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## Key challenge for (bio-)pharmaceutical products

### **Key challenge:**

### **Medical safety**

Medication safety is key and (cross-) contamination unacceptable

Key contamination sources:

- → Air particles
- Input: Raw materials, containers, closures
- ---> Personnel



### **Products:**

### Injectables

- Cancer drugs (ADC, Cytotoxics)
- Cell & gene therapy (Advanced Therapy Medicinal Products (ATMPs))
- Medical drugs (Thrombosis, EPO, blood plasma products, botox, etc.)
- → Vaccines: Flu, COVID-19, etc.

Increased infection risk as their application bypasses many of the human body's natural defenses

### In particular true for:

## High-value biopharma drugs

- Risk of significant economic
   losses if high-value biopharma drugs
   get contaminated
- Risk of cross-contamination increases with small batch size of fast-growing personalized medicine



## Isolators – Mission critical for (bio-)pharmaceutical processes

### **Solution:**

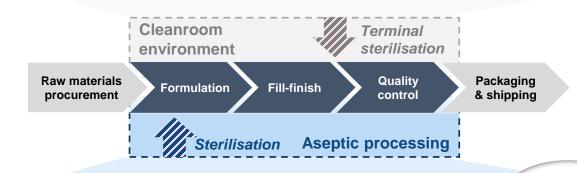
### **Medication sterility**

### Traditional pharma

Pharma products mainly chemical based

### Cleanroom

- Filling / closing in cleanroom with terminal sterilization
- Inappropriate for complex biopharmaceuticals





### Biopharma of today and tomorrow

New products mainly biotechbased (sensitive to heat and pressure)

### **Isolators**

+ Filling/closing under aseptic conditions eliminating effectively all contamination risk

skan

- Reduced cleanroom footprint and running costs and environmental-friendly
- Complex process results in high market entry barriers



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Pharma Integration:

completion of projects

Divesture in 2020 and in-house

## Customer proximity strengthened through accelerated decentralisation

### Allschwil CH

### Headquarters / production sites

- Engineering, sales, service, assembly, R&D, laboratories
- Approx. 26,682 m<sup>2</sup>



### Stein CH

### **Production site**

- Prototype construction, steelwork, E-Beam competence
- Approx. 6,923 m<sup>2</sup>



### Görlitz DE

### **Production site**

- Focus: Steelwork, production, assembly, qualification
- Approx. 26,649 m<sup>2</sup>







### Gembloux BE

### **Production site / AT**

- Aseptic Filling equipment (Closed Vial® Technology)
- Approx. 3,590 m<sup>2</sup>

### Raleigh US

### Sales & services office

- Sales and life cycle support Americas
- Approx. 1,200 m<sup>2</sup>

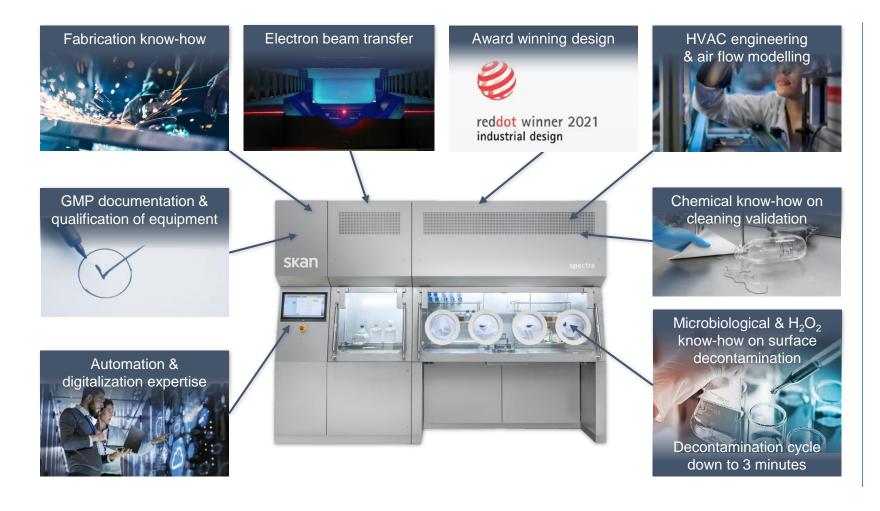


### Okinawa JP

### **Production site**

- Sales, assembly, and life cycle support Far East
- Approx. 2,170 m<sup>2</sup>

## Technology & innovation leadership

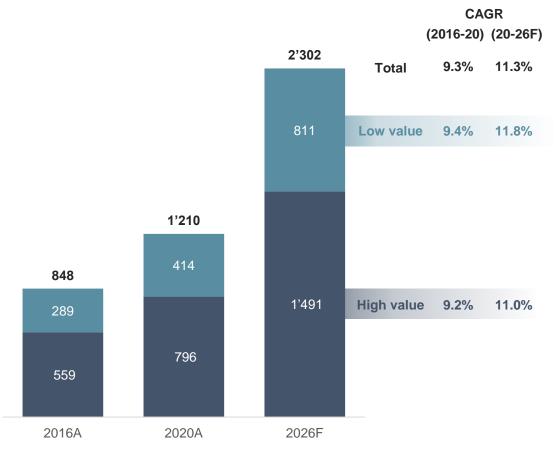


- Technology leadership & foresight allows SKAN to be the market defining player
- Continuous active contribution to new guidelines & regulations through industry standards setting organisations (ISPE, PDA, ISO)
- Pure-play business model enables an undiluted focus of resources to drive technology and innovation
- More than 1,400 employees globally, of which more than 50% have an academic background, such as scientists and engineers to ensure seamless innovation and production

