Biotest AG

Financial Year 2022 Results

Hybrid Meeting

March 23, 2023

Biotest

From Nature for Life

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 FY 2022

- Marketing authorization and launch of **Yimmugo®** in Nov. 2022
- Expansion of **EU plasma collection centres** continued:
  now 34 centres in Germany, Hungary and Czech Republic
- **R&D** pipeline projects are progressing
- **Sales** FY 2022: € 516.1 million, +0.1% vs. FY 2021;
  Adjusted EBIT FY 2022: € 60.7 million,
- New Management Board members appointed: Dr. Jörg Schüttrumpf (CSO), Peter Janssen (COO) and Ainhoa Mendizabal (CFO)

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Business update

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Biotest Group – Yimmugo® Launch

IgG Next Generation since Nov. 2022:

Yimmugo®

Approved in Germany and Austria
- for immunodeficiencies and immunomodulation

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Yimmugo®: Well-tolerated with a favorable safety profile

Across the pivotal, multicentre Phase III trials in patients with PID or ITP, **Yimmugo infusion rates up to 8 mL/kg/h were well tolerated**, illustrating that the individualised approach was associated with a good adaptation to high infusion rates[1].

- **Yimmugo®** shows low rates of infusion related adverse events[1,2]
- **Yimmugo®** has a physiological osmolality[3]
- **Yimmugo®** shows no thrombogenic activity[4]
- **Yimmugo®** has a low level of anti-complementary activity[4]
- **Yimmugo®** is sugar-free[3]

ITP, Immune thrombocytopenia; PID, Primary immunodeficiency disorder.

1. *Krivan et al. Efficacy, safety and pharmacokinetics of a new 10% normal human immunoglobulin for intravenous infusion, BT595, in children and adults with primary immunodeficiency disease; Vox Sanguinis.*
2. *Safety, Efficacy and safety of Yimmugo® (10% IVIg) in adult patients with chronic immune thrombocytopenia (ITP), Transfusion medicine. Manuscript in print.*
3. *Yimmugo® SmPC.*
4. *Maneg et al. Biochemical characterization and stability of IgG Next Generation (BT595) / Yimmugo® (10 % IVIG preparation) from manufacturing preserving total immunoglobulin potential of human blood plasma. Manuscript in preparation.*

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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:	Submission in March 2023
	Ungarn:	No marketing authorization required; sales with german packaging material
	Saudi Arabia:	License agreement
	USA:	BLA planed…

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Acceleration and advancing Biotest product portfolio

Acceleration of Fibrinogen and Trimodulin development:

- Acceleration of clinical studies (Fibrinogen „AdFirst study“; 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:

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

Cooperation and integration with Grifols S.A.

Ongoing cooperation activities with Grifols S.A.

GRIFOLS

- Takeover completed as of April, 26th, 2022
- Encouragement to accelerate Fibrinogen & Trimodulin development, intensified exchange in the areas of commissioning, quality, R&D, FDA inspection support, further indications and process optimisations identified
- Partnership with Grifols enabling future long-term securing of plasma supply
- Access to US markets for Biotest products
- Value increase through scalability of production volumes for Fibrinogen, Yimmugo and Trimodulin

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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
- **Challenge**: Recruiting of skilled and trained personal in time

