Rentschler Biopharma SE

Initial perspectives

October 2024

DRAFT

BAIN & COMPANY

Disclaimer

- This material and the analysis contained herein (the "Report") was prepared by Bain & Company ("Bain") over a limited time period and is not to be disclosed in whole or in part to any third party without Bain's explicit prior written permission. In the event Bain does grant permission for the Report to be disclosed to a third party, Bain will not permit the third party to rely on the Report unless explicitly agreed between Bain and such third party in writing.
- The analysis and opinions contained in the Report are based on information from publicly available sources. Bain has not independently verified this information and makes no representation or warranty, express or implied, that such information is accurate or complete. Projected data and conclusions contained herein are based (unless sourced otherwise) on the information described above and Bain's best judgment and should not be construed as definitive forecasts. Bain does not have any duty to update or supplement any information in the Report. This Report does not purport to address all risks and challenges facing Client, its business and the markets within which it operates, nor all possible market conditions.
- No responsibility or liability whatsoever is accepted by any person including Bain & Company, Inc. or its affiliates and their respective officers, employees or agents for any errors or omissions in this Report, save insofar as Bain may expressly agree in writing.
- This Report does not constitute (i) an offer or solicitation to purchase or sell any securities or assets or (ii) a recommendation by Bain to purchase or sell any securities or assets. Each potential participant in the financing of any investment discussed herein should make their own independent assessment of the investment.
- The assessment was prepared during a period of significant macroeconomic uncertainty. While a downside scenario was considered, it does not necessarily reflect the potential worst case scenario.
- This Report is not complete without an accompanying oral discussion and presentation by Bain.

AGENDA

Investment considerations

Business overview

Market overview

Competitive landscape

ESG assessment

What we like about the Rentschler Biopharma opportunity and areas to test further

INVESTMENT CONSIDERATIONS | INITIAL PERSPECTIVES | PRELIMINARY

What it is

- **~€290M (FY23) and 25-30% ebitda German family-owned mid-sized CDMO** focused on **mAb and recombinant protein** API manufacture; <5% portfolio virus-based vaccines due to recent expansion
- Customer portfolio is largely **small-mid pharma / biotechs**; low large pharma
- **30% revenue CDMO svcs** (regulatory support, scale-up process dev., GMP readiness) but **typically delivered only in concert with API manufacture**
- **~70% portfolio clinical,** with rising commercial focus
- **Three manufacturing sites:** mAb and protein manufacture in Germany & USA; viral vaccines in UK
- **~13% growth p.a.** ('18-23) largely organic due to acq. of Biontech covid vaccine contact & cross-value chain alliances

What we like

- **Large, attractive market for biologics with resilient tailwinds**
  - Reference mkt of ~ €10-12B in mAbs and recombinant protein API manufacture, and including ~ €1B in virus-based vaccines
  - Robust secular growth (mAbs/proteins ~8-10%, viral vaccines ~5-8%) due to biologics demand & outsourcing (customer demand for niche tech. expertise)
- **Top 5 European mAb CDMO due to robust mAb/protein capabilities and differentiated customer service, targeting mainly SMID pharma**
  - Strong track record and reputation as established, reliable and quality player in recombinant proteins (130 formats) and mAbs (>300 molecules), with esp. longstanding expertise in multispecifics
  - Flexible, personalized approach to effectively capture small to mid pharma customers unable to access larger CDMO services; with >20% portfolio from large pharma post covid vaccine contract
  - Robust offering with clinical / commercial presence & strategic alliances enabling E2E integrated value chain (formulation - Leukocare to F&F - Vetter)
- Rentschler has delivered **strong topline growth above-market**, due to strategic entry into viral vaccines, strategic alliances and capacity expansion
  - Timely entry into viral vectors in 2020/21 (incl. UK plant build) to win Biontech covid vaccine contract
  - Capacity expansion in Milford US, internal cell line development to enable commercial play (now ~30% revenue)
- Significant value creation opportunities include:
  - (1) enhance commercial excellence / marketing presence in core biologics esp. in US to fill hopper & enhance mAb capacity utilization in USA
  - (2) double down in viral vaccines
  - (3) expand into innovative modalities e.g. ADCs, CGT, likely leveraging M&A
  - (4) enter in-house F&F, likely leveraging M&A

What needs further diligence

- **Resilience of core business based on current revenue** splits
  - Commercial vs clinical
  - Reliance on covid vaccine, vs other vaccines, mAbs and proteins
  - USA vs Europe
  - Extent of use of strategic alliances
  - Large pharma vs emerging pharma vs small biotech
- **Diversity of customer portfolio** (% # contracts & revenue from top 10-20 customers and mix of SMID vs large customers; by modality)
- **Manufacturing site capabilities, capacity utilization & potential**
  - Modality / unique capabilities per site
  - Utilisation per site and level of customer / contract sharing across sites
  - Revenue per site and impact of investments to date
  - Any capex investment plans underway
- **Extent of differentiation and moat vs key competitors (esp. other mid-sized CDMOs) & customer appetite to increase SOW**
  - Unique technical capabilities e.g. multispecifics, own cell line dev., proteins
  - Perception of viral vaccine capabilities, key gaps
  - Quality control position (9 FDA observations: procedural gaps /record keeping)
- **Strength of current portfolio and pipeline feasibility**
- **Value creation opportunity beyond core (impact and feasibility)**
  - Cross-sell potential: shift from strategic alliance to in-house formulation/F&F
  - Cost-value benefit and customer interest in entry into other modalities e.g. ADCs, CGT
  - M&A target pipeline

Mfg. capabilities enhancement, developing in-house F&F capability, geo. expansion, commercial excellence dev., & supply chain efficiencies emerge as key VC levers

VALUE CREATION LEVERS

PRELIMINARY

Lever		Description	Potential Upsides	Implementation Ease	Rationale
Revenue Levers	API Manufacturing Capacity Expansion	• **Augment** manufacturing **capacity** in **viral vectors**			• Leads to **more effective** addressal of **capacity shortages** in the market alongside helping capitalize on the **growing demand** for **CGT** (through viral vector production), strengthening **competitiveness**
	In-House Fill & Finish Capabilities	• Build or more likely acquire robust **in-house F&F** capabilities as opposed to relying on **third party alliances** for end-to-end integrated offering			• Helps capture the **F&F supply-demand gap** (created by the GLP-1 drugs market which is rapidly growing at 8-10%) positioning Rentschler as a **one-stop shop** preferred by large pharma clients
	Expanding to ADCs[1] Production	• **Expand** modalities coverage e.g. ADCs[1] with purification / conjugation capabilities; likely via M&A; CGT also an opportunity			• Helps **establish presence** in the **ADC segment** of the large molecule space growing at **12-14%**
	Geographic Expansion	• Double down in **USA** and explore opportunities in **Japan**			• Facilitates further access to large markets (US currently contributing only ~30% to revenue)
	Commercial Excellence	• **Strengthen BD** account mgmt. and pricing strategy to build **more robust pipelines,** esp. in **commercial projects;** and enhance appeal for SMID customers			• **Access more stable pipeline revenue via commercial projects** (currently only ~30% portfolio, and multi-year / more predictable, vs clinical projects with more uncertainty between trial phases)
	Marketing presence	• Strengthen presence at tradeshows, visibility of offerings in the market and sponsorship of own conferences			• Greater market awareness of company quality will support filling of site capacity esp in new US facility and new UK viral vector capability
	Sustainability Initiatives	• Strengthen value proposition to customers via better **water mgmt**, **circular economy, green chemistry**, etc.			• **Strengthens** company's **already elaborative** sustainability initiatives and increases **appeal** to **increasingly eco-focused** pharma clients
Cost Levers	Supply Chain Efficiencies	• **Optimise procurement costs** of raw material inputs			• **Reduces cost**, ensures meeting tight **production deadlines**, enhances **scalability** and ropes in **internal efficiencies**
	Optimizing mfg. site utilization	• **Enhance utilization** of the Milford and Stevenage production sites			• Optimizes **costs** & **operational efficiency** at both sites (currently Rentschler at 40-50% capacity vs industry leaders at ~60%)
Mergers and Acquisitions to boost capacity		• Enter **strategic M&A** to expand into M&A, new modalities e.g. ADCs, and to enhance current capacity in viral vaccines			• Fragmented market with significant target pipeline availability; helps provide access to **faster growing modalities** (e.g. ADCs, CGT), and more integrated value chain offering to better compete