## Highly dynamic niche market with strong end market growth

### Strong growth of aseptic manufacturing<sup>(1)</sup>

Isolator market by value (EURm)

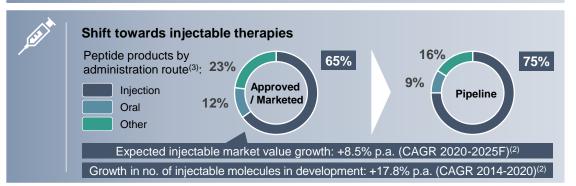


### **Key growth drivers**



### **Underlying biopharma industry growth:**

- Global pharmaceutical industry: +4.5% p.a. (CAGR 2021-2026F)<sup>(2)</sup>
- → Cell & gene therapy market: +58% p.a. (CAGR 2020-2024F)<sup>(2)</sup>
- → Highly potent APIs market: +8.9% p.a. (CAGR 2020-2024F)<sup>(2)</sup>





### Shift towards personalized medicine requiring aseptic manufacturing

- Growing demand for injection administration
- → Growing demand for smaller batch sizes (e.g. expected orphan drug sales growth +10.8% CAGR 2020-2024F<sup>(2)</sup>)
- Increased risk of cross-contamination addressed by isolators



### Continuing trend of pharma outsourcing

- Increased outsourcing via CMOs is driving the demand for isolation equipment
- Global CMO market: +6.3% p.a. (CAGR 2020-2025F)<sup>(2)</sup>

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## Protected market leadership in aseptic processing underpinned by high entry barriers and significant switching costs

### **Market entry barriers**

### **SKAN's value proposition**

Market leadership

Technological edge

Stringent regulatory environment

Mission criticality of aseptic processes

Lock-in effect



Mastery of difficult to replicate knowhow on highest-performance isolators



Process warranty regarding all regulatory (e.g. FDA, EMA, Swissmedic) required qualifications & timeline



Swiss brand, engineering & reputation provide trust in isolator safety



Large installed base of isolators and leading global services incl. tech transfer & consumables across product lifecycle



# Equipment & Solutions ("E&S")



## Comprehensive portfolio for aseptic manufacturing processes

Cleanroom

### **Business** Pure contrib. **Solutions**

### **Process Solutions**

### **Business** contrib.

**Aseptic Technologies (AT)** 

Proprietary, automated

gene therapy integrated

within isolator

closed-vial filling equipment

for small/medium-batch cell &

**Integrated Process Solutions** 

Integrated processes

### **Pure Solutions** Trading

Trading of Laboratory/ cleanroom equipment, mostly in Switzerland

- → Horizontal/vertical workbenches
- Fume cupboards
- Particle counters



### **Customized Solutions ("CusSol")**

**Customized and modular isolators** 

- Customer-specific isolator solutions for aseptic manufacturing and filling
- Process warranty incl. complete GMP compliance



### System Solutions ("SysSol")

- flexibly with process tools
- Close collaboration with process tool partners



Modular isolators equipped



### **Process Automation**

Global process solution providing automated (robotic) process handling fully integrated within the isolator







### GMP requalification Performance studies

Services

- Material studies
- CFD studies
- Cleaning validation

Life cycle support

### Consumables

- Closed vials
- Connectors
- Filling kits

### Services

- Rent a machine
- Life cycle support



### Consumables

Refer to process consumables

### Services

- Refer to process services
- Digital integration into MES<sup>(1)</sup> and ERP systems

### Consumables Personal

- protective equipment
- Biosanitizer

### Services

→ Qualification

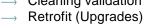
### Consumables

- Biological Indicator
- Electron Beam (bulbs)
- Spares (gloves, filters, etc.)









## Clear growth strategy

### **Objectives:**

→ Continue growth track-record
 → Increase recurring revenue base
 → Expand profitability



Fortify market leadership



Expand addressable market towards integrated process systems



Increase exposure to aftermarket services & consumables revenues



Accelerate digital transformation

- Investment in production capacity expansion and scale-up
- Continuous innovation to meet customer's demand and to maintain technical leadership
- Continuous active contribution to new guidelines & regulations
- Grow service revenues with everincreasing installed base of isolators

- Scale-up of Aseptic Technologies
- Intensified joint developments with established fill-finish partners
- In-house development of automated process equipment in combination with isolator technology
- Increasing, global product lifecycle support with expanding installed base of isolators
- Further development of innovative consumables (e.g. closed vials, transfer systems, filling kits)
- Additional service offerings of "pre-approved" solutions to help customers shorten time-to-market
- New financing models such as pay per use and off the shelf delivery

- Increased augmented reality service support to increase reaction time and reduce long distance travel
- Increased Virtual Reality design support
- Industry 4.0
  - Artificial Intelligence for preventive maintenance
  - "One button release" paperless
     GMP compliant documentation

Process Solutions

Services

Integrated
Process Solutions

Consumables

Services & Consumables

All

Business units

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Equipment & Solutions.
Services & Consumables

## New drugs increase consumption of AT-Closed Vial®

### Seven AT filled drugs on the market:

Customer	Product area	Phase
Daiichi-Sankyo	DELYTACT®: Oncolytic virotherapy for brain cancer	
Boehringer Ingelheim	ARTI-CELL® FORTE: Cartilage repair for veterinary applications	
Janssen Oncology  LEGEND  BIOTECH	CARVYKTI™: Lentivirus used for the production of a drug against multiple myeloma	
ATARA BIO	EBVALLO™: Monotherapy for the treatment of Epstein-Barr virus	
Krystal	VYJUVEK™: Treatment of wounds in patients with dystrophic epidermolysis bullosa in collagen type VII alpha 1 chain gene	
VERTEX CRISPR	CASGEVY™: Therapy for the treatment of sickle cell disease and transfusion-dependent Beta Thalassemia	
Pfizer	BEQVEZ™ / DURVEQTIX®: Therapy to treat Hemophilia B	

- Besides the expansion of the installed base of SKAN equipment, which requires maintenance, requalification and spare parts, the volume in the Services & Consumables segment was driven by higher sales of AT-Closed Vial<sup>®</sup> and associated disposable products.
- This confirms the expectation that the commercialization of new drugs increases the consumption of AT-Closed Vial<sup>®</sup>.
- Today, 7 in AT vials filled drugs are on the market which received 16 approvals by 6 major health authorities, including FDA, MHRA and EMA (31.12.2023: 7 drugs with 14 approvals).
- → The development pipeline of drugs in AT-Closed Vial<sup>®</sup> is likely to be in the region of 450 active ingredients.
- Besides the sale of ready-to-fill closed vials and disposable products also the demand for AT production equipment increases.

## Pre-Approved Services well on track

- With its Pre-Approved Services, SKAN will offer customers the possibility to carry out their stability tests on our systems.
- This will allow our customers to shorten the time-to-market for a new drug significantly.
- Investments in Pre-Approved Services to continue throughout 2025.
- Furthermore, we expect regulatory approval of Pre-Approved Services by the End of 2025.

### Key data

→ Equipment:

At start: filling equipment with potential to expand At full capacity: a wide range of products can be handled

---> Commercial use:

Q1/2026E: Start of commercial use with successive increase in capacity utilization over several years until full capacity is reached

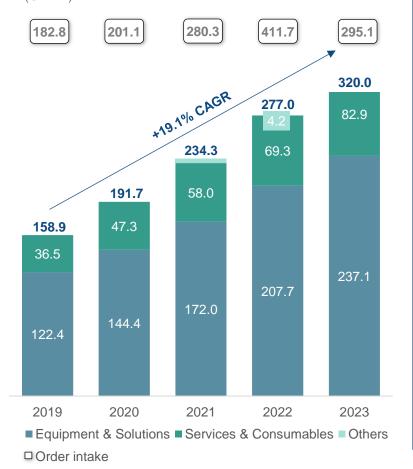
→ Volume and return:

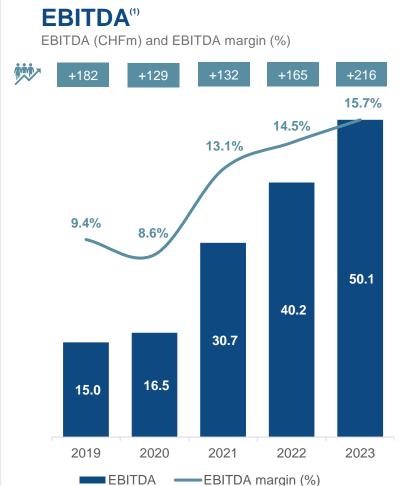
Expected sales volume at full capacity: CHF 50 million Expected return: EBITDA margin of up to 50%



# Excellent financial profile with above-market growth and high revenue visibility

## **Net revenue & order intake**(1)







Consistent, above-market revenue growth (+19.1 CAGR 2019-2023)



**Strong revenue visibility** based on order backlog of CHF 312.1m as of end of 2023



Margin expansion following important development costs and personnel ramp-up



**High ROCE**<sup>(2)</sup> despite important investments (2023: 19.7%)



Current net cash position and strong cash flow generation to finance future investment needs



**Negative working capital** 

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<sup>2)</sup> Defined as reported EBIT / (Total Assets – Short-term Liabilities)

# Century of biology: Shift toward injectable biotech drugs drives need for aseptic process solutions







## Financial targets and outlook

Metric	2024 Targets®	Mid-Term Outlook
Group net sales growth  Segment net sales growth <sup>(2)</sup>	Mid- to upper teens  E&S S&C	Mid- to upper teens  E&S S&C
EBITDA margin	13 - 15%	Gradually increase profitability level to upper teens in the mid-term. Potential for further increase beyond mid-term period.