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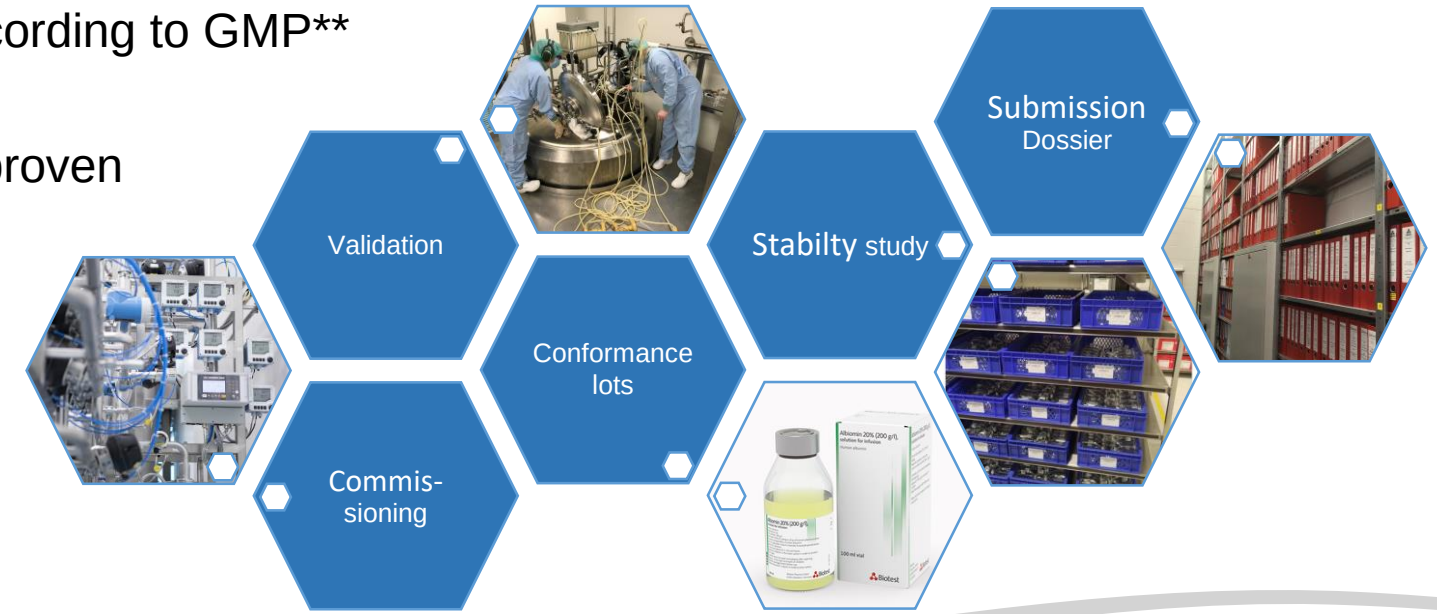
Biotest Next Level – Fibrinogen & Trimodulin

Continue commissioning of BNL for Fibrinogen & Trimodulin:

- Up-scaled* equipment is put into operation
- Processes will be validated according to GMP**
- Comparability to product in clinical studies needs to be proven

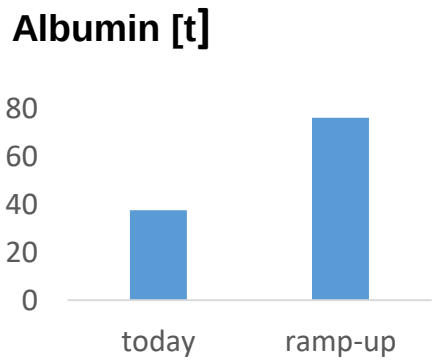


*: from Clinical Manufacturing Plant;
**: GMP = Good Manufacturing Practise

Biotest Next Level – Human Albumin

Capacity increase of Human Albumin

- Along with Yimmugo® production the capacity of Albumin production has been increased
- Additional purification line for Human Albumin will be established
- Additional attractive markets (e.g. USA and China) can be addressed



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Market Dynamics & Plasma

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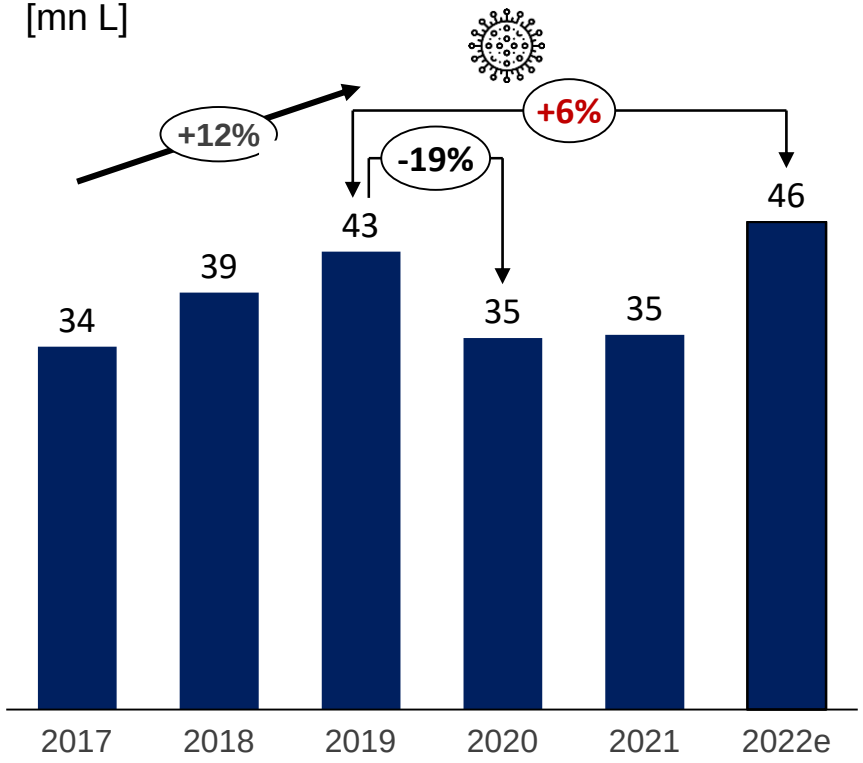
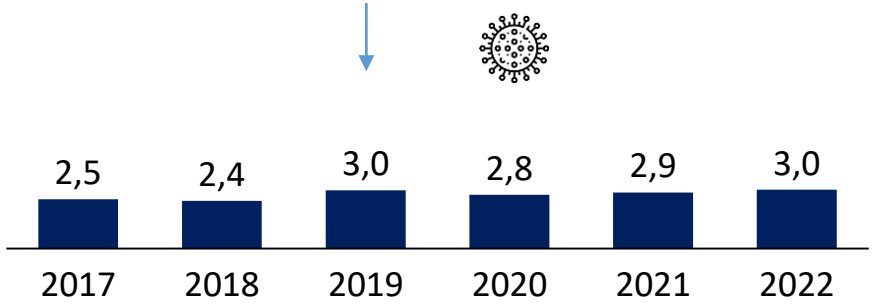
US plasma collections increase again… EU plasma collection rising slowly…

US Plasma Collections
[mn L]



Source: Market and Pricing Insights FC based on PPTA, MRB (2021), RBC Capital Markets analysis

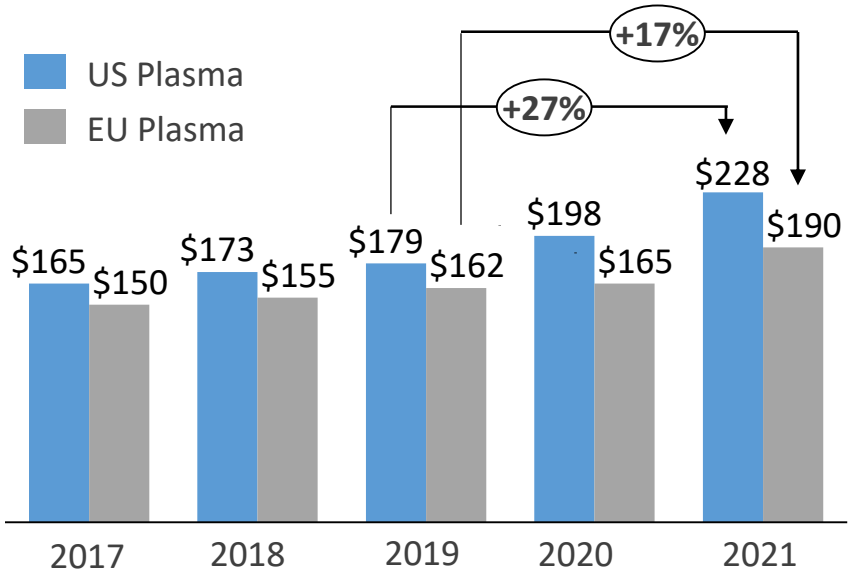
EU Plasma Collections
[mn L]



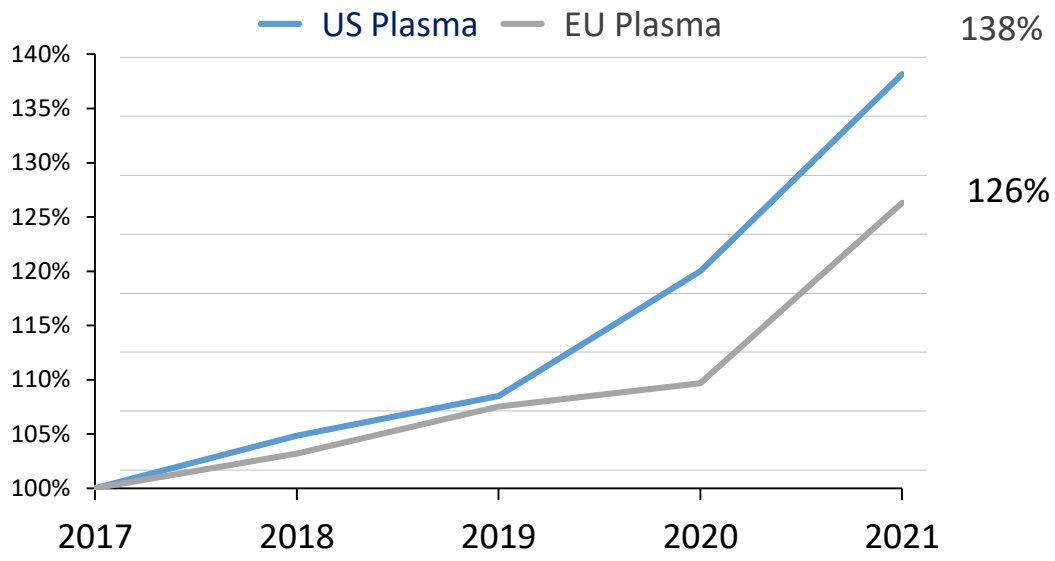
Source: Market and Pricing Insights based on PPTA

…and increase of prices accelerated during the pandemic overall

Source Plasma Price Development [USD]



Source Plasma Price Index [USD], base 2017



- Global plasma prices increased significantly during pandemic
- **Plasma costs are expected to remain high,** due to inflation, rising energy costs, higher wages, donor compensation and continued high demand for plasma
- Increase in 2022 and 2023 will go (at least) with inflation

Source: Prices according to Marketing Research Bureau (IBPN 04/18, 04/19, 03/20, 03/21, 02/22)

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

Europe: 34 plasma collection centres

- 7 new centres in 2022 **in Czech Republic**:
  Kolín, Mladá Boleslav, Ostrava, Pelhřimov, Prag, Uherský Brod and Zlin

Access to US Plasma

- Establishment of own centres
- Long-term supply contracts with **Grifols**

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Expansion of plasma collection centres ongoing…

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Financials FY 2022

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Income statement
(€ million)

	FY 2021	FY 2022	Dev. in %
Sales	**515.6**	**516.1**	0.1
thereof: Therapy	461.6	459.5	- 0.4
Plasma & Services	46.7	50.3	+ 7.8
Other Segments	7.3	6.2	- 15.8
COGs and operating expenses	-562.7	-532.7	5,3
Operating profit (EBIT)	**-47.1**	**-16.6**	**+ 64.7**
Financial result, taxes	-16.3	-15.1	-0.1
Earnings after tax (EAT) Biotest Group	**-63.4**	**-31.7**	**31.7**

Delivering on Guidance for FY 2022

	Guidance FY 2022	*FY 2022*	
Sustainable revenue growth			
Revenue Biotest	€ 465 – 515 m	€ 516 m	
Operating Profit/ loss (EBIT)			
EBIT Biotest	€ - (20-25) m	€ -16 m	**+ 64%** 

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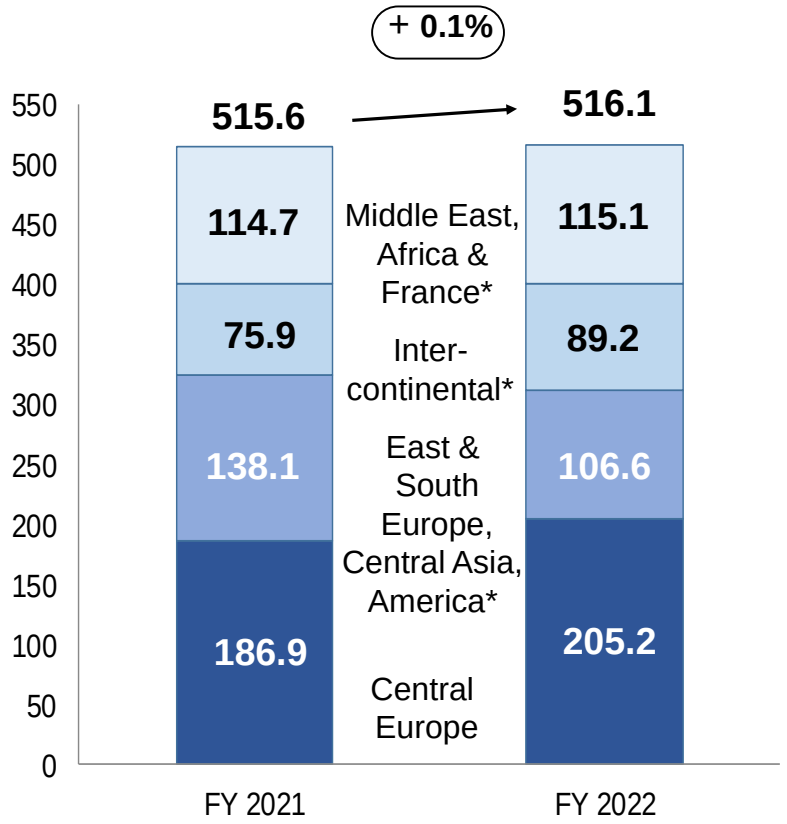
Sales development of sales regions
(€ million)



*: The prior-year figures have been adjusted in line with the definition of the sales regions in 2022

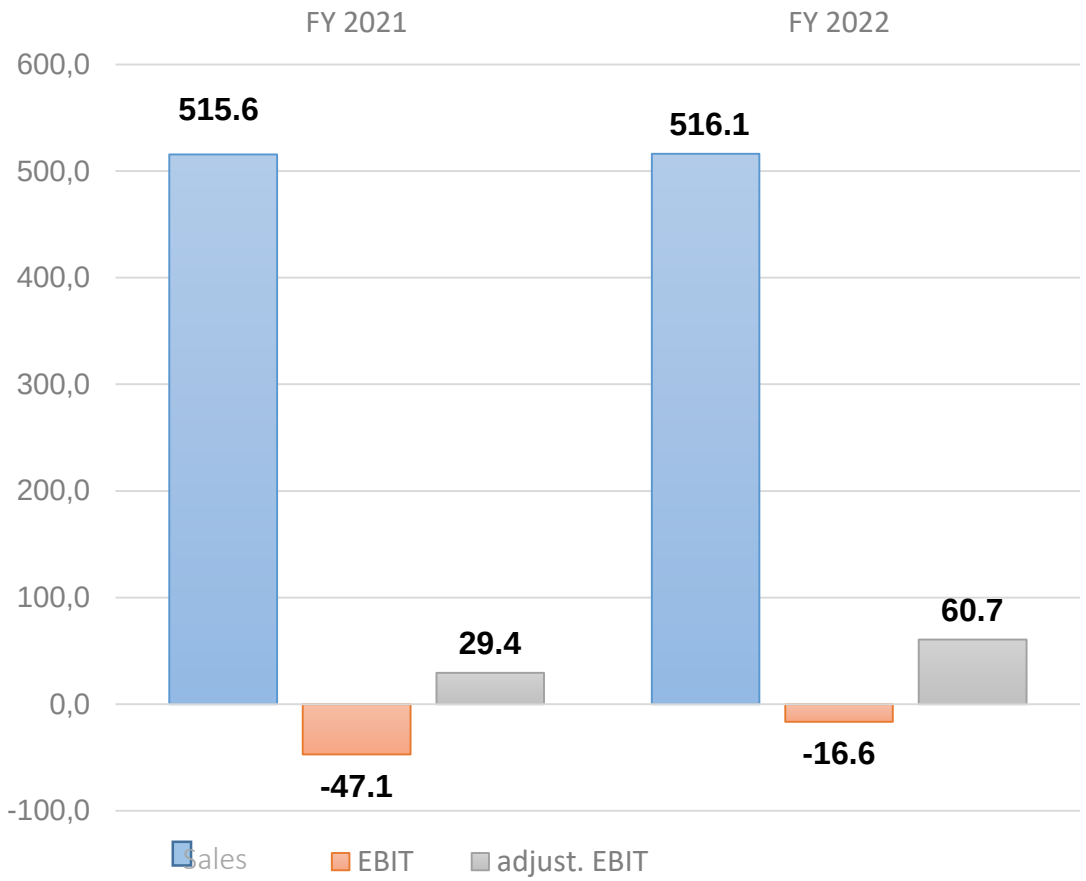
- **Central Europe**: +9.8%, wheras Germany contributed a large part with increased sales volumes of Intratect® and first sales of Yimmugo®
- **Intercontinental region*:** +17.5% with high sales volumes in UK with Intratect ®

EBIT reported and adjusted
(€ million)

	FY 2021	FY 2022	Dev. in %
EBIT reported	**-47.1**	**-16.6**	**+64.7**
Biotest Next Level facility costs	39.0	40.7	+4.4
Biotest Next Level R&D costs*	37.5	36.6	-2.3
EBIT adjusted	**29.4**	**60.7**	**>100**

**: R&D costs for BNL development projects (Fibrinogen, Trimodulin, Yimmugo, IgG Next Gen)*

FY 2022 at a glance



- **Sales increase** in **Central Europe** and **Intercontinental** compared to the previous year
- FY 2022 EBIT +64.7% higher vs. FY 2021 EBIT
- FY 2022 EBIT includes **Biotest Next Level expenses of € 77.3 m** (FY 2021: € 76.5 m)
- **FY 2022 adjusted EBIT: € 60.7 m** (> 100%) vs. FY 2021 adjusted EBIT of € 29.4 m

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Biotest Next Level costs in FY 2022

1. **BNL facility costs**: **€ 40.7 million**;
   - Facility costs (energy, building costs, maintenance, etc.)
   - Depreciation
   - Personnel costs (for ramp-up, commissioning etc.)
   - Project administration

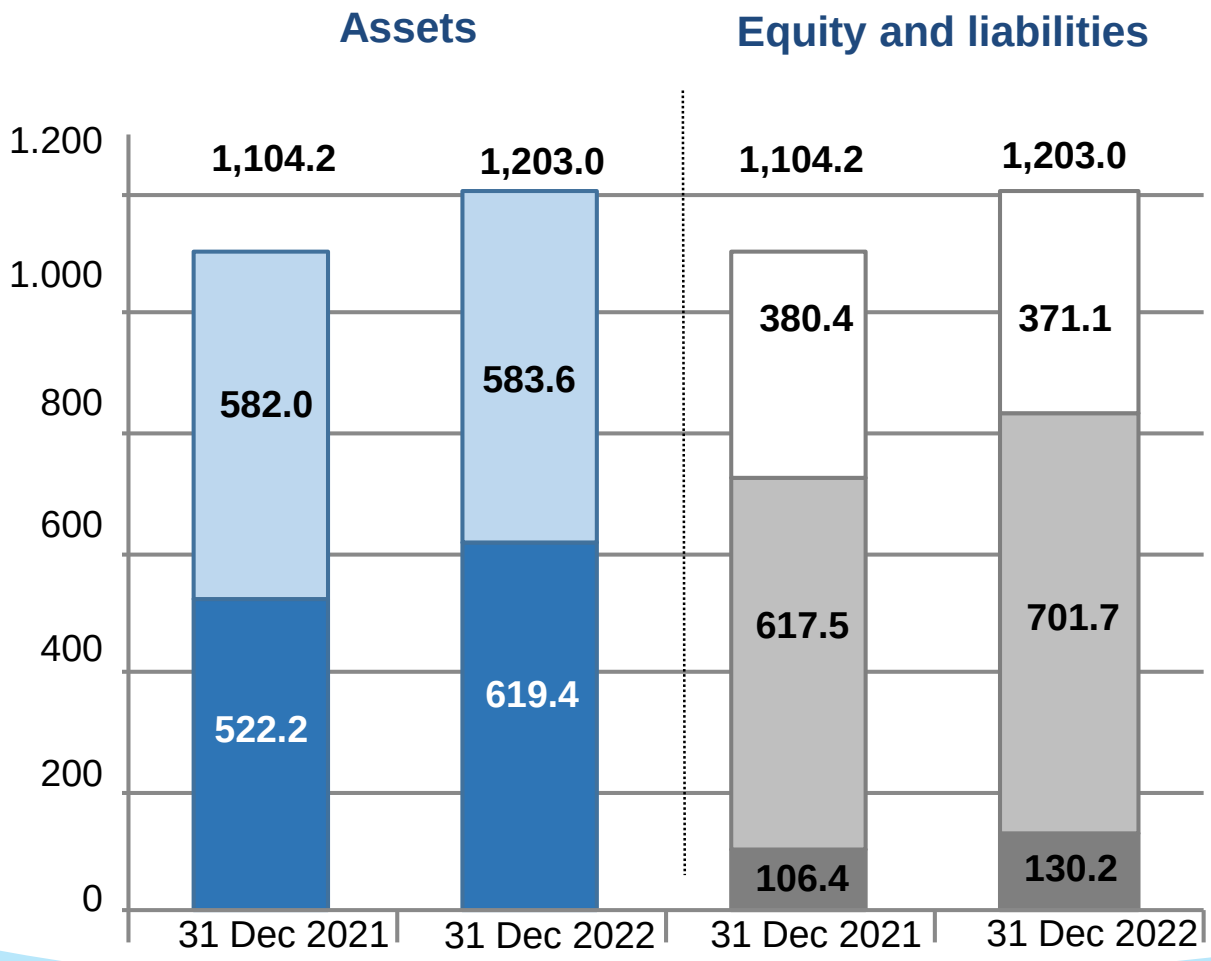
2. **BNL R&D** costs in total: **€ 36.6 million**; thereof:
   - € 6.9 million - IgG Next Generation
   - € 18.4 million - Trimodulin (IgM concentrate)
   - € 11.3 million - Fibrinogen

Total BNL costs: **€ 77.3 million** in FY 2022

Ramp-up of BNL:
- Yimmugo: routine production started in May 2022
- For Trimodulin and Fibrinogen: the commissioning of the production lines is being prepared

Acceleration
of phase III R&D projects Trimodulin and Fibrinogen

Statement of financial position as of 31 December 2022
(€ million)



Net debt as of 31 Dec. 2022:
€ 502 m

Equity ratio as of 31 Dec. 2022:
30.8%

Cash flow from operating activities
January – December 2022 (€ million)

	FY 2021	FY 2022
Operating CF before Changes in Working Capital	**26.1**	**19.8**
Cashflow from Changes in Working Capital	**21.4**	**-45.2**
thereof: Changes Inventories	6.1	-49.5
Changes Trade Receivables	15.8	-14.6
Other Changes	-0.5	18.9
Interest & Tax expense	-13.7	-15.1
Cashflow from Operating Activities	**33.8**	**-40.5**

Guidance 2023

Guidance 2023:

Revenue: Upper single-digit percentage growth range compared to 2022

- growth will be mainly driven by immunoglobulins

EBIT: Between € -20 million and € -15 million

- higher investments in R&D projects
- ongoing costs for ramp-up of the Biotest Next Level plant (€ -30 to € -40 m.)
- high level of plasma purchase prices
- high prices (+15-25%) for other important operating materials such as ethanol
- high prices for electricity, gas and oil
- supply shortages

Sustainability

List of investments or expenditures in sustainability projects:

- Installation of Photovoltaic system
- Heat recovery system
- Electricity charging stations

The SUSTAINABILITY Code Signatory 2022

prepared according to CSR Directive Implementation Act

Improvement in energy efficiency of products compared to the previous year (EFFAS E13-01):

Energy consumption at the Dreieich site in KWh per liter of plasma processed was 66.3 KWh/l in 2022; in 2021, this value was 71.6 KWh/l.

Goal: Complete climate neutrality of the Biotest Group **by 2035** at the latest

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R&D update

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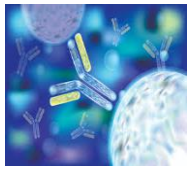
Development Projects – General Overview

Product	Phase I	Phase II	Phase III	Trial Status	Clinical Trial Report
IgG Next Generation			PID	done	done
			ITP	done	done
			SMX planned for 2024		
Fibrinogen		congenital fibrinogen deficiency (984)		done	done
			Acq. fibrinogen def. ADFIRST	ongoing	
Trimodulin		Covid-19 ESsCOVID		done	done
			sCAP (996) ESsCAPE Trimodulin Phase III	submitted	
			Covid-19 (1001) TRICOVID Trimodulin Phase III	ongoing	
Cytotect CP			PreCyssion (997)	ongoing	

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

Clinical phase III trials in congenital and acquired Fibrinogen deficiency

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…

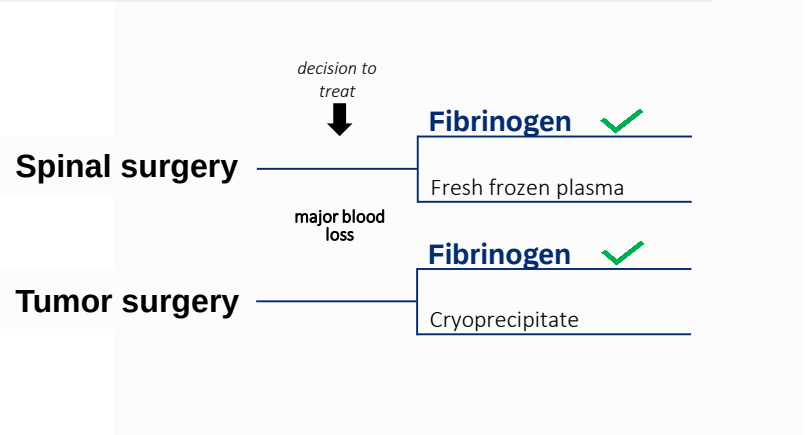
- Expected pharmaco -kinetics and -dynamics (Phase I), excellent efficacy and safety (Phase III)
- 175 bleeding events (BEs) treated in 36 patients of all age groups
- Overall hemostatic response assessments of 175 BEs demonstrated a treatment success in nearly all cases
- **Study completed**

Acquired FD[1]

ADFIRST

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

- Non-inferiority study compared to standard of care (fresh frozen plasma or cryoprecipitate)
- Interim analysis with 120 patients (June ’22) confirms planned patient number
- Recruitment ongoing – 182 of 200 evaluable patients treated
- Other interim analysis to define final sample size expected in Q1 2023



[1] FD: Fibrinogen deficiency

In addition, a broader indication for the US is in discussion.

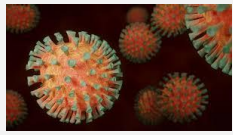
Two Trimodulin phase III trials in COVID-19 and sCAP*

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

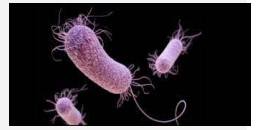
COVID-19 patients



334 subjects

- Patients on low-flow oxygen, high-flow oxygen, non invasive ventilation
- Patients with early systemic inflammation (CRP> 50 mg/L)
- Trial ongoing; Countries approved/ planned: 12/15
- Sites open/planned: 19/62
- Patients enrolled/planned: 7/334

sCAP patients



480 to 590 subjects

- Patients on invasive mechanical ventilation
- Patients with inflammation (CRP >70 mg/L)
- SARS-CoV-2 negative
- Submissions ongoing; Countries approvals/planned: 1/20
- Sites open/planned: 0/136
- Patients enrolled/planned: 0/~580

** sCAP: severe community acquired pneumonia*

Clinical phase III trial with Cytotect® CP in preventing maternal-fetal transmission of CMV*

Objective PreCyssion trial: **Pre**vention of maternal-fetal **Cy**tomegalovirus transmi**ssion**

Demonstrate efficacy and safety of Cytotect® CP in preventing maternal-fetal transmission of CMV

Study Design

Pivotal, clinical Phase III (open-label, single-arm, prospective, multicenter trial with historical control group

- Trial ongoing
- Countries planned/approvals: 1/1 (Germany)
- Sites open/planned: 4/5
- **80 patients – 29 of 66 patients recruited** *(as of March, 2023).*
  Recruitment dependent on the course of the pandemic (hygiene measures reduce CMV transmissions)

** CMV: Cytomegalovirus*

FY 2023 Milestones

H1 2023:

- Trimodulin Phase III ESsCAPE trial - study initiation
- Biotest Yimmugo® BLA FDA submission

H2 2023:

- Fibrinogen AD ADFIRST trial completed and top line results
- Cytotect (PreCyssion) last Patient expected

Summary

- R&D Fibrinogen and Trimodulin projects progressing well
- High R&D investments in 2023
- Despite increase in sales EBIT will be negativ
- Further integration towards Grifols progressing well





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Financial calendar 2023 and contact

Financial calendar 2023

23 Mar 2023	FY 2022
04 May 2023	Q1 Report
10 Aug 2023	H1 Report
02 Nov 2023	Q1-Q3 Report

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