High Low

Note: (1) Antibody-Drug Conjugates
Source: Company website; Market participant interviews; Lit. search

AGENDA

Investment considerations

Business overview

Market overview

Competitive landscape

ESG assessment

Rentschler Biopharma SE is a CDMO (revenue of ~€290M in 2023) with offerings across formulation, development & manufacturing, for small-mid and biotech

BUSINESS OVERVIEW | COMPANY PROFILE

PRELIMINARY

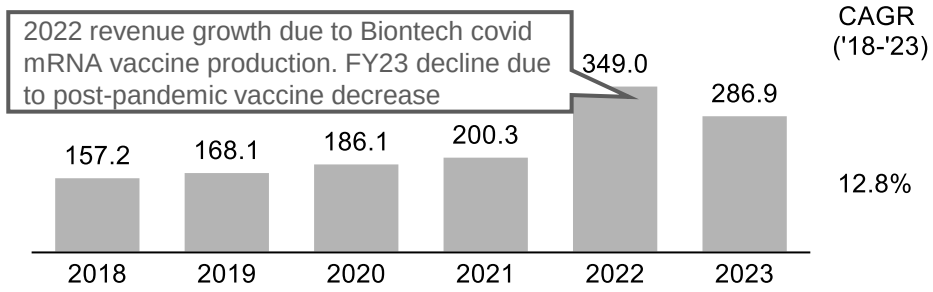
Company overview

Key facts

Headquarters	Germany
Founded	1927 in Laupheim; CDMO business started in 1997
Ownership	Private; 100% owned by Rentschler family
# employees ('23)	~1K
Facilities	Stevenage, UK; Milford, USA; Laupheim, DE
Description	Rentschler Biopharma is a **CDMO** offering outsourcing services for **bioprocess development**, **cGMP manufacturing**, and product **approval strategies** from **clinical studies** to market approval

Financial overview

Rentschler Biopharma SE revenue[1] and EBITDA (in €M)



	2018	2019	2020	2021	2022	2023
Operating Revenue (€M)	164.5	176.1	192.5	210.4	354.9	306.3
EBITDA (€M)	46.7	38.2	39.4	52.0	126.2	85.9
EBITDA margin (%)	29.7%	22.7%	21.2%	26.0%	36.2%	30.0%

Client base & molecular expertise

- **Strong and sustainable customer base,** largely split between **small-mid biotech companies** and **pharma** (incl 17/20 world's top pharma); **160+ clients** globally (since 1997); ~**60%** of clients work on **>1 project**
- ~50 years of experience in **process development** and **manufacturing of biopharmaceuticals,** with expertise in >**300 molecules** and **130 therapeutic protein** formats e.g., monoclonal antibodies, modified proteins etc.

Rentschler clients: Chiesi, Pfizer BIONTECH, Genmab, Aridis, CureVac

Product portfolio focus

API manufacture

Development and production of APIs for clinical trials (Phase I to III) and for commercial supply, with supporting services (quality control, GMP readiness testing etc.)

Biologics >95%

Rentschler Biopharma SE (Laupheim, Germany), Rentschler Biopharma Inc. (Milford, USA)

Large molecules such as monoclonal antibodies (mAbs), recombinant proteins, and therapeutic enzymes, using mammalian or microbial cell lines, through cell line development and purification

Viral Vectors <5%

Rentschler ATMP Ltd. (Stevenage, UK)

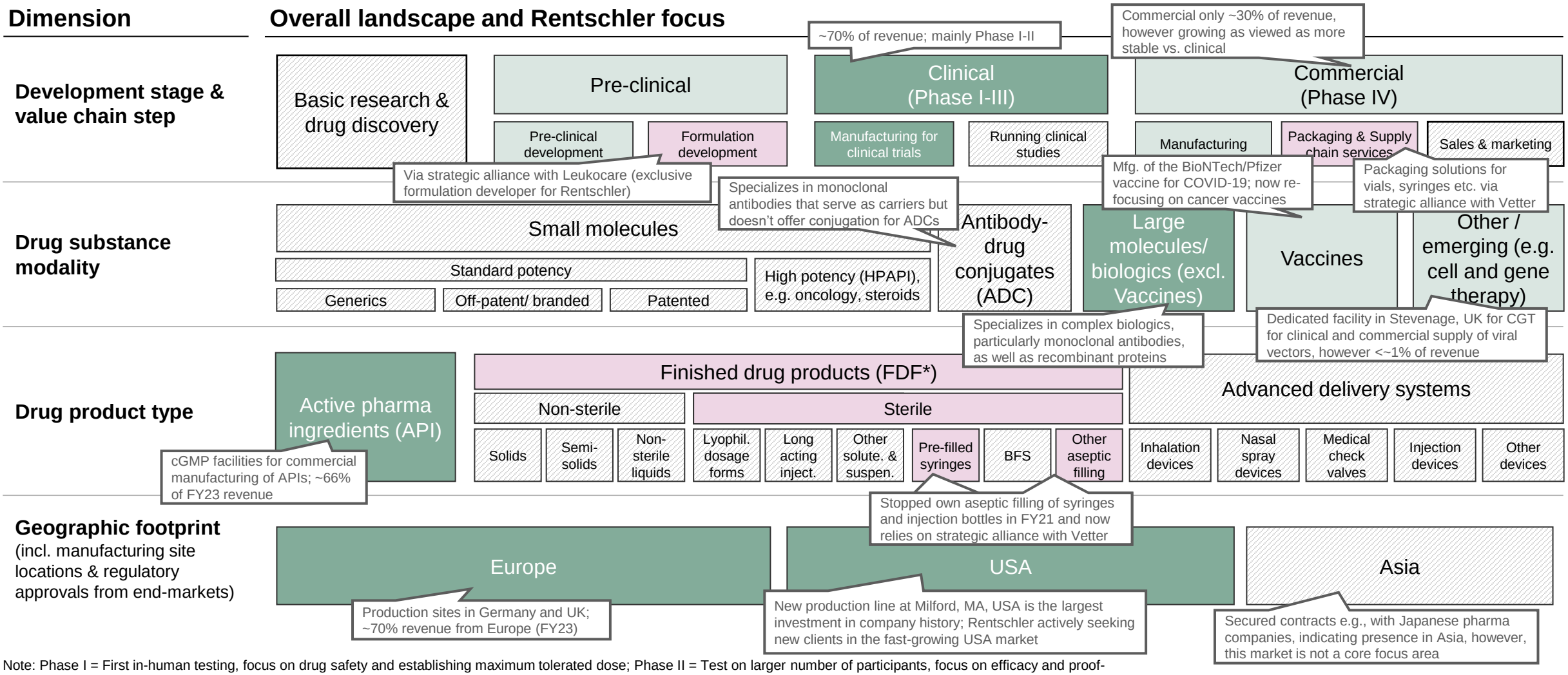
Engineered viruses used to deliver therapeutic genes in **gene therapy** using high-quality batches of vectors such as **AAVs (adeno-associated viruses)**, **LVVs (lentiviral vectors),** and **adenoviruses**

Note: 1) Revenue figures shown include Sales Revenue only – 'Other Operating Income' and 'Reduction in the inventory of products' not included as part of revenue; 2) Details on other sources of revenue not disclosed in company reports
Source: GlobalData;Company information; Annual reports; Lit. search

Rentschler focused on APIs for biologics, emphasizing clinical stage projects and increasingly targeting commercial stage, with three facilities in Europe and the USA

BUSINESS OVERVIEW | VALUE CHAIN

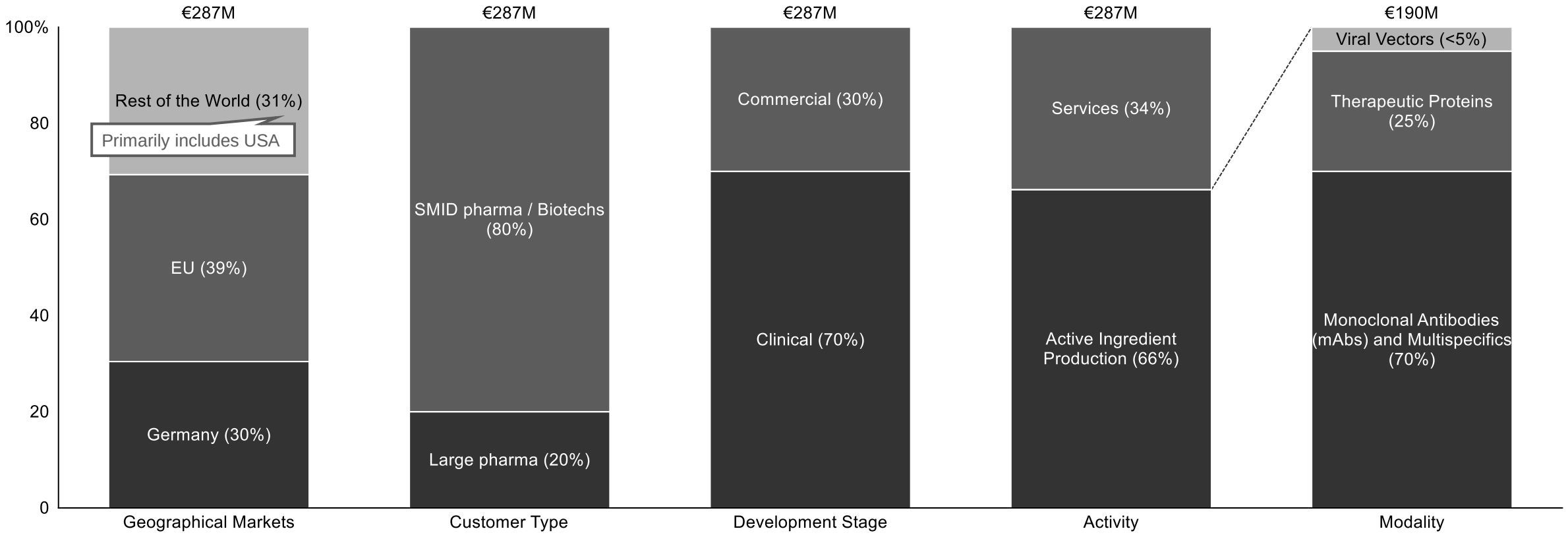
Rentschler focus: *High* *Medium* *Low or none* *Via alliance* / PRELIMINARY



Note: Phase I = First in-human testing, focus on drug safety and establishing maximum tolerated dose; Phase II = Test on larger number of participants, focus on efficacy and proof-of-concept; Phase III = trial on which regulators base drug approval decision; Phase IV = Drug approved and manufactured at commercial scale; (*) FDF = Finished dosage forms;
Source: Company website, Lit. search, Market participant interviews

>50% of revenue comes from international markets with API production being the revenue driving activity & clinical stage being the revenue-driving development stage

Sales revenue breakdown (%), 2023



Note: (*) Details on other sources of revenue not disclosed in company reports; Revenue split basis Customer Type and Modality indicative, basis primary research
Source: Company website; Annual reports; Market participant interviews; Lit. search.

Rentschler Biopharma provides a range of offerings including API manufacturing and CDMO support services, as well as formulations and F&F services via alliances

PRELIMINARY

	API Manufacturing		Other services offered via alliances	
	Biologics (mAbs and therapeutic proteins)	**Viral Vectors**	**Formulation Development**	**Fill & Finish (Xpert Alliance)**
Description	• Active ingredient manufacturing for clinical/ commercial **complex biologics** with focus on monoclonal antibodies **(mAbs) and multi-specifics** as well as therapeutic proteins e.g., **recombinant proteins** • Broad portfolio of cultivation methods including **fed-batch, continuous** and **perfusion processes**	• cGMP manufacturing for **viral vectors,** including **adeno-associated virus** (AAV) and **lentivirus vectors** (LVV) for **commercial** and **clinical** supply, for **gene therapy** applications • **Started off with AAV** services, and expanded to include **LVV manufacturing** at Stevenage, UK facility in Sep 2024 • **Proprietary HEK293 cell line** for advanced therapy projects	• **Formulation development** via **strategic alliance** with **Leukocare**, Rentschler's exclusive formulation developer since 2018 • Based on Leukocare's proprietary SPS **(Stabilizing and Protecting Solutions) technology** which significantly improve the stability of therapeutic proteins	• Clinical/ commercial **fill & finish solutions** (encapsulating the formulated drugs into its consumable forms, such as **vials and syringes**) via **strategic alliance with Vetter** (since 2020)
Share of Revenue (est.)	~ 60%	< 5%	*n/a*	*n/a*

CDMO Support Services ~33% revenues
(e.g., Regulatory Support, Quality Control & Assurance, Process development for GMP readiness, analytical development, Project Management Services, Assistance with Approval Documents, etc.)

Note: Share of revenue by division indicative, basis market participant interviews
Source: Company website; Market participant interviews; Lit search.

Rentschler has grown through strategic alliances, and expansion of manufacturing sites and into new modalities / technologies

BUSINESS OVERVIEW | TIMELINE

PRELIMINARY

Growth type | Organic | Site M&A | Strategic Partnership

1997

Start of CDMO business

Rentschler entered the business of contract development and manufacturing of biopharmaceuticals

2006

Foundation of Rentschler Biopharma Inc.

Established the USA subsidiary, Rentschler Biopharma Inc., to tap into the significant growth potential offered by the market

2014

Launch of proprietary cell line development platform TurboCell

Rentschler Biopharma introduced TurboCell, an advanced platform designed to **accelerate and optimize cell line development** for biopharmaceutical production

2017

LEUKOCARE

Alliance between Rentschler Biopharma and Leukocare

Rentschler Biopharma formed a strategic alliance with Leukocare, **acquiring a 10% stake** to strengthen collaborations in **formulation development** and enhance biopharmaceutical production processes

2019

Acquisition of site in Milford, MA, USA

Rentschler Biopharma expanded its global manufacturing capabilities by **acquiring a state-of-the-art production facility from Shire** plc in Milford, Massachusetts, to **enhance its service offerings in the USA**

2020

VETTER

Strategic collaboration with Vetter

Rentschler Biopharma entered a strategic collaboration with Vetter, combining expertise to **offer fill & finish solutions for biopharmaceuticals**

2020

Entry into mRNA technology

Rentschler Biopharma expanded its capabilities in **mRNA technology**, positioning itself to support the development and manufacturing of mRNA-based therapeutic and vaccine vectors (not production of the mRNA itself)

2021

New Modalities and site in Stevenage, UK

Rentschler expanded into new therapeutic modalities with the establishment of a facility in Stevenage, UK, dedicated to **advancing cell and gene therapies, with a focus on viral vaccines**

New long-term loans worth >€100 million were issued in FY23 to finance the expansion investments at the subsidiary Rentschler Biopharma Inc., Milford (USA), as well as to set up the business operations of Rentschler Stevenage (UK).

2021

New manufacturing line at Milford site, MA, USA

Groundbreaking of a new manufacturing line at its Milford, MA, facility (became operational in 2024) to increase capacity for **large-scale biopharmaceutical production** and enhance its ability to meet **client demand in North American market**

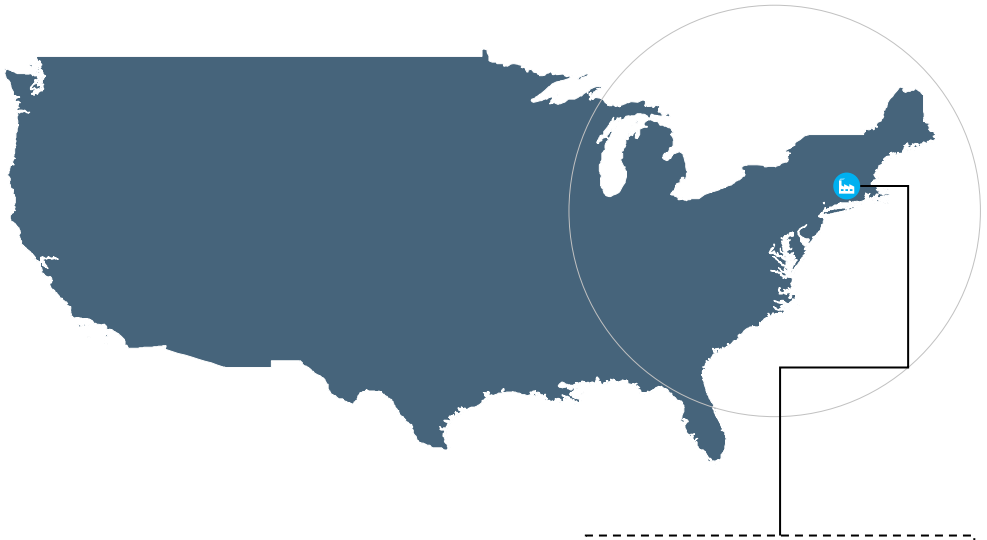
Source: Company information; Annual reports; Lit. search

Rentschler, headquartered in Germany, with a production site in the UK for viral vectors, and sites in Germany and the US for mAbs and other complex biologics

BUSINESS OVERVIEW | GEOGRAPHICAL FOOTPRINT

United States

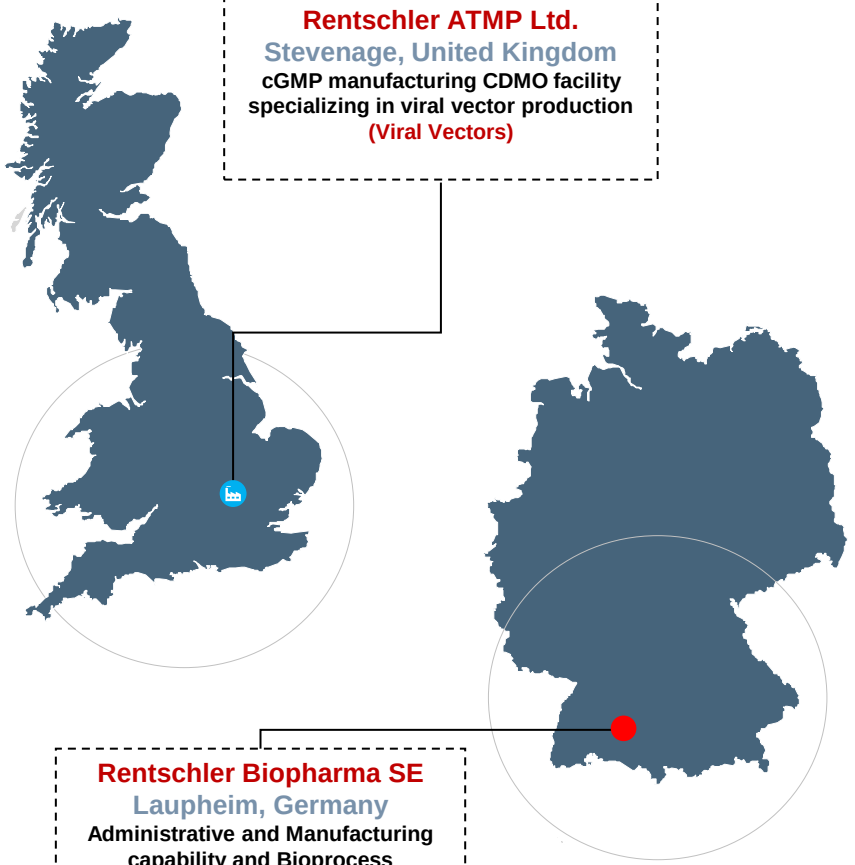
BCN:
- Sites that were marked as 'Advanced therapy' referred to facilities that specialize in development of advanced therapeutic products, including gene & cell therapies etc., in line with the official website (https://www.rentschler-biopharma.com/en-us/company/en-stevenage/)
- There are only 3 sites mentioned on Rentschler's official website with their corporate HQ located in Laupheim, Germany (https://www.rentschler-biopharma.com/en-us/company/locations-overview/)



Rentschler Biopharma Inc.
Milford, Massachusetts
Manufacturing capability for large-scale clinical & commercial cGMP (mAbs)

United Kingdom & Germany

Rentschler ATMP Ltd.
Stevenage, United Kingdom
cGMP manufacturing CDMO facility specializing in viral vector production (Viral Vectors)



Rentschler Biopharma SE
Laupheim, Germany
Administrative and Manufacturing capability and Bioprocess development for large-scale clinical & commercial cGMP (mAbs)

● Headquarters (incl administrative site) ● Manufacturing & Development

Source: Company website; Annual reports

AGENDA

Investment considerations

Business overview

Market overview

Competitive landscape

ESG assessment

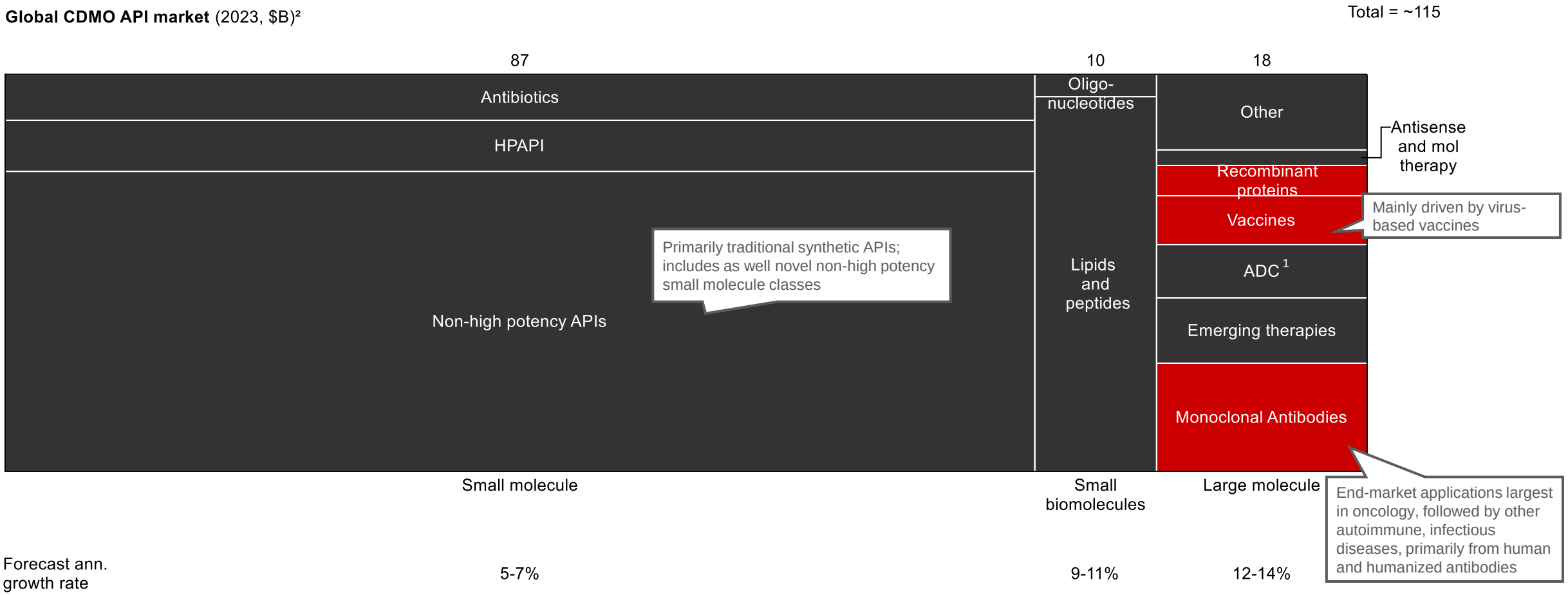
Rentschler's reference market is ~$10-12B, focusing on API manufacture for mAbs, recombinant proteins and vaccines, and growing focus on emerging therapies

MARKET | BIOLOGICS API

Rentschler's reference market

/ DIRECTIONAL / PRELIMINARY

Global CDMO API market (2023, $B)[2]

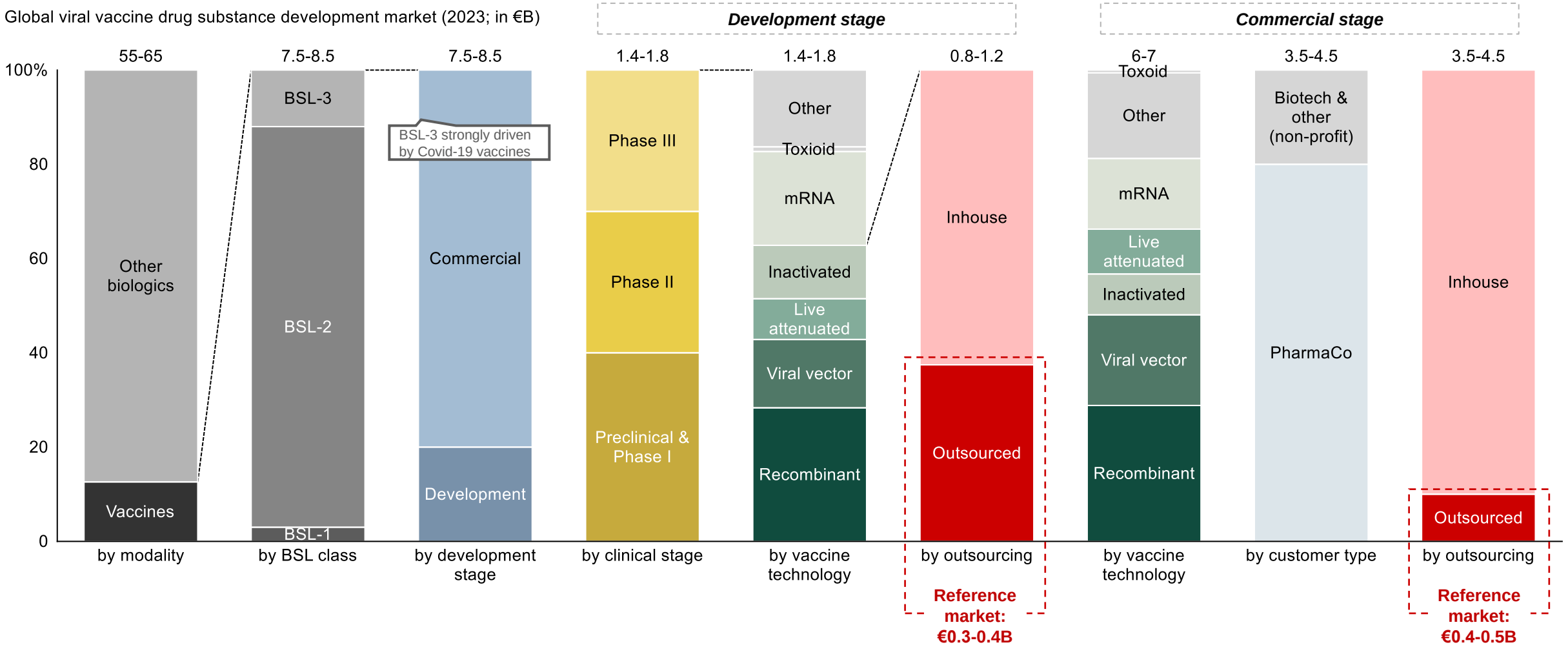


Note: (1) ADC = antibody drug conjugates, global API end market ~$2B, ~10% ann. growth., PharmaCos tend to keep manufacturing In-house, limited number of CDMOs with capability; 2) 2020 segmentation & growth trends applied to 2023 market size
Source: Visiongain; Mordor Intelligence; CPA; Markets and Markets; Lit search; Market participant interviews

The global outsourced market for clinical and commercial production of viral vaccines is €0.7-0.9B

MARKET | VIRAL VACCINES

/INDICATIVE



Note: "Other" vaccination technologies include, e.g., peptide vaccines, dendritic cell vaccines | Source: EvaluatePharma; PharmaProjects; VaccinesEurope; Market participant interviews

The reference market is growing at 8-10% p.a. driven by underlying pharma market growth and outsourcing penetration

MARKET GROWTH

PRELIMINARY

Reference market: API manufacture for MAbs, recombinant proteins and viral vaccines

~8-10%

1 End-market pharma volume

- **Ageing populations and increased life expectancy** driving global demand for pharmaceutical products
- Increased **prevalence of chronic disease** associated with protracted/ lifelong courses of medication
- **Increased healthcare access** (incl. better insurance coverage) particularly in emerging/ developing markets
- **Growth in new originator drugs** coming to market fuelled by increasing clinical trial pipeline and R&D investment

×

2 Pharma outsourcing penetration

- **Outsourcing trends** driven by cost pressures in pharma industry, as well as CDMO capability augmentation, expected to continue
- Ongoing **PharmaCo divestment of production capacity** (particularly in lower complexity segments with lower margins)
- Increasing role of **specialized pharma & biotechs** in innovation and commercialization with higher dependence on outsourcing
- High **baseline level of outsourcing** in lower complexity segments limiting runway for further penetration

×

3 Average unit price

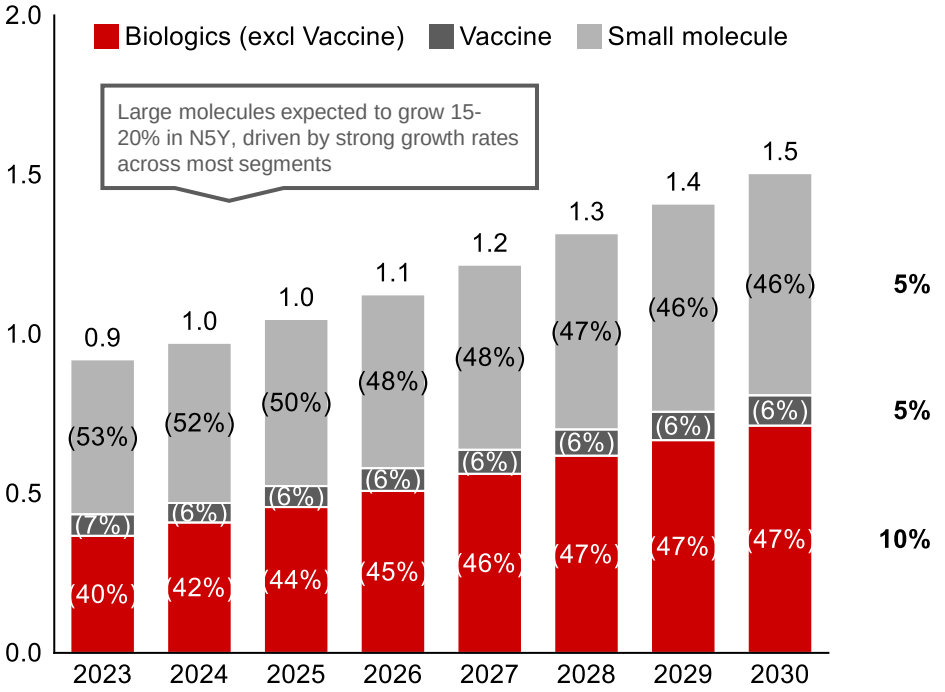
- **Increasing commoditization** of highly fragmented CDMO market, particularly for low complexity technologies
- Growing role of **off-shore CDMOs** as they expand capabilities to compete in more attractive segments
- **Mix effect** as pharmaceutical products trend towards high complexity technologies with greater unit price

Note: Growth rates as '20-'25 CAGR; Average exchange rate of 1.18 USD used to transfer USD values into EUR within this document

1 Volumes of all biologics molecules including vaccines growing at 8-10% p.a.

MARKET GROWTH

Global Pharmaceutical Market by Technology ($T, 2023-'30F)



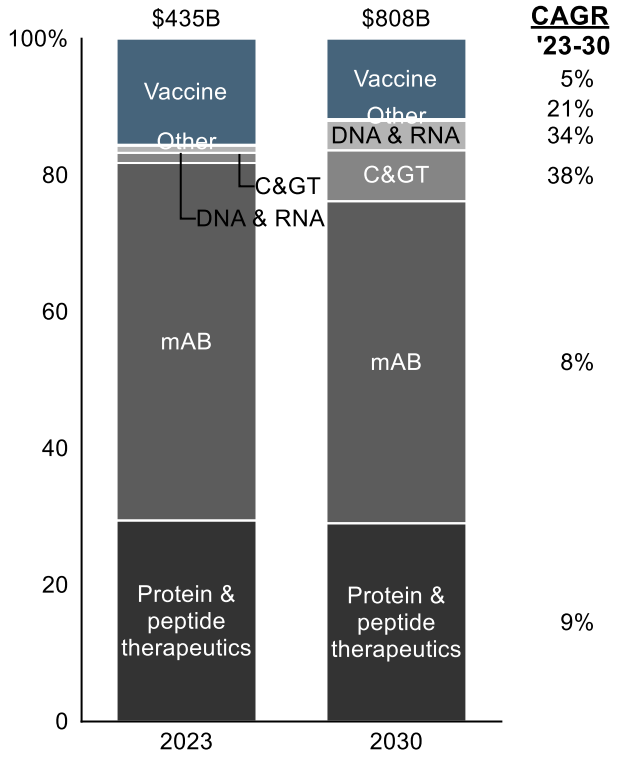
CAGR 23-'30

5%

5%

10%

Biologics and Vaccine product revenue by technology ($B)



CAGR '23-30

5%
21%
34%
38%
8%
9%

Product count	709	1,485

Commentary

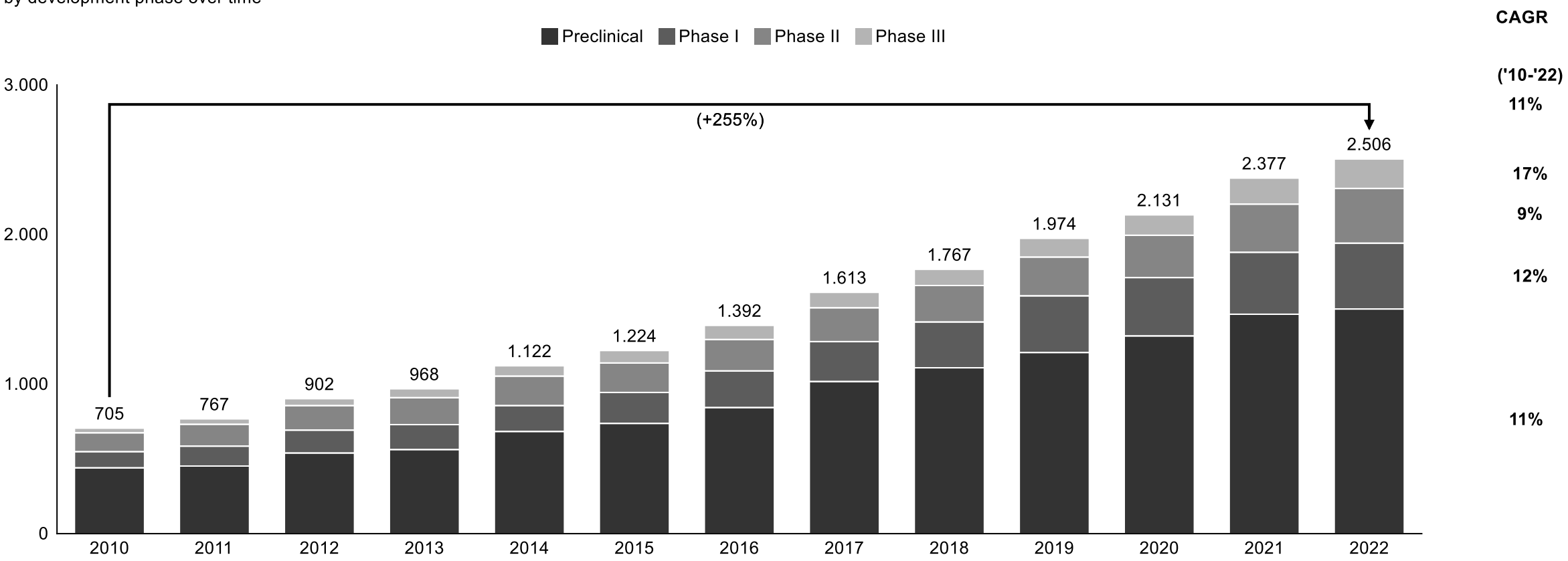
- **Proteins and peptides to grow** ~10% 2023-'30 driven by **increased specialty**
- Vaccines experienced strong growth in recent years fueled by COVID-19, but is expected to growth at a lower pace **(~5%) going forward driven by continued vaccine development activity (of mRNA vaccines in particular)**
- **Other large molecules (blood and blood components, allergenics or somatic cells among others) see growth of 10-20% in '22-'27**, but rest on several factors that may impact future development

Source: Evaluate Market Data; Mordor Intelligence

1 The number of mAbs across all clinical trial phases is increasing at 10%+ p.a.

MARKET GROWTH

Number of Biological Protein Antibodies (mAbs)
by development phase over time



Source: Bain analysis

2 **Biologics |** Outsourcing to CDMOs is increasingly relevant as Pharma Cos look for cost efficiencies, capacity, and capability expansion

MARKET GROWTH

Significant cost pressures on biopharma players; CDMOs can help lower costs

- **Biopharma players face significant challenges,** incl.
  - **Declining R&D productivity**
  - **Rising costs** to develop and bring new drugs to market
  - **Reimbursement pressure**
  - Heightened levels of **regulatory scrutiny**
- **Outsourcing to CDMOs can help to lower costs**

Evolving technology is driving significant R&D; CDMOs help with required capability augmentation

- **Increasing number of products across technology platforms is driving the size of investment required to build in-house capabilities; CDMO assist to overcome gaps**
  - Outsourcing early-stage technologies can reduce the risk of investing in manufacturing technologies while pipeline uncertainty is still so high
  - The span of required technology platforms is increasing: partnering with CDMOs allows Biopharma players to strategically phase their investment timelines and choose their platforms

CDMO industry maturing; provides economies of scale leading to cost flexibility vs in house

- **CDMO industry is maturing; aggregation of demand lead to economies of scale**
  - Large customers **comfortable** with outsourcing work that could be performed in-house; CDMOs have **demonstrated ability** to perform quality work
  - CDMOs **aggregate demand** enabling them to **achieve higher utilization** and lower per unit costs in service lines
- **Large pharma companies use CDMOs as means to avoid fixed costs and use flexible capacity as needed**

Source: Industry reports, expert interviews, Bain analysis

1-3 Risks | Limited long-term disruptions expected; BioSecure Act seen as an opportunity for US/ European players to gain market share

MARKET GROWTH

Impact N5Y: Opportunity | Threat | High | Medium | Low | Very Low

DIRECTIONAL

		Impact	Description	Rationale
Tailwinds	**BioSecure Act**		• Bill **introduced to US House** (H.R.7085) in Jan 204 to **prohibit federal contracting of biotechnology companies** connected to 'foreign adversaries' **targeting Chinese firms** • **Expected tailwind for US and European** CDMOs/ CPOs as customers of implicated Chinese firms look to move future projects	• Manufacturers will likely **move to US, European (specifically Eastern Europe** owing to cost-effectiveness and quality workforce) **and India based** CDMOs or CPOs as insourcing is not in their core/ a priority for investment • Rentschler's **recent US expansion** positions it to meet rising demand from clients looking to diversify supply chains away from China. However, it may face **increased competition** from both European and rapidly expanding Indian CDMOs, with **Indian firms likely attracting clients through cost advantages**
	Covid Impact		• Covid led to **increased demand for vaccine,** prompting pharmaceutical companies to rely heavily on CDMOs for their fill & finish (**F&F) and** contract packaging organisation **(CPO) capabilities** as well as **timely and cost-effective delivery**	• The pandemic **accelerated advancements in mRNA technology**, generating interest in RNA-based therapies beyond just COVID-19 vaccines • As demand has stabilised, the pandemic has shifted mix towards more **complex biologics and advanced therapies**; **Rentschler's expertise** in manufacturing these complex formats positions it well to meet this evolving market demand
Headwinds	**Supply chain**		• Supply chain disruption driven by **shortages in the availability** of core primary (e.g., vials) and secondary (e.g, boxes, cartoning) packaging, as well as **service interruption** of distribution partners	• Heavily commoditized market where **suppliers ensure high service levels** due to relatively easy ability to switch • **Rentschler primarily reliant on Vetter** for fill and finish and secondary packaging, and any **significant disruptions** in Vetter's operations could lead to **project delays** or **lost business opportunities** for Rentschler
	CRDMO business model		• The **transition of** CDMOs to Contract Research, Development, and Manufacturing Organizations (CRDMOs) is leading them to offer end-to-end services – from **discovery to commercialization**	• The CDMO business model will be a **key differentiator** for biologics CDMOs as **demand for early development services** for new modalities is increasing rapidly **to support early-stage pipeline,** challenging traditional CDMOs
	Insourcing		• **Risk of pharmaceutical firms insourcing** discovery or pre-clinical trial activities in the future	• **Some evidence of pharma cos. looking to insource** capabilities (e.g., Novo acquisition of Catalent, Lily investing in in-house capabilities to fulfil GLP demand) though overall **increase in demand expected to outgrow what sponsors are adding in-house** and a slight shift towards more outsourcing expected across value chain steps
	Inflation Reduction Act		• **Inflation Reduction Act** (U.S.) introduced in 2022 to address drug pricing and **Medicare spending** for top 50 most expensive drugs • **Negotiations underway for Top 10 drugs**, to be completed by Sep 2024 with new prices effective in 2026 and more drugs to follow	• Maximum Fair Price (MFP) negotiations shorten the economic lifecycle for **small molecule drugs to 9 years** and **large molecules to 13 years**, **impacting small molecules more severely** due to the shorter timeline; Rentschler**, primarily focused on large molecules**, would experience a **relatively smaller risk**
	CDMO & LCC competition		• **Increased competition** in fill & finish (F&F) and packaging segments from CDMO expanding into the value chain (e.g., secondary packaging) or low-cost-competitor (LCC)	• **Cost not a key KPC** given niche technical expertise, which is main advantage LCC offer; moreover, BioSecure Act reduces the threat from Chinese players, while Indian firms may gain market share in Gx/ small molecules where manufacturing is in LCCs

Source: Company website, Lit. search; Market participant interviews

AGENDA

Investment considerations

Business overview

Market overview

Competitive landscape

ESG assessment

Market can be split between very large integrated CDMOs (e.g., Catalent, Lonza), mid-sized biologics players (e.g., Rentschler) and small / niche specialists

COMPETITIVE LANDSCAPE | ARCHETYPES

Key: Typically offered | May be offered | Not offered

PRELIMINARY

		Small biologics CDMOs	Mid-sized biologics CDMOs	Large one-stop-shop CDMOs
Description and value proposition		Focus on manufacturing **limited number of specialty APIs** typically in 1 modality	Players with **API manufacture** +/- **fill-finish** services in multiple but **not all biologics modalities** • Pure API manufacturers • Integrated API manufacturers offering F&F	**Comprehensive end to end service from API manufacture through to FDF**, with a **broad portfolio** of technological capabilities and APIs
Company revenue		<€100M	€0.1-1B	€1B+
Negotiating power in the value chain		**Low** unless technical niche (e.g. ADCs and CGT)	**Medium to high** (depending on the specialty biologics and specific processes)	**High,** esp. for large pharma customersand for drugs with peak sales forecasts
Modality coverage	**Small molecules**	Likely not offered	Likely not offered	✓
	Biologic modalities	Very few (~1-2)	Fewer number vs. larger CDMOs	Likely all
Value chain coverage	**API Manufacturing**	Limited	✓	✓
	Finished Drug Product	Likely not offered	May rely on **third-parties**	Yes, **end-to-end** offerings
Typical customers		**Small to mid-sized biotech** or **specialized pharma firms** that require **tailored solutions**	**Mid-to-large sized biotech companies** looking to outsource generic **value-chain processes**, while retaining control over other **aspects of development**	**Large pharma** seeking comprehensive services to **streamline their operations** and **reduce time-to-market** for new products
Example companies		NORTHWAY BIOTECH, CELONIC	ABZENA, Rentschler Biopharma, AGC Biologics, IDT	patheon by Thermo Fisher Scientific, Catalent, Lonza, SAMSUNG BIOLOGICS, Recipharm, Boehringer Ingelheim

Source: Market participant interviews; Bain analysis; Lit. search

Rentschler's competitors include KBI Biopharma & AGC Biologics; and IDT Biologika in viral vaccines; many of these have in-house manufacturing and fill-finish services

COMPETITIVE LANDSCAPE | COMPETITOR DETAILS | PRELIMINARY

	Mid-sized Biologics CDMOs				Large one-stop-shop CDMOs	
Company	Rentschler	KBI BIOPHARMA	AGC Biologics	IDT	Lonza	WuXi Biologics
Description	Full-service CDMO (through strategic alliances) with focus on large molecule mfg.	Full-service CDMO with broad portfolio and focus on protein-based biologics	Full-service CDMO across development, clinical, and commercial mfg. stages	Clinical & commercial mfg.- focus on fill-finish services, infectious diseases, oncology	Diversified CDMO group with end-to-end offerings – biologics, small molecules, CGT	Offers end-to-end solutions from discovery to manufacturing in biologics, CGT
Ownership	Private	Private	Private	Private	Public	Public
HQ	Laupheim, Germany	North Carolina, USA	Seattle, USA	Dessau-Rosslau, Germany	Basel, Switzerland	Wuxi, China
Revenue (€M)	€287M	€500-1,000M *(est.)*	€835M[1]	€275M	€4,751M[2]	€2,214M
EBITDA margin (%)	30%	*n/a*	22%[1]	6%	30%[2]	40%
Molecule types	Monoclonal Antibodies, Recombinant Proteins	Monoclonal Antibodies, Proteins, ADCs, CGT	Monoclonal Antibodies, Proteins, Vaccines, ADCs, CGT	Vaccines, CGT	Monoclonal Antibodies, Proteins, Vaccines, ADCs, CGT	Monoclonal Antibodies, Proteins, Vaccines, ADCs, CGT
Clinical / Commercial	Primarily Clinical	Both	Both	Primarily Clinical.	Both	Both
Value chain coverage	Primarily Clinical Mfg.	End-to-end	End-to-end	Primarily Clinical Mfg.	End-to-end	End-to-end
Strengths	• Good track record • Technical expertise • Steady outlook for commercial business	• In-house capability for cell line development • Analytical development and process optimization • Expertise across modalities	• Extensive experience in microbial, mammalian systems • Advanced gene therapy capabilities	• Expertise in viral-vector manufacturing, inc. F&F capabilities and BSL3[4] operations	• Scale and global footprint • Integrated capabilities from drug substance to drug product	• Global supply chain • Focus on innovation • "Follow-the-Molecule" strategy helps accelerate biologics development
Weaknesses	• Recent expansion yet to yield expected profits • Few recent quality issues discovered via FDA inspections	• Caters mostly to small to mid-size biotech • Tech. gaps in CGT and viral vector capabilities	• Slow paced innovation compared to peers • Falling customer service levels	• Lack of global presence • Lack mfg. capabilities (mostly specialize in vaccines)	• Difficulty in catering to smaller clients • Weak presence in other markets ex. Europe	• Biosecure act affecting sales in US and Europe • Lack of investment in customer service

Formulation development offered via strategic alliance with Leukocare, fill-finish via Vetter

Note: Financials for FY23 unless indicated otherwise; (1) For parent Co. AGC Inc.'s Life Science division (2) For Biologics and CGT division (3) Investigational New Drug (4) Bio-safety Level 3 laboratories; Used to study infectious toxins or diseases that may be transmitted through air and can potentially lethal infections | Source: Company website; Crunchbase; Market participant interviews; Lit. search

Best-in-class offerings and technical expertise seen as prerequisites; ability to scale with customer pipeline, track record, etc. typically drive vendor selection

PURCHASING BEHAVIOR | KPCS

PRELIMINARY

KPC definition and rationale

What we have heard

	KPC	KPC definition and rationale	What we have heard
Qualifying factors	**Best-in-Class Offerings**	• **High quality, timeliness, compliance** (regulatory and cGMP) and **ability to supply** are highly valued as clients need to obtain **regulatory approvals** and seek to **minimize risk** and **avoid compliance issues** • **High switching costs** if issues with CDMOs arise	*"Not having F&F capability is a little concerning because it shows that they are still growing and doesn't show they are a one-stop-shop; large pharma cos. prefer a one-stop shop as it gets difficult for them to monitor a third-party for F&F and a CDMO for mfg."* - Customer
	Technical expertise	• Offering **relevant API formulation, manufacturing capabilities** and **expertise** • Ability to **foresee challenges** like **issues with scaling** or **process deviations** more effectively	*"One of the best CDMOs, wide experience with a wide variety of clients, project management department is one of the bests in the industry and they have good leadership team and technical expertise"* - Former Project Leader
Higher	**Alignment with current and future pipeline**	• Ability to scale with the client's **evolving pipeline** (from pre-clinical to commercial stage) • Reduces need to **switch partners** midstream which can be **costly** and **time-consuming**	
	Track record and experience	• Proven ability to **meet deadlines, navigate regulations** & **maintain quality** • Ensures CDMO understands **nuances** of specific **biopharma products** & **therapeutic areas**	*"Experience over multiple years of operations… good technical expertise and track record."* - Customer
	Preferred Vendor Status	• Ensures benefits like **priority access** to resources, **favorable pricing**, **faster response times** • Important when **rapid scale-ups** or **regulatory submissions** are required	*"Good relationships with certain big pharma – lots of repeatability there."* - Former Senior Director Business Development
	Value-Add Proposition	• Services beyond core manufacturing (e.g., **regulatory support, supply chain management, strategic support,** or **post-market activities**) make the partnership more attractive	*"Regular status reporting but no real-time reporting, that can be especially helpful during pandemic events"* - Customer
Lower	**Cost**	• **Competitive** pricing that **aligns** with the value proposition preferred • More important for **large pharma** companies	*"Not very competitive in pricing… considered premium"* - Former Senior Director Business Development

Source: Market participant interviews

Rentschler delivers on most KSFs.....

COMPETITIVE LANDSCAPE | KSFS

PRELIMINARY

Key success factors	Capabilities	Typical customers	Rentschler differentiation
Deep niche technical capabilities and expertise	• Key technologies & equipment e.g., own cell line, range of bioreactor scales, viral vector tech • Experienced expert FTEs	• Small pharma • Big Pharma	• Strong **track record** with 50+ years of experience**, quality** and **expertise** in **mAbs and multi-specifics** • **One of first few** players in **multi-specifics** • **Proprietary HEK293 cell line** for advanced therapy projects
Full value chain coverage	• One-stop-shop vertical integration, development through to FDF – Via alliances or in-house	• Small pharma	• **Strategic alliances** with Leukocare as the exclusive provider for **formulation development,** and with Vetter for **fill & finish** services (e.g., vials and syringes)
Clinical and commercial offerings	• Expertise in clinical & commercial production • Seamless comm transition: – Scale up processes/quality control	• Big pharma • Small pharma	• **Facilities designed to support both** clinical and commercial manufacturing, with **flexibility in operations**
BD based on personal C-suite relationships	• Full potential BD approach: – C suite members involved in proposal phase – Partnership behaviours – Underpinned by strong marketing & tradeshow presence	• Small pharma	
Efficient supply chain and manufacturing footprint	• Optimised operations to maintain utilisation ~60% across sites	• Big pharma	• **Dedicated manufacturing facilities** for biologics and viral vectors respectively, and recent **capacity expansions** • **Reduced timelines with process intensification** e.g., sped up the cell culture step of its biomanufacturing process by 35% by “seeding” the bioreactor with a larger number of cells (2020)

Source: Company website; Annual reports; Market participant interviews

Market participants cite strong track record in mAbs / proteins & Multi-specifics, as well as flexible approach; lacking in-house FDF and some fringe tech capability gaps

ASSET OVERVIEW | STRENGTHS & WEAKNESSES | PRELIMINARY

	Strengths		Weaknesses	
Technical expertise	**Strong MAB, protein expertise**	Expertise in mAbs with >300 different molecules and protein production on around 130 therapeutic protein formats e.g., Fc fusion proteins, monoclonal antibodies, modified proteins etc. *"Lot of expertise, high client service; easier for small companies to get through"* - Former Sr. Director, Bus. Development	**Limited capabilities in own cell lines**	In-house cell lines yet to be fully developed *"Do not have in-house capabilities for cell therapy…. can manufacture viral vectors for vaccines or gene therapies"* - Former at Competitor
	Strong multi-specific capabilities	*"Well versed in multi-specifics… one of the first few players in this area"* - Former Sr. Director, Bus. Development	**Limited diversity in modality (e.g., no ADCs, CGT)**	*"May offer specific cell lines or plasmids, but not differentiated on technical capabilities"* - Former at Competitor
	Full-service CDMO (via alliances)	Offers entire value chain through strategic alliances with reputable partners (e.g. Leucocare in Formulation, Vetter for Fill & Finish) *"It is critical to work with a team that has strong AAV experience....& will be a true partner every step of the way"* -Customer	**Low track record in viral vectors**	Viral vector capabilities relatively nascent compared to other established CDMOs *"Only started viral vector mfg. which seasoned CDMOs are already doing"* - Customer
	Quality and track record	Strong reputation in mAbs and protein production, for premium services supported by good project management capabilities and demonstrated through client repeatability *"One of the best CDMOs.., project mgmt. dept. one of the best in industry"* - VP Business development, Competitor	**Lack of in-house FDF**	*"Having in-house FDF services is a plus, taking away quality lapses from outsourcing to third-parties"* - Customer
Non-technical factors	**Flexibility and personalization**	Offers personalized services compared to larger firms, which often struggle to cater to smaller clients on custom clinical and service requirements	**High Pricing**	*"They are at an 8 or 9 in pricing on a scale to 10"* (1 being most affordable, 10 being premium) - Former Project Leader
			Low visibility in marketing	*"Not the strongest sales and marketing or Business development arm; quite quiet, not v present at tradeshows* - VP Business development, Competitor

Source: Market participant interviews; Company website

AGENDA

Investment considerations

Business overview

Market overview

Competitive landscape

ESG assessment

Materiality | In the CDMO industry, GHG emissions, water stewardship, hazardous substances, and labour practices are highly material (1/2)

BCN: Updated 21st Oct

/ OUTSIDE-IN VIEW

E Environment
Living within our planetary boundaries

High — **GHG emissions**
Reducing & offsetting GHG emissions contributing to climate change

High — **Water stewardship**
Sensible water use, water quality, and watershed management

Medium — **Material use, waste & circularity**
Responsible sourcing and use of resources, incl. product, