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#### **Unaudited Financial Results**

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# **Agenda**

1	Market overview
2	Company overview
3	Strategy
4	Performance & financial targets
5	Corporate Governance, calendar and contact



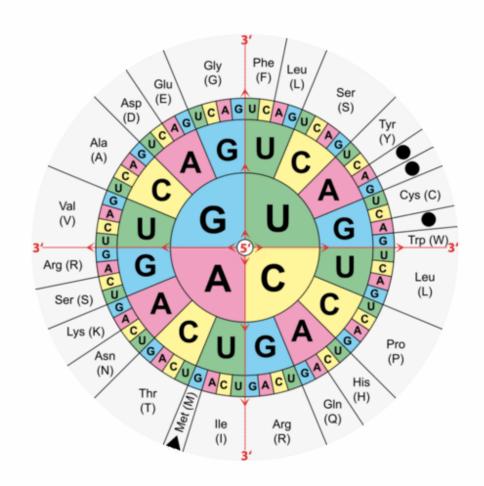
## Peptides and Oligonucleotides: "The world of TIDES"

It all starts with amino acids and nucleobases

## What are peptides?

Peptides are short chains of (up to ~100) amino acids linked by chemical bonding between their respective carboxyl and amino groups.

Peptides are in every cell and tissue in the body.



# What are oligonucleotides?

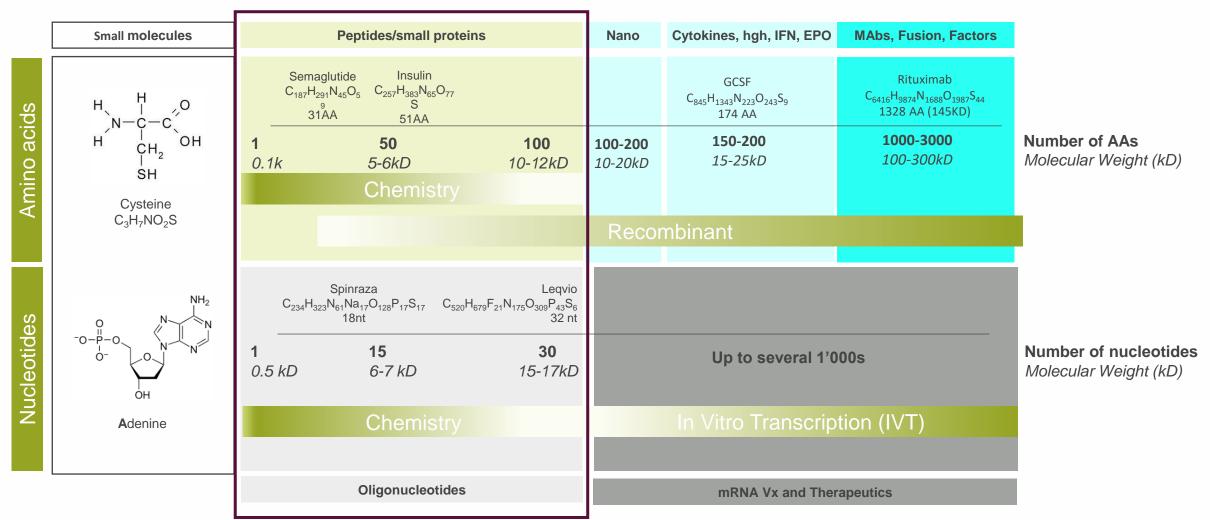
Oligonucleotides are a class of single- or double-stranded small synthetic nucleotides (up to 20-30 mer).

Therapeutic oligonucleotides act on different stages of pathological gene expression.



# TIDES: a sweet spot within the various therapeutic modalities

Positioning of chemically synthesized TIDES



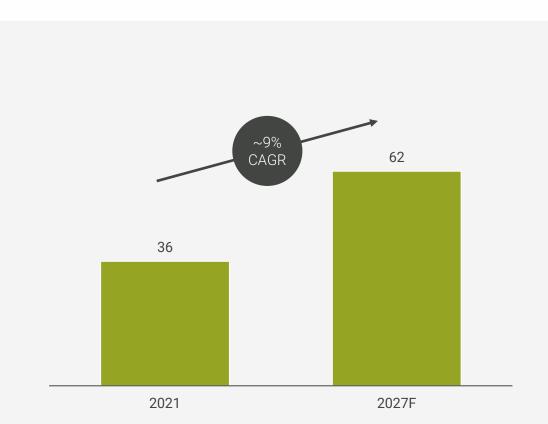
Source: Wikipedia.



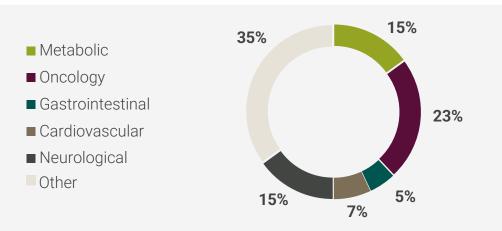
## Peptide-based drugs market with structural growth momentum

Broad therapeutic areas with significant product pipeline

### Estimated peptide therapeutics end market (\$ Bn)<sup>1</sup>



## ~81 drugs FDA approved and ~800 in development<sup>2</sup>



- Growth driven by a growing number of approved peptide drugs, growing patient population (cancer, metabolic disorders, etc.) and increasing genericization of key originator peptides.
- Broad therapeutical areas of application resulting in rich project pipeline globally
- Increasing number of expected product approvals for years to come



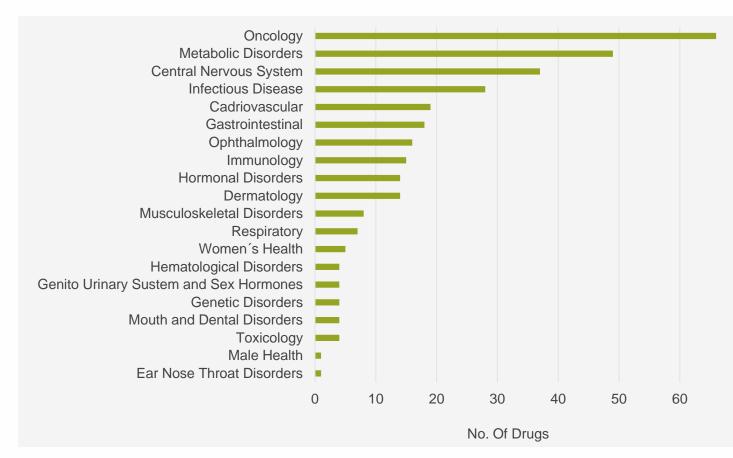
<sup>&</sup>lt;sup>1</sup>Source: IMARC 2021, Peptide therapeutics market 2022-2027, (July 2022).

<sup>&</sup>lt;sup>2</sup>Including projects in clinical and pre-clinical development. Source: GlobalData, Drugs Database, (accessed 17 August 2022).

## >250 peptide-based drugs in clinical development

Good clinical progress reported in 2022 across multiple drugs

## Peptide-based drugs in clinical development<sup>1</sup>



Ca. 60 relevant news events in 2022<sup>2</sup>

- 3 FDA approvals, 4 commercial launches, 5 phase III trial results, 10 phase II trial results, 5 investigational new drug submissions
- In oncology >10 advanced projects (phases II and III) and numerous earlier stage projects, also with anticancer vaccines
- In metabolic disorders, strong clinical results published in new therapies for diabetes and obesity, some of which with blockbuster potential

<sup>1</sup>From clinical phase I to phase III. Source: GlobalData, Drugs Database, (accessed 17 August 2022).

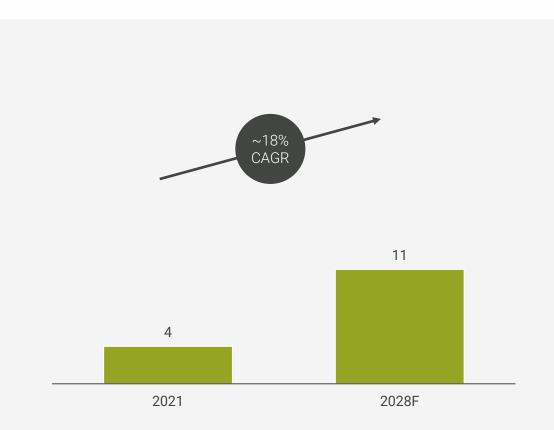


<sup>&</sup>lt;sup>2</sup>News until November 2022 related to project initiation, clinical progress (incl. study initiations, updates, results) and drug approvals.

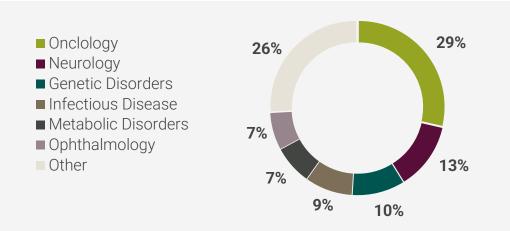
# Oligonucleotide market more nascent compared to peptides

Emerging CDMO market - ~80% of rich drug development pipeline still pre-clinical

### Estimated oligo therapeutics end market (\$ Bn)<sup>1</sup>



## >900 drugs in development, of which >700 pre-clinical<sup>1</sup>



- Originator R&D projects across therapeutical areas, with potentially expanding application, i.e. from rare diseases to diseases with wider patient populations
- R&D activities in earlier stage with >700 pre-clinical projects;
   ~190 projects in clinical development, of which 24 in phase III;
   currently 15 drugs FDA approved





# Addressable peptide API market of ~\$ 1.2 Bn

Continued trend towards outsourcing and specialization

### Market structure



### **Outsourcing trends**

- Innovative drug development processes resulting in rich pipelines across modalities
- Pharma and biotech customers to focus on core competencies, time to market and productivity
- Higher complexity of emerging peptide APIs, including shift towards chemical synthesis
- Evolving regulatory requirements and high capex requirements resulting in need for critical scale

### **CDMO** success factors

Specialized technical expertise and know-how

GMP capabilities with high delivery performance

Ability to meet evolving regulatory requirements

Continued capacity building with high utilization

Reputation and market access for pipeline building

Innovation mindset and high customer satisfaction



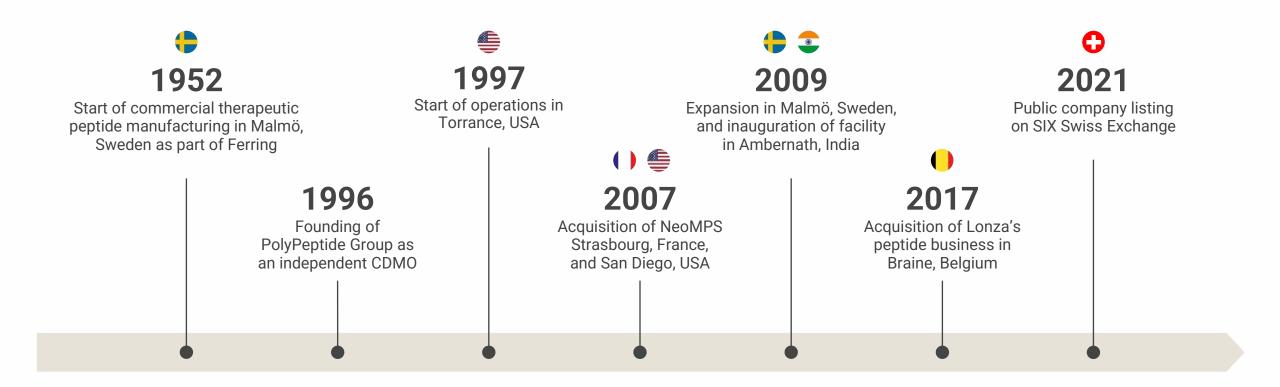
<sup>&</sup>lt;sup>1</sup>Based on a study commissioned by PolyPeptide and completed in early 2021.

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# 70+ years of experience in peptide manufacturing





## Comprehensive services for complex peptides

Supporting customers over product life cycle in three business areas

### **Custom projects**



### Pre-clinical and clinical phases I-III

Full spectrum manufacturing and associated CMC services supporting pre-clinical development.

Process designed in partnership with the customer to be scalable through the development process.



### **Contract manufacturing**



#### Commercial, after regulatory approval

Expertise in process development, manufacturing scale-up, regulatory filings, and launch preparation.

Continuous yield improvement is key.



### **Generics and cosmetics**



## Generics with non-originator customers and cosmetics

Manufacture of a range of peptidebased generics and cosmetics at commercial scale for multiple customers.



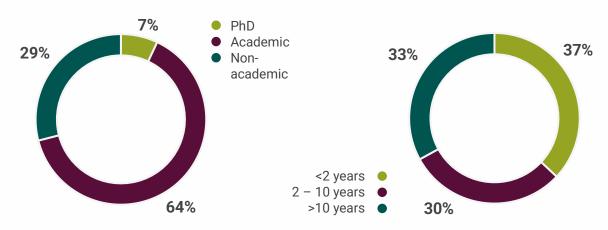


# ~1'200 employees worldwide with deep knowledge

Network of six GMP-certified sites on three continents for services across development phases

- A global market leader for innovative clinical and commercial stage peptide drug substances
- Manufacturing around half of all approved peptide API's and strong custom project pipeline
- Long-term partner for customers, from biotech start-ups to large pharmaceutical companies

## Employees by qualification and experience <sup>1</sup>



## Footprint with customer proximity in Europe, the US and India<sup>1</sup>











# **Production sites overview (1/2)**

Specialized facilities from experimental to large scale production<sup>1</sup>

<b>Malmö</b>	Braine-l'Alleud	( ) Strasbourg	Torrance	San Diego	Ambernath
PalyPept de System Control of the Co			He popular	N. Pulpheton	
Heritage of PolyPeptide.  Large facility for all peptide batch sizes and all segments.	Site with largest liquid phase synthesis in operations, major solid phase capacity expansion ongoing; facility for all peptide batch sizes and all segments.	Special focus on innovation and cosmetics. Smaller facility for most peptide segments.	Mid-sized site, also servicing personalized medicine, handling most peptide batch sizes for all business areas; lab space and pilot GMP facility to serve oligonucleotides.	Designed to efficiently handle smaller peptide batch sizes for all segments, incl. radio- labelled peptides.	Designed to handle generic peptides, manufactured mostly in mid-sized batches.
~12,800 m	~30,000 m	~6,100 m	~14,000 m	~4,800 m	~8,100 m
303 employees	410 employees	134 employees	203 employees	68 employees	78 employees
>30 years	>30 years	>20 years	>20 years	>20 years	>10 years

<sup>&</sup>lt;sup>1</sup>Status December 2022; headcount as of 30 June 2022.



## **Production sites overview (2/2)**

Specialized facilities from experimental to large scale production<sup>1</sup>

	<b>Malmö</b>	Braine-l'Alleud	Strasbourg	Torrance	San Diego	Ambernath
USFDA	8 inspections 1997, 2001, 2004, 2005, 2008, 2009, 2013, 2016	6 inspections 2001, 2005, 2009, 2012, 2014, 2017	3 inspections 2009, 2014, 2019	15 inspections 1999, 2000, 2001, 2002, 2004, 2008, 2009, 2010, 2011, 2012, 2013, 2015, 2017, 2019, 2021	14 inspections 1992, 1995, 1998, 2004, 2005, 2005, 2009, 2009, 2010, 2011, 2012, 2015, 2017, 2019	<b>2 inspections</b> 2016, 2019
Local	9 inspections 2003, 2004, 2007, 2010, 2017, 2015, 2019, 2021, 2022	6 inspections 2008, 2011, 2014, 2017, 2020, 2022	5 inspections 2006, 2010, 2014, 2017, 2020	1 inspection (State of California) 1997	2 inspections (State of California) 1990, 2002	6 inspections 2011, 2014, 2018, 2021-1, 2021-2, 2022
Other	2007, 2011, 2015, 2016, 2017, 2018  2017 2005 & 2009 2012	2001, 2005, 2009 2012, 2013, 2014, 2016 2011	2015  2017  World Health Organization 2022	2007	2011 & 2016 2005  World Health Organization 2011, 2016	2014 2012, 2016, 2019  World Health Organization  2013, 2015, 2015, 2017, 2019, 2022
ESG	SILVER 2022 ecovadis Sustainability Itating	SILVER 2022 ecovadis Sustainability Rating	2022 ecovadis Sustainability listing	SILVER 2022 ecovadis   Sattainability   Izating	COLD 2022 ecovadis Sustainability Rating	BRONZE  2022  ecovadis Sustainability Butters



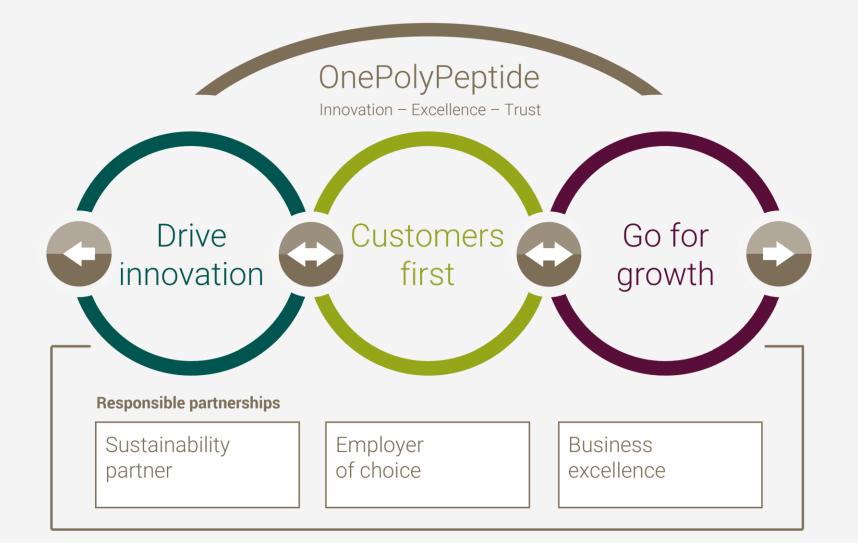


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# **Integrated strategy**

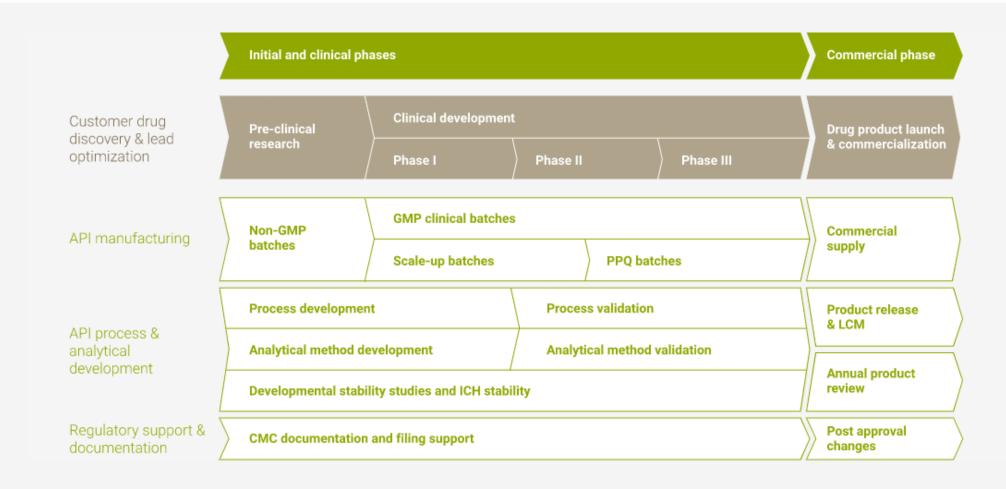




## **Customers first 1/2**



"Start here – stay here": Providing expert knowledge along product life cycle



Legend: API – Active pharmaceutical ingredient; CMC – Chemistry, manufacturing & controls; GMP – Good manufacturing practice; ICH – International council for harmonization; LCM – Life cycle management; NDA – New drug application; PPQ – Process performance qualification

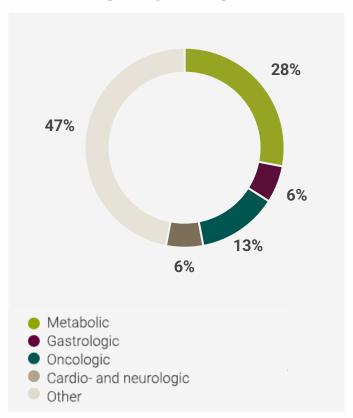


## **Customers first 2/2**



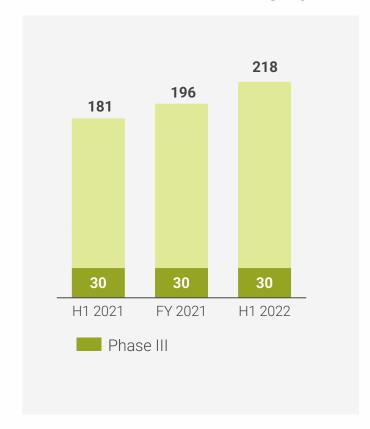


### Revenue split by therapeutical area<sup>1</sup>



<sup>&</sup>lt;sup>1</sup> Approximate split as per 30 June 2022.

## **Number of active custom projects**



### Product portfolio and projects pipeline

- Coverage across therapeutical areas
- Half of projects in fast-growing areas of metabolic disorders (incl. diabetes and obesity) and oncology
- Early-stage projects now including several oligonucleotides projects

### Revenue and volume dynamics

- Expected growth driven by late-stage phase III projects, depending on regulatory progress and market launch strategies of customers
- Currently preparing for significant volume expansion projected to outpace anticipated revenue growth

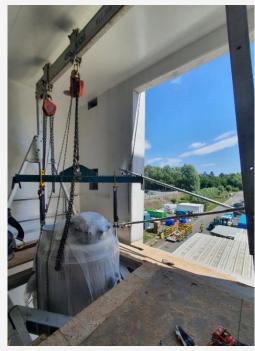


## Go for growth 1/2

Large-scale solid phase synthesis capacity in Braine-l'Alleud (Belgium)



- Finalizing large scale reactor capacity, including associated infrastructure, e.g., tank farm, automation, various preparation vessels, etc.
- Construction works largely completed, key process equipment delivered and positioned in 2022
- Planned to be in operation in 2024 for ramp-up of significant production volumes, incl. commercial agreement announced on 19 December 2022 with annual order value of around EUR 100 million











## Go for growth 2/2

Downstream infrastructure in Malmö (Sweden) and oligo cGMP facility in Torrance (California)





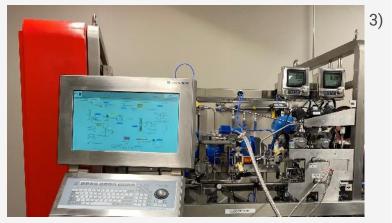
- 1) Lyophilization line
- 2) Large-scale purification in Malmö with automatized loading / unloading system







cGMP facility in Torrance for oligonucleotides, incl. 1) synthesis 2) lyophilization 3) purification





## **Drive innovation 1/2**

## Improving cost, time, quality





- Advanced monitoring automation
- Improved automated processes for peptide synthesis and purification
- In silico predictive tools
- MES



- Alternative isolation technologies
- Flow chemistry
- Mechanochemistry
- Electrochemistry



- Innovative analytics
- Particle analysis
- LIMS

#### **Culture of innovation**

- Innovation culture being embedded in the organization
- Global "Innovation and Technology" group in Strasbourg and Torrance
- Go from idea to concept all the way to deployment at scale
- Incubator for new business (services and product) ideas

#### Established external collaborations network















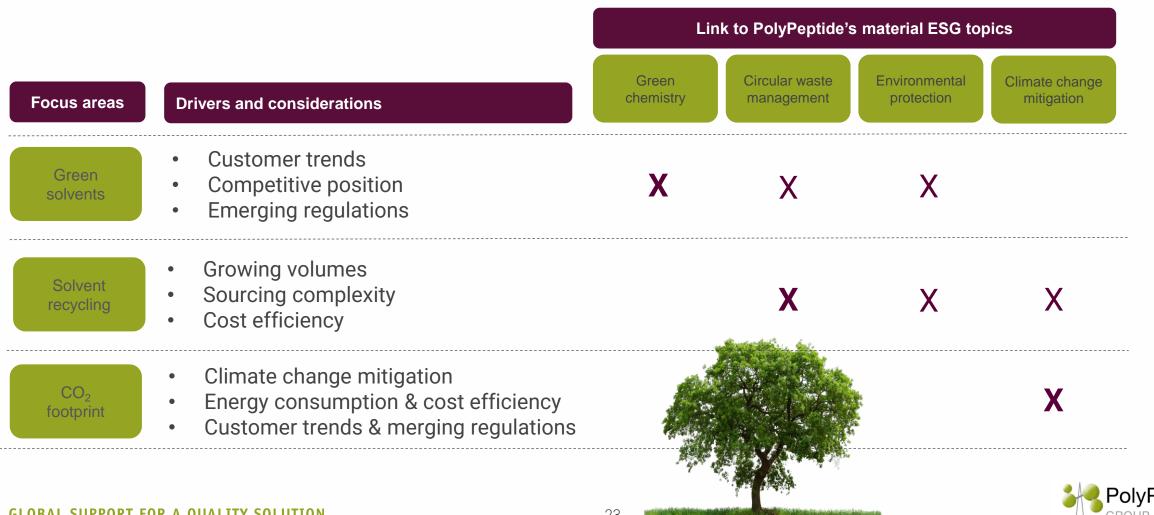




## **Drive innovation 2/2**

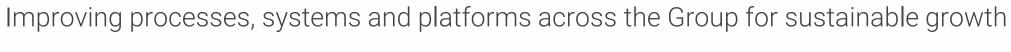


Multi-faceted green chemistry program to reduce environmental footprint



## OnePolyPeptide









Braine-l'Alleud



Strasbourg



**Torrance** 











Right balance between global integration of systems and local diversity

Sales & marketing Development, regulatory, IP

Operations

Quality

Innovation & technology

Human ressources

Legal & compliance

Finance & IT

IR, ESG, Corp. comms.

PolyPeptide Management Committee



## Responsible partnerships





Five-step materiality assessment

### **Twelve material ESG topics**

### **Sustainability partner**

- Green chemistry
- Circular waste management
- Environmental protection
- Climate change mitigation

### **Employer of choice**

- People development
- Employee health
- Diversity & inclusion

#### **Business excellence**

- Supply chain engagement
- Product quality
- Stakeholder dialogue
- Data protection
- Ethics & compliance

### Established ESG agenda 2022+

- First focus on
  - Green chemistry
  - People development
  - Supply chain engagement
- Definition of metrics and targets
- Broadening of CO<sub>2</sub> footprint assessment
- Broadening of various certification programs
- Decision on reporting standard for FY 2023



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## EBIT and result for half year

Result for the period down by 58.4% with basic EPS of € 0.31

### **Summary P&L** € m

	H1 2018	H1 2019	H1 2020	H1 2021	H1 2022
Revenue	81.6	90.7	87.8	135.1	133.7
EBITDA	20.6	22.7	18.5	39.9	26.7
margin %	25.2%	25.0%	21.1%	29.5%	20.0%
D&A	-6.8	-7.5	-8.4	-9.1	-11.2
Operating result	13.8	15.2	10.2	30.8	15.5
margin %	16.9%	16.8%	11.6%	22.8%	11.6%
Net financial result	-0.6	-0.9	-0.9	-1.3	-2.6
Income tax charges	-2.8	-2.9	-1.5	-4.9	-2.6
Result for the period	11.6	11.4	7.8	24.6	10.2
margin %	14.2%	12.6%	8.9%	18.2%	7.7%

### H1 2022 margins

- EBITDA margin of 20.0%
- EBIT margin of 11.6%
- Net profit margin of 7.7%

H1 2022 tax rate of 20.2%

Basic earnings per share (EPS) of € 0.31

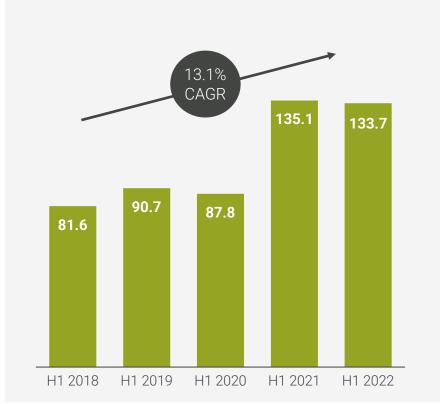


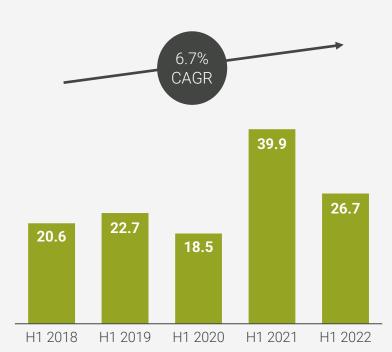
## Revenue and reported EBITDA

H1 2022 results in the context of historical trends, partly affected by the coronavirus pandemic

**Revenue** € m

**Reported EBITDA** € m





# H1 2022 revenue of € 133.7 m, YoY -1.1% or -3.3% at constant currency rates

- Original plan for broadly stable revenue
- Challenges within a more demanding market environment, with several deliveries slipping into H2

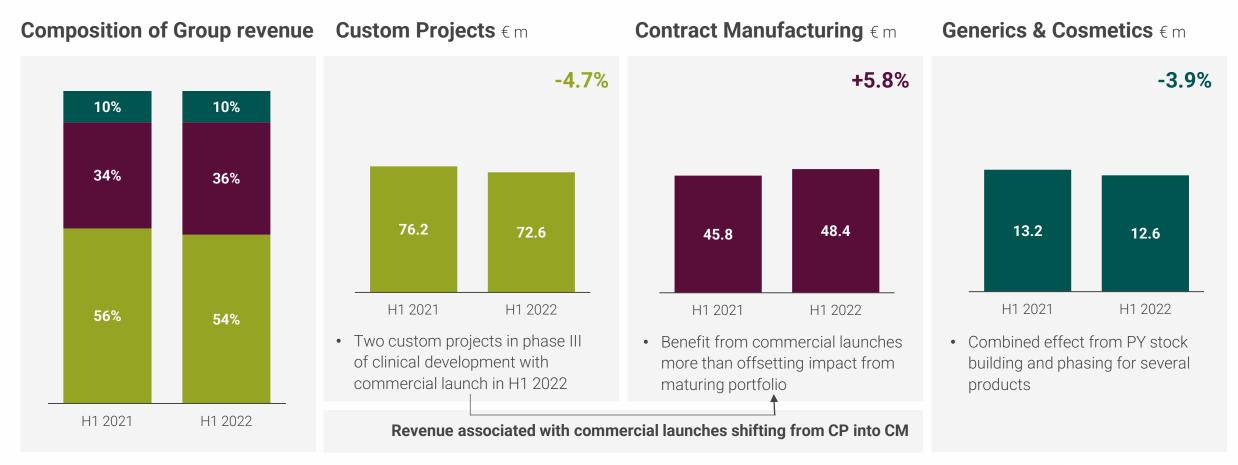
### H1 2022 EBITDA of € 26.7 m, YoY -33.1%

- Larger-than-expected drop, driven mostly by amplified inflationary pressure but also by operational challenges
- Strong PY period
- Increased personnel cost ahead of growth



# Revenue by business area

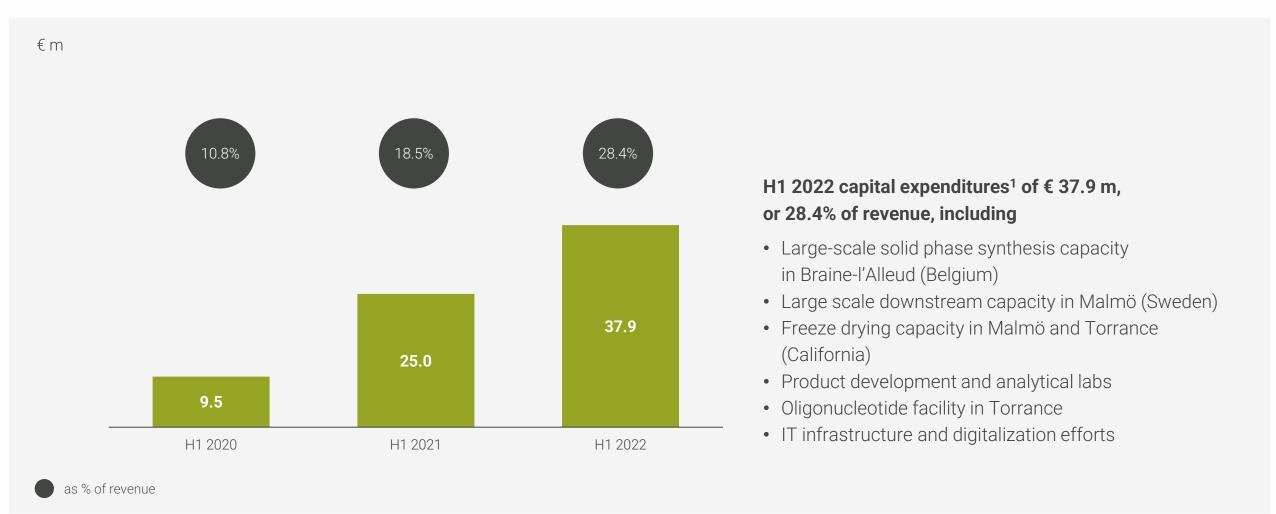
Reported Group revenue broadly stable across business areas





## **Capital expenditures**

Continued capacity expansion, but also new capabilities, digitalization and modernization



<sup>&</sup>lt;sup>1</sup> Capital expenditures defined as investments in intangible assets and property, plant and equipment capitalized during the reporting period.



## **Trading update 2 December 2022**

Several operational issues having an adverse impact

Ambitious manufacturing and delivery schedule for Q4 2022



### **Technical equipment**

Malfunctioning equipment leading to the temporary suspension of two manufacturing lines

### Manufacturing processes

Issues affecting yields and output for a limited number of products

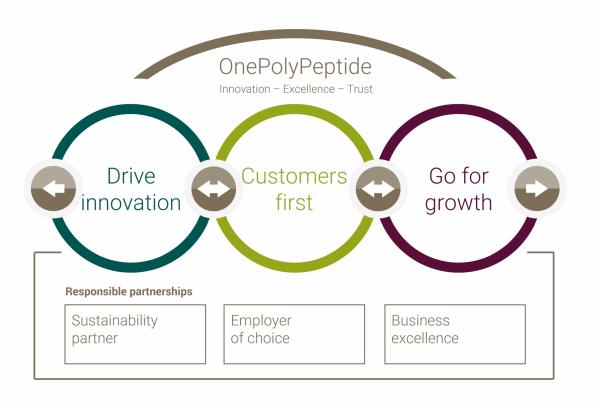


Rescheduled deliveries in coordination with customers



## Measures to restore performance

Delivery performance as key performance indicator



- Close engagement with the small number of affected customers to meet their requirements that shifted to 2023
- Series of specific measures taken to ensure high operational reliability and on-time-in-full delivery performance
- Accelerate efforts to harmonize processes and systems across the Group, consistent with the Group's integrated strategy
- Appointment of Jens Fricke as Global Director Operations and member of the Executive Committee



## Financial implications

Updated guidance for 2022

Material impact on financial result for 2022, with revenue loss of around EUR 20 m and adverse adj. EBITDA impact of around EUR 25 m

Guidance (new)

Revenue EUR ~285 m

Adj. EBITDA margin ~15%

Capex as % of Revenue >25%

Guidance (old)

Revenue growth 8-10%

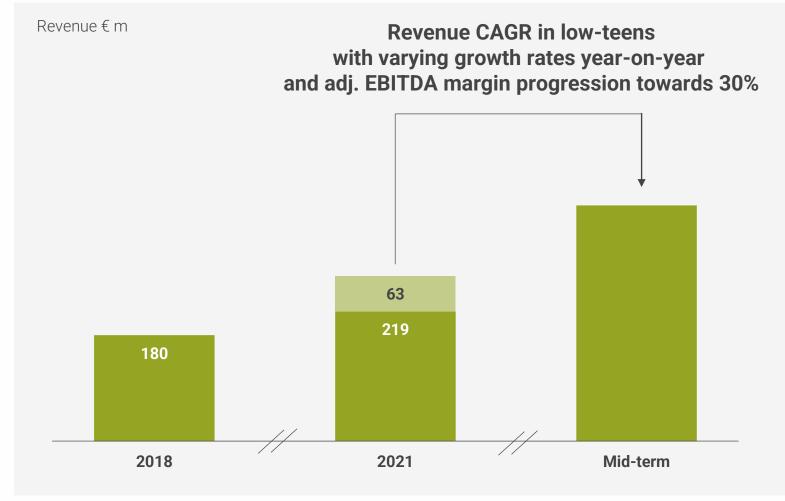
Adj. EBITDA margin 22-25%

Capex as % of Revenue >25%



## **Updated mid-term outlook**

Revenue CAGR in low-teens, expectation of varying yoy growth rates



### **Considerations**

- Structural market trends
- · Custom projects portfolio
- Uneven phasing
- Coronavirus pandemic
- Macroeconomic environment
- Geopolitical situation





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# **PMC – PolyPeptide Management Committee**



Raymond De Vré △ Belgian, CEO



Jon Holbech Rasmussen
Danish, Director Global
Development, IP and Regulatory



Neil Thompson △
British, Director Global Sales
and Marketing



**Landon Piluso** American, Director Global Quality



Jens Fricke  $\Delta$  Danish, Director Global Operations



Olivier Ludemann-Hombourger French, Director Global Innovation and Technology



Christina Del Vecchio △
Swiss / Swedish, General
Counsel



Monika Casanova German, Chief HR Officer



Jan Fuhr Miller  $\Delta$ 



Michael Stäheli Swiss, Head IR / Corporate Communications / ESG



## **Board of Directors**

## Chairman and members appointed in 2021 in context of IPO



Peter Wilden
German
Chairman



Philippe A. Weber Swiss Independent Member



Jane Salik American Member



Beat In-Albon Swiss Independent Member



Erik Schropp
Dutch
Member



Patrick Aebischer  $\Delta$ Swiss Independent Member

Chair  $\Delta$ Member O

Remuneration & nomination committee
Innovation & technology committee
Audit & risk committee

The Board of Directors is responsible for PolyPeptide's overall direction and oversight of management, and holds the ultimate decision-making authority, with the exception of matters reserved for shareholders.

Visit our website or the section Corporate Governance in the Annual Report 2021 for the detailed CV's

polypeptide.com/
report.polypeptide.com/ar/21/board-of-directors/



## IR contact and financial calendar

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#### **Share information**

PolyPeptide Group AG has been listed on the Swiss Stock Exchange (SIX) since 29 April 2021 under the symbol SIX: PPGN, Swiss security number 111 076 085 and ISIN CH111 076 085

### **Share register**

areg.ch ag

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Phone: +41 (0) 62 209 16 60 / info@areq.ch

#### Selected events in 2023

12.01.2023 Baader Helvea Swiss Equities Conference, Bad Ragaz, Switzerland

13.01.2023 Octavian Swiss Seminar, Flims, Switzerland

### **Corporate events in 2023**

14.03.2023 FY 2022 results

12.04.2023 AGM 2023

15.08.2023 HY 2023 results

Visit our website for the detailed event calendar polypeptide.com



## **Analyst coverage**

BANK OF AMERICA

Currently suspended



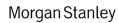
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