Biotest AG

Nine Month 2023 Results
Conference call

November 2, 2023

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Disclaimer

- This document contains forward-looking statements on overall economic development as well as on the business, earnings, financial and asset situation of Biotest AG and its subsidiaries. These statements are based on current plans, estimates, forecasts and expectations of the company and thus are subject to risks and elements of uncertainty that could result in deviation of actual developments from expected developments.
- The forward-looking statements are only valid at the time of publication. Biotest does not intend to update the forward-looking statements and assumes no obligation to do so.
- All comparative figures relate to the corresponding last year´s period, unless stated otherwise.

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Biotest Group – Highlights Q1-Q3 2023

- **Technology Transfer and Licensing** agreement and **Master Distribution** agreement signed between Biotest AG and Grifols S.A. on 31 May 2023 with effect from 1 January 2023
- Expansion of **EU plasma collection centres** continued: now 36 centres in Germany, Hungary and Czech Republic
- **R&D** pipeline projects are progressing
- **Sales** Q1-Q3 2023: € 500.3 million, +38.7% vs. Q1-Q3 2022
  EBIT Q1-Q3 2023: € 125.4 million vs. € -19 million in Q1-Q3 2022
  EBITDA Q1-Q3 2023: € 152.2 million vs. € 7.8 million in Q1-Q3 2022

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Business update

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Yimmugo® - Launch in Germany followed by other markets…

Yimmugo®

	Germany:	First Sales in November 2022
	Austria:	Marketing authorization in December 2022
	UK:	Marketing authorization in August 2023
	EU:	Registration process in several countries initiated
	USA:	US Food and Drug Administration (FDA) accepts BLA application in August 2023

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Acceleration and advancing Biotest product portfolio

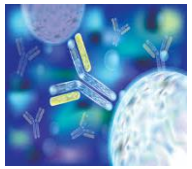
Acceleration of Fibrinogen and Trimodulin development:

- Acceleration of clinical studies
  - Fibrinogen „AdFirst study“: last patient in end of Sept. 2023
  - Trimodulin: „TRICOVID”; “ESsCAPE study”
- Commissioning of fractionation plant Biotest Next level for Fibrinogen & Trimodulin (validation, conformance lots, stability study, submission of dossier)

Preparations ongoing to enter the US market:

- FDA inspection of Biotest Next Level ongoing
- Preparation of production of Yimmugo batches for the US market
- Acceptance of Biologic License Application (BLA) and ongoing clinical trial of Fibrinogen
- Distribution partner in the US will be Grifols

Development Projects – General Overview

Product	Phase I	Phase II	Phase III	Trial Status	Clinical Trial Report
IgG Next Generation			PID	done	done
			ITP	done	done
Fibrinogen		congenital fibrinogen deficiency (984)		done	done
			Acq. fibrinogen def. ADFIRST	ongoing	
Trimodulin		Covid-19 ESsCOVID		done	done
			sCAP (996) ESsCAPE Trimodulin Phase III	ongoing	
			Covid-19 (1001) TRICOVID Trimodulin Phase III	ongoing	

PID=Primary Immune Deficiency; ITP=Idiopathic Thrombocytopenic Purpura;
sCAP=severe community acquired pneumonia

Congenital and Acquired Fibrinogen Phase III clinical trials

Congenital FD[1]

Phase I/III study: Largest clinical trial in congenital fibrinogen deficiency worldwide
Treatment of adults and children

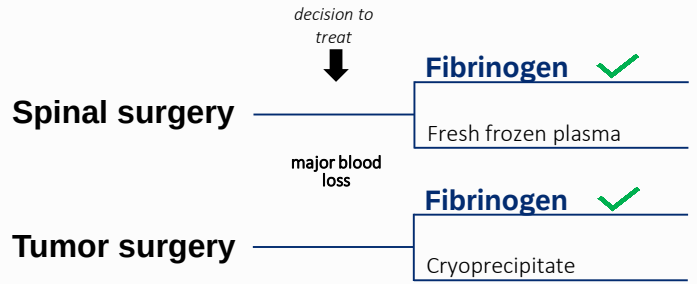
- Results confirm high expectations regarding efficacy and safety…
- Study completed ✓

Acquired FD[1]

ADFIRST

Phase III study in **major spinal surgery** and **pseudomyxoma peritonei (tumor) surgery**

- Interim analysis (Mar ’23) confirms planned patient number
- **Last patient recruited and treated** end of Sept. ´23; in total 200 evaluable patients
- **Clinical Trial report** to be finalised by mid 2024



[1] *FD: Fibrinogen deficiency*

Two Phase III Trimodulin trials ongoing

TRICOVID Trimodulin Phase III *(Start 2022)*

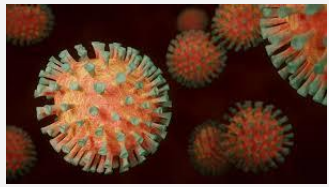
ESsCAPE Trimodulin Phase III *(Start 2022)*

Randomized, placebo-controlled, double-blind, multi-center, phase III trials investigating the efficacy and safety of Trimodulin in adult hospitalized patients

COVID-19 patients

334 subjects

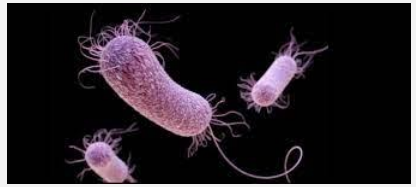
- Patients on low-flow oxygen, high-flow oxygen, NIV
- Patients with early systemic inflammation
- Extension to broaden indication under evaluation



sCAP patients

480-590 subjects

- Patients on invasive mechanical ventilation (within <12h)
- Patients with inflammation (CRP >70 mg/L)
- SARS-CoV-2 negative
- 136 study centres in 20 countries planed



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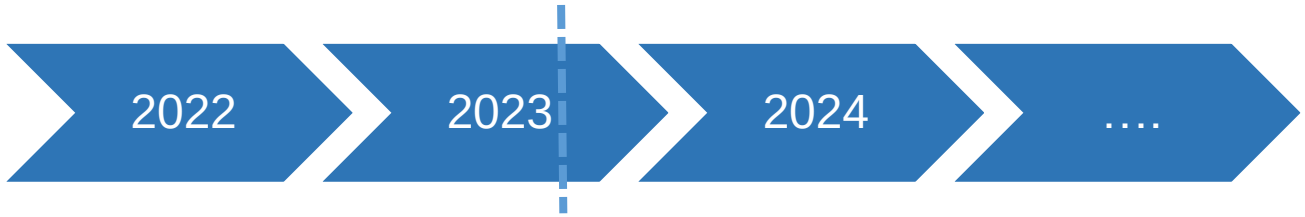
Biotest Next Level – **Yimmugo®**

Ramp-up manufacturing of Yimmugo ®



- Starting in 2022, the amount of **Yimmugo®** produced is to be increased from 1 batch up to 6-7 batches per week
- **Target:** produce more batches more efficiently
- **Challenge**: - Recruiting of skilled and trained personal in time
  - Sufficient availability of external service providers regarding automation

Biotest Next Level – Fibrinogen, Albumin & Trimodulin

Continuation of commissioning of Biotest Next Level plant for Fibrinogen, Albumin & Trimodulin

- Commissioning of plant for purification of Fibrinogen & Trimodulin started
- Validation of processes according to GMP*
- Comparability with the product in clinical studies must be demonstrated
- Commissioning of the manufacturing plant for Albumin is currently in preparation.
- Target is to achieve the status for the plant ready for production for Albumin end of the year 2024.

** GMP = Good Manufacturing Practice*

Expansion of plasma collection centres – incl. access to US Plasma

Europe: 36 plasma collection centres

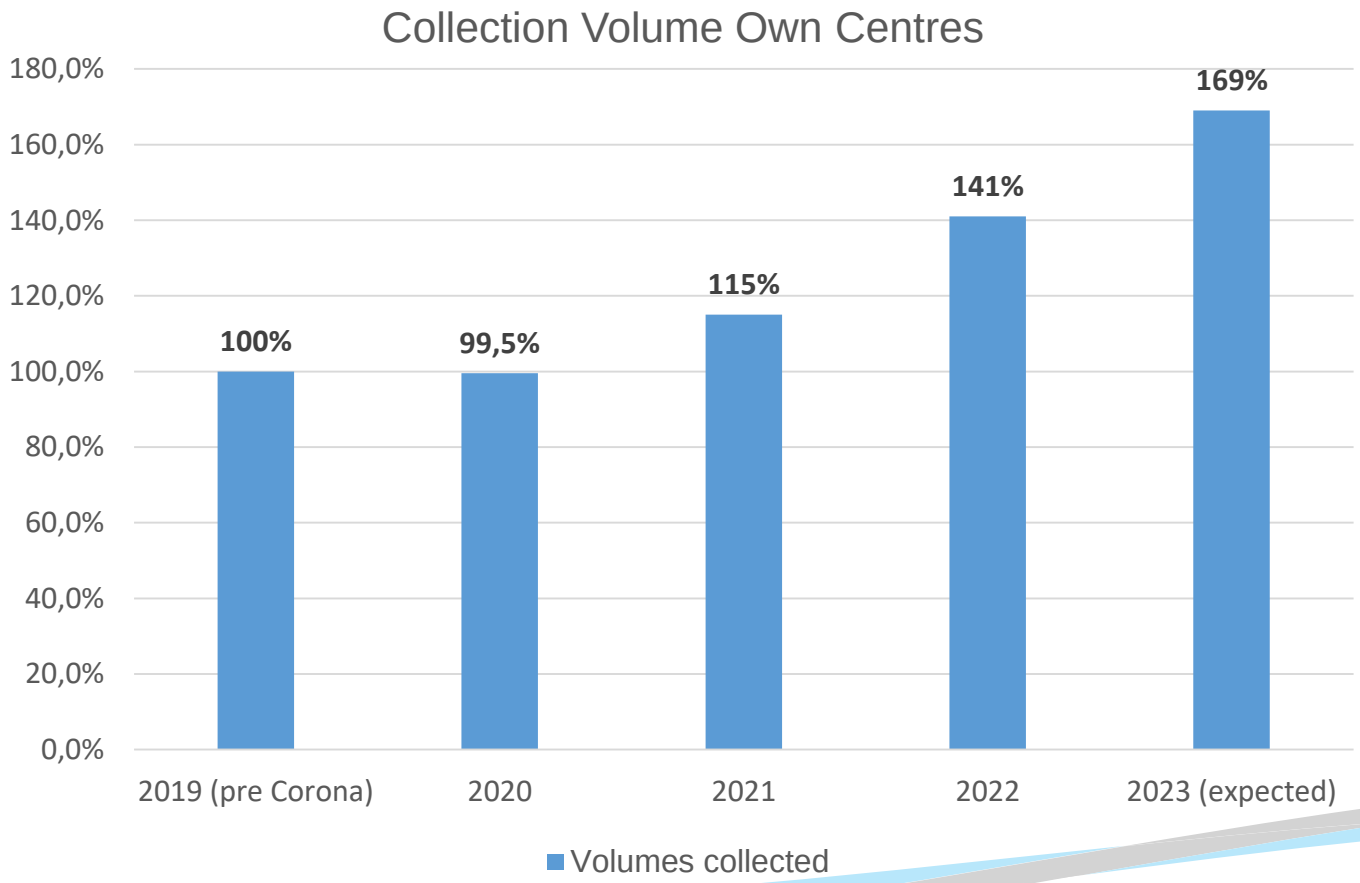
- 2 new centres in **2023** in **Germany** and **Hungary**
- 7 new centres in 2022 in Czech Republic

Access to US Plasma

- Long-term supply contracts with **Grifols** and other third parties

Biotest Plasma Collection

Biotest Plasma collection volume: ~ 70% higher than before Corona (2019)



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Cooperation and integration of Biotest and Grifols S.A.

Current focus on cooperation & intergration

- **Acceleration of Fibrinogen & Trimodulin development**, intensified exchange in the areas of commissioning, quality, R&D, FDA inspection support, further indications and process optimisations identified
- **Technology Transfer and Licensing agreement** (TTLA) signed between Biotest AG and Grifols S.A. on 31 May 2023 with effect from 1 January 2023
- **Master Distribution agreement** signed on May 31 2023:
  joint commercial reach through distribtion collaboration in existing markets:
  „One face to the customer“

GRIFOLS

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Technology Transfer and License Agreement with Grifols S.A.

1. Technology Transfer and License Agreement

- For this, know-how for the development and manufacturing of Yimmugo®, Trimodulin and Fibrinogen has been and will be disclosed to Grifols with remuneration on three levels

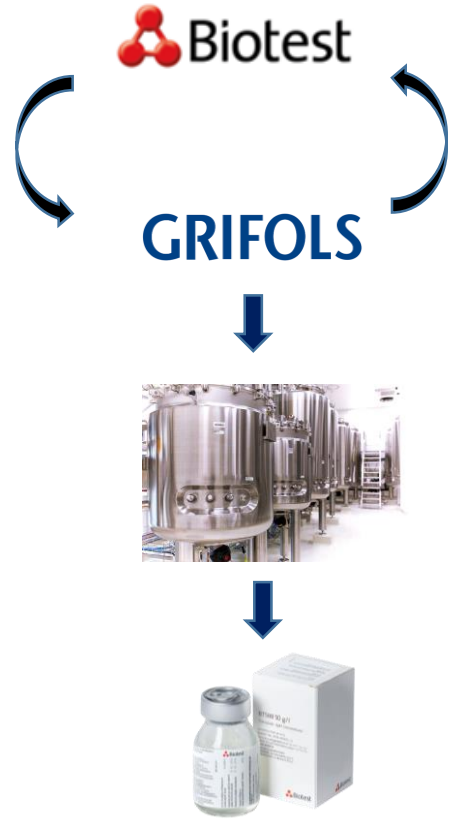
    1. For the **Technology Disclosure** (6 technology components) Biotest will receive a three-digit million amount
    2. For **acceleration & completion of the R&D projects** Biotest will receive a three-digit million amount

    For 1) and 2) Biotest will receive **in total** a mid three-digit million amount in several installments between 2023 and 2026

    3. Grifols will pay Biotest **royalties** in the high single-digit percentage range of net sales of the licensed products for a period of 30 years from the date of commercialization

- Grifols has been granted a semi-exclusive license to manufacture and market three products - Yimmugo®, Trimodulin and Fibrinogen - worldwide

➢ **Total valuation: € 1.1 – 1.6 billion**



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Master Distribution Agreement between Biotest and Grifols S.A.

2. Master Distribution Agreement

Biotest and Grifols will join forces in core markets to strengthen their joint position also by securing plasma supply, optimized manufacturing capacity and a strong research pipeline.

Target: the availability of leading immunoglobulins should be ensured!

Current Focus

- Optimise distribution structures in existing markets
  - e.g. by selling 5 Biotest sales companies (Spain, Italy, Brasil, UK and France) to Grifols and thereby obtaining „one face to the customer“
  - Preparations for Germany for „one face to customer“ ongoing
- Exploit additional business opportunities through coordinated collaboration between the two companies

Financials Q1-Q3 2023

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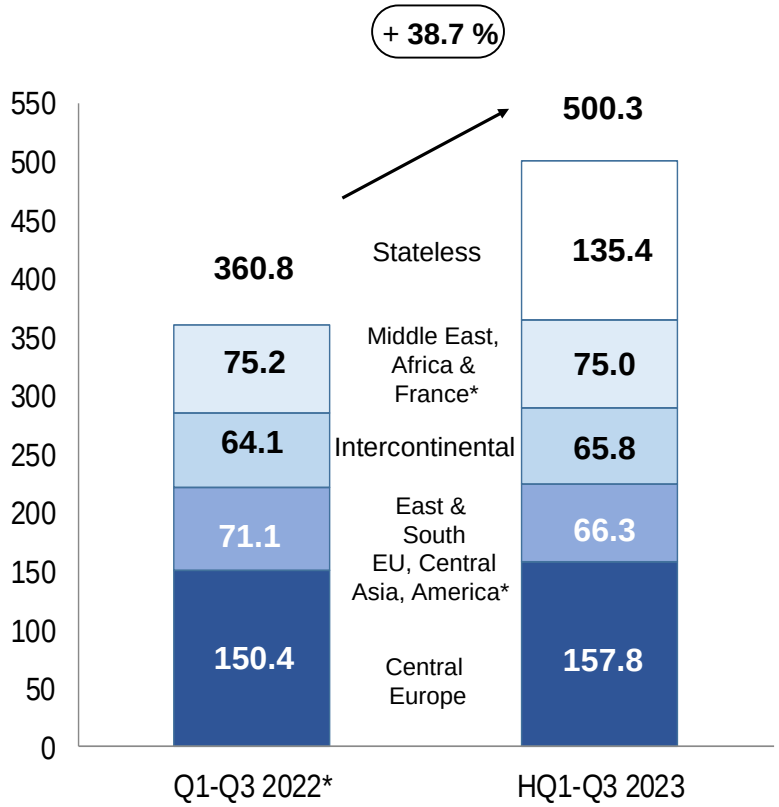
Income statement
(€ million)

	Q1-Q3 2022	Q1-Q3 2023	Dev. in %
Sales	**360.8**	**500.3**	38.7
thereof: Therapy	317.8	464.1	46.0
Plasma & Services	38.5	31.3	- 18.7
Other Segments	4.5	4.9	8.9
COGs and operating expenses	-379.8	-374.9	1,3
Operating profit (EBIT)	**- 19.0**	**125.4**	> 100
Financial result, taxes	-15.2	-37.0	- 43,4
Earnings after tax (EAT) Biotest Group	**-34.2**	**88.4**	> 100

Sales development of sales regions
(€ million)



*: The prior-year figures have been adjusted in line with the definition of the sales regions in 2023

- **Central Europe**: +4.9%, whereas Germany contributed a large part also with the sales of Yimmugo® of € 16.1 million

- **Stateless revenue:** € 135.4 million relate to revenue generated under Technology Transfer and Licensing Agreement with Grifols, S.A., Barcelona

EBIT reported and adjusted
(€ million)

	Q1-Q3 2022	Q1-Q3 2023	Dev. in %
EBIT reported	**- 19.0**	**125.4**	> 100
Expenses for Biotest Next Level	63.9	-	- 100.0
Earnings from technology disclosure and development services	-	-112.3	-
Disposal gain (5 subsidiaries)	-	-23.1	
EBIT adjusted	**44.9**	**-10.0**	>-100

- EBIT in Q1-Q3 2023 amounted to € 125.4 million and includes expenses of € 67.8 million for the ramp up of the production in the Biotest Next Level facility (prior-year period: € 63.9 million). With the launch of Yimmugo® in November 2022 in Germany, the Biotest management considers this project as completed and therefore the expenses for Biotest Next level are no longer recognised as exceptional items.

- In the 2023 financial year the exceptional items relate to the revenue from technology disclosure and development services charged to Grifols S.A. related to the TTLA and the gain on the disposal of five Biotest subsidiaries.

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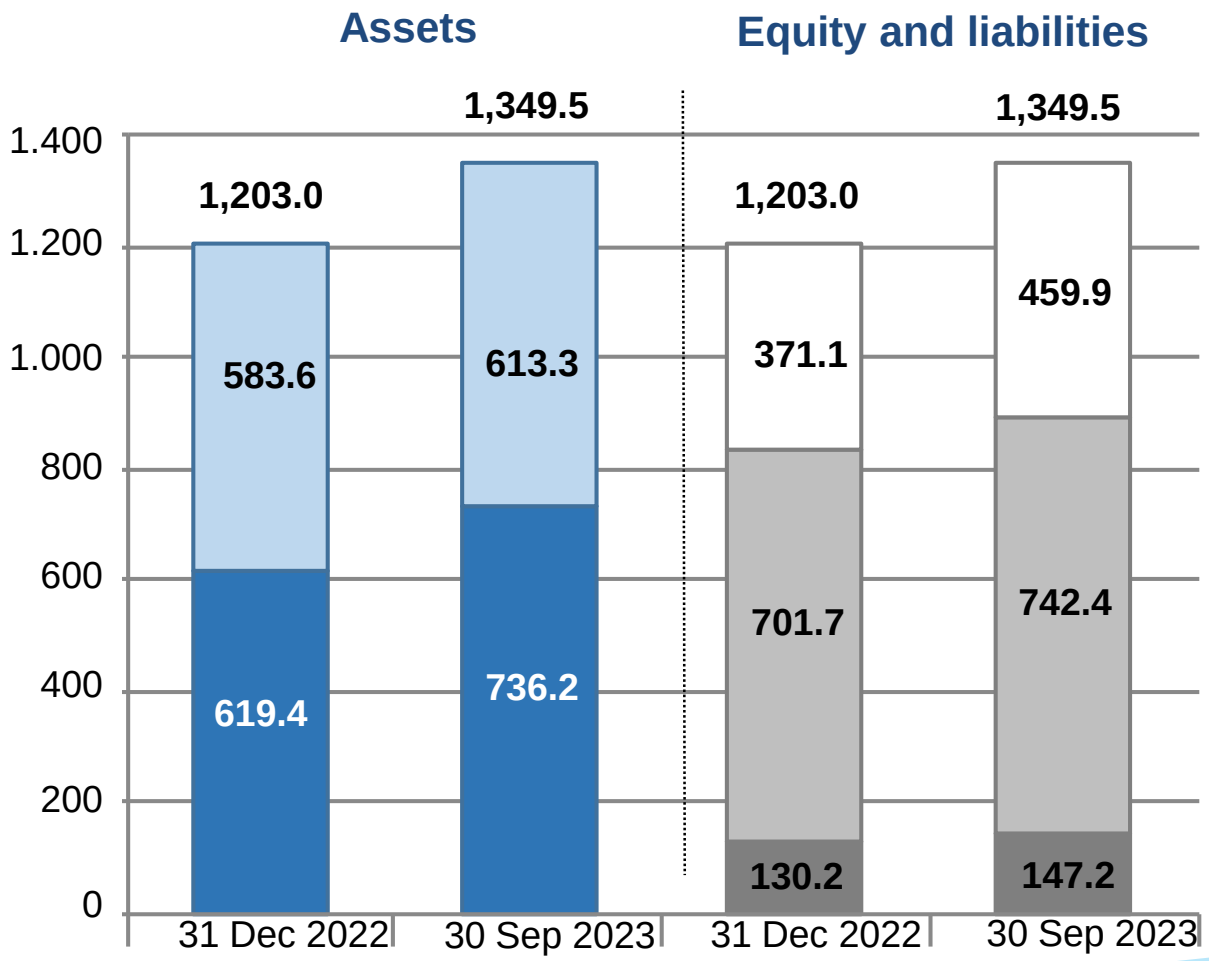
Balance Sheet as of 30 September 2023
(€ million)



Net debt as of 30 Sep. 2023: € 602 m

Equity ratio as of 30 Sep. 2023: 34,1 %

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Cash flow from operating activities
January – September 2023 (€ million)

	Q1-Q3 2022	Q1-Q3 2023
Operating CF before Changes in Working Capital	**8.8**	**130.4**
Cashflow from Changes in Working Capital	-13.7	-179.3
thereof: Changes Inventories	-24.4	-79.5
Changes Trade Receivables	17.3	-94.3
Other Changes	-6.6	-5.5
Interest & Tax expense	-11.8	-20,1
Cashflow from Operating Activities	**-16.8**	**-69.0**

Guidance 2023

Guidance 2023:

Revenue: The Executive Board continues to aim for a mid-single digit percentage increase in revenue for 2023 vs. 2022, excluding the revenue from the Technology Transfer and Licensing agreement.

EBIT: After the conclusion of various agreements , including the Technology Transfer and Licensing agreement with Grifols S.A, Barcelona, Spain, and the sale of commercial affiliates in 5 countries to Grifols, the Executive Board raised the EBIT guidance in October for the year 2023 from a level that may exceed € 100 million to € 130-170 million. A more precise determination depends on the revenue and earnings recognition of the final project milestones.

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Summary

- R&D Fibrinogen and Trimodulin projects progressing well
- High R&D investments in 2023
- After various agreements with Grifols, S.A. further collaboration opportunities with Grifols are progressing well





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All the Best

Effective as of Jan 1st, 2024:

Good luck !

Ainhoa Mendizabal

Jörg Schüttrumpf — **Peter Janssen**

CSO **CFO** **CEO**

Financial calendar 2023 and contact

Financial calendar 2023

02 Nov 2023	Q1-Q3 Report
28 Mar 2024	FY 2023

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