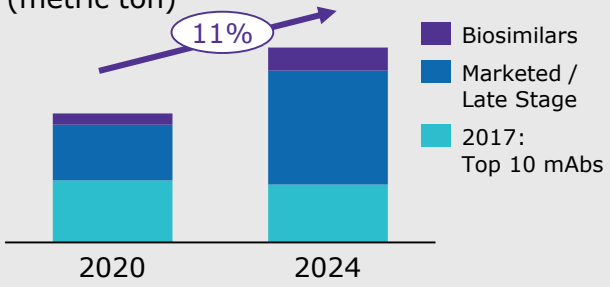
BioContinuum™ – next-gen monoclonal antibody platform



mAbs democratization:

Global Volume Demand

(metric ton)



Source: Evaluate Pharma

Templated Manufacturing:

mAbs templated 30 years ago

Next generation bioprocessing

Needs

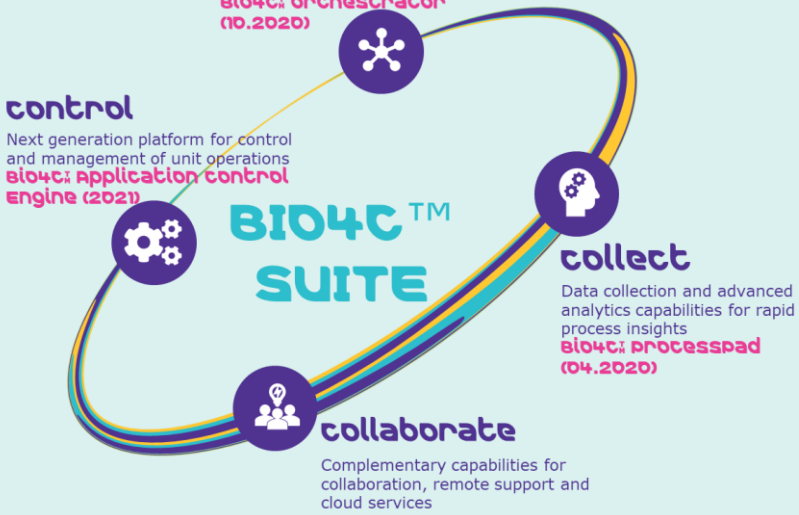
- Greater Flexibility
- Improved Utilization
- $ Cost Control

portfolio

Processing

- Perfusion Bioreactor
- Natrix membrane chromatography
- In-Line Dilution
- Single Pass TFF

Cybernation

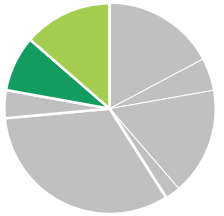


Benefits

- Multi-product facilities
- Process efficiency
- Flexible digital tools

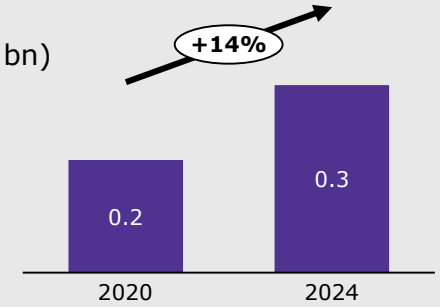
Additional acronym: TFF = tangential flow filtration

Products and services focused on nucleic acid therapies



Base market for non-viral delivery

Accessible market (€ bn)



COVID-19 provides market tailwind

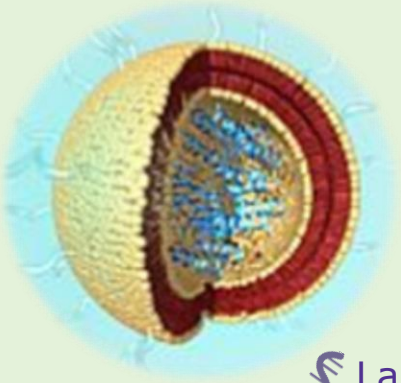
- 2 approved RNA drugs, 400 in pipeline
- Collaborating on 20+ COVID-19 programs
- COVID-19 could accelerate market growth ~4x

Needs

Catalog and customized cGMP synthetic lipids

Portfolio

Simplifying RNA based drug delivery and manufacturing



Synthetic Cholesterol for integrity

Lipids for stabilization and non-viral delivery

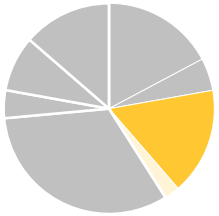
Launching RNA **formulation services**

Benefits

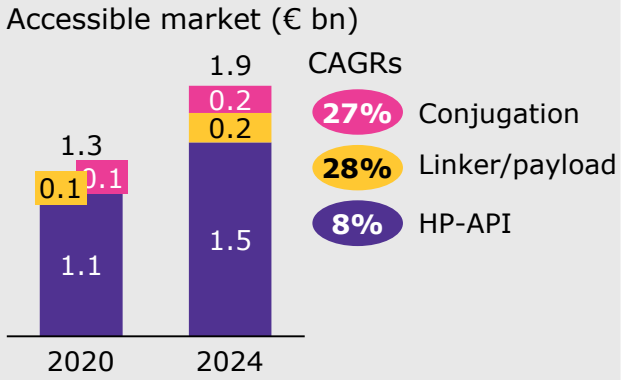
Accelerating RNA based **drug delivery and manufacturing**

Additional acronym: cGMP = current good manufacturing practice

Investing to forerun in Antibody Drug Conjugates



Strong growth in ADCs



High demand for all components

- 9 approved ADCs, 300+ in pipeline
- Oncology driven market – global interest

Needs

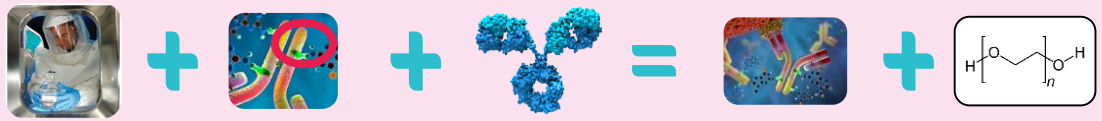
- **Regulatory expertise**
- **Conjugation know-how**

Portfolio

Step-share in 7 of 9 commercial ADCs

Capacity | **Bio Readiness**

Payload + Linker + mAb = ADC + PEGs



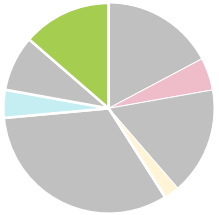
Assay Development & Testing

Benefits

Seamless **capabilities, integration and execution**

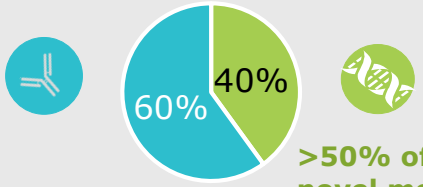
Additional acronym: PEG = poly ethylene glycol

Contract testing – innovating in rapid molecular methods



Origins of Growth

Contract testing sales split (2019)



>50% of growth from novel modalities

Process intensification

Rapid molecular methods allow for quicker release testing

Globalization

Rapid growth of China domestic & export market

Needs

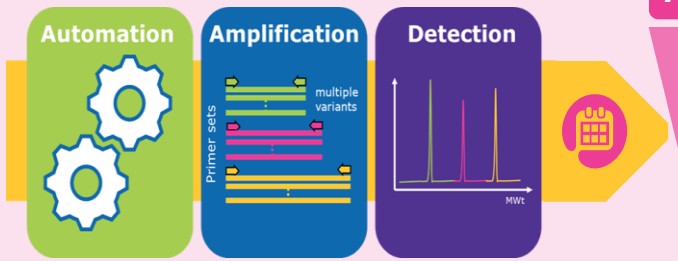
Reliable and rapid results

Capacity and flexibility

Global operations

The **Blazar™** platform detects multiple targets by PCR and is a viable alternative to traditional assays

portfolio



Available

Blazar™ Rodent panel
Reduce animal testing

Blazar™ CHO/mAb panel
Reduce time to result;
35 → 7-10 days

Blazar™ Human panel
Virus testing for Cell & Gene Therapies

2024

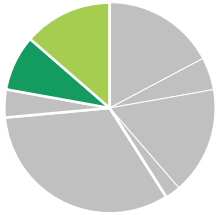
Sterility panel
3 day test for Cell Therapies

Benefits

Reduce **time to result** and **animal use**

Additional acronyms: PCR = polymerase chain reaction; CHO = Chinese hamster ovary

Innovation lifting the development of cell and gene therapies



Cell Therapy:
Cells that augment, repair, replace or regenerate tissue

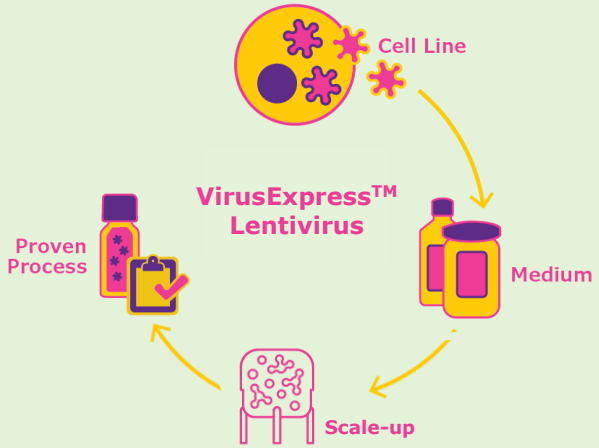
Gene Therapy (ex vivo):
Correcting or modifying genes in a cell prior to their use for cell therapy

Gene Therapy (in vivo):
Correcting or modifying genes or gene expression *in vivo*

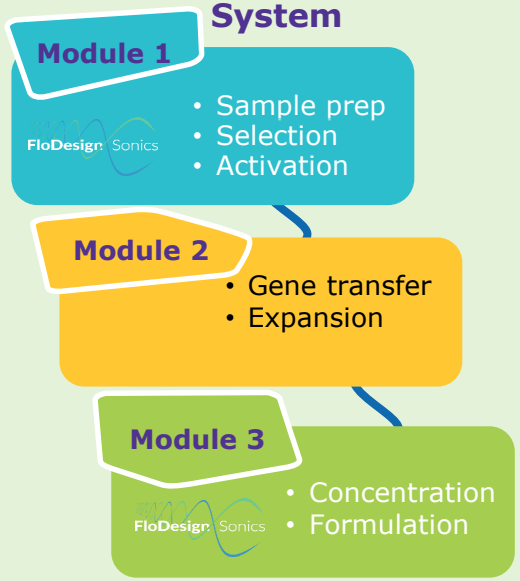
Needs — **Industrialization of manufacturing processes**

portfolio

Templated Lentivirus Production



Cell Therapy Manufacturing System



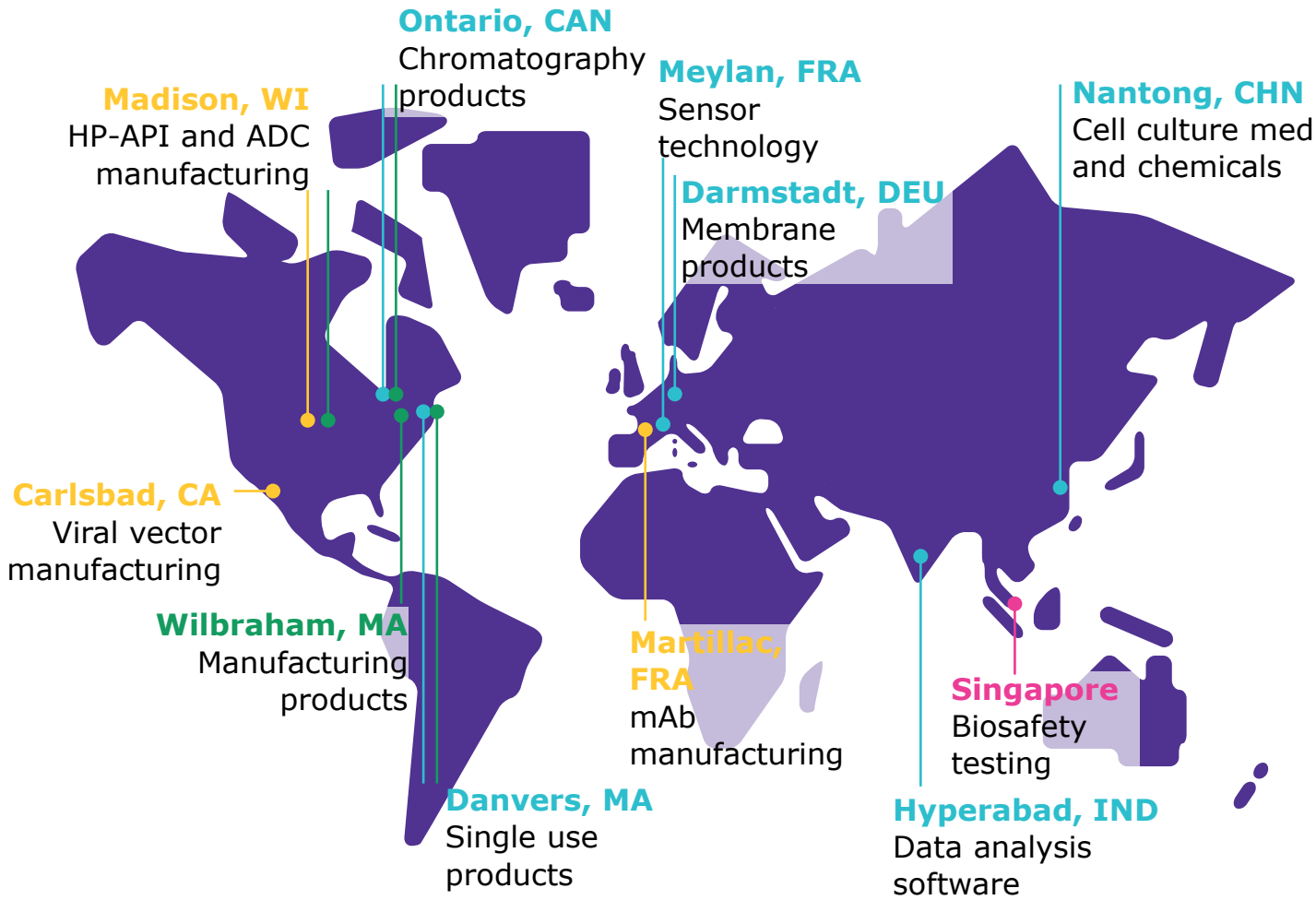
Benefits

Suspension growth for **high titers**

Closed, modular system for CAR-T therapies

Additional acronym: CAR-T = chimeric antigen receptor T cell

Globally investing to meet market demands



>€425 m[1] invested across products and services to expedite patient access

- Products – traditional modalities
- Products – novel modalities
- CDMO
- Testing

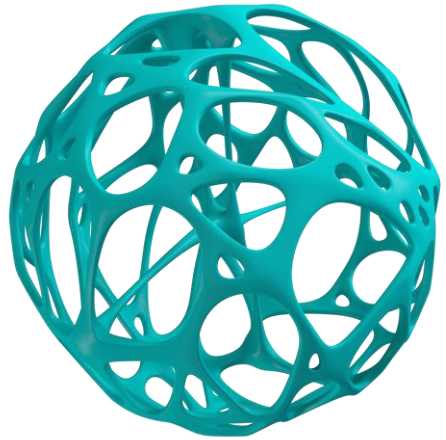
[1] Publicly announced investments since 2017
Additional acronym: CDMO = contract development and manufacturing organization

03

executive summary

Process Solutions

Key takeaways



- **Strong position in attractive markets**
- **Innovation is critical to maintain and grow market share**
- **Expand CDMO and CTO activities to serve all modalities**
- **COVID-19 provides market tailwind**

Additional acronym: CTO = contract testing organization

Q&A

Andrew Bulpin (Head of Process Solutions)
Matthias Bucerius (Head of Actives & Formulation)
Benoit Gourdier (Head of Process Solutions Services)
Angela Myers (Head of Gene Editing & Novel Modalities)
Darren Verlenden (Head of BioProcessing)

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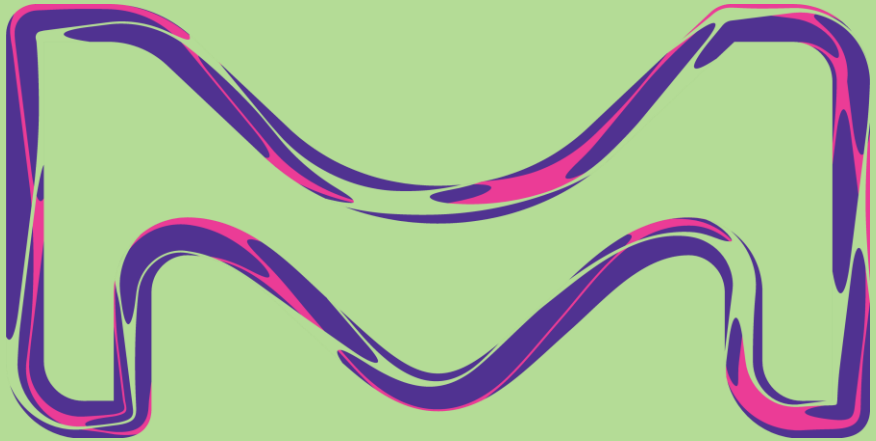

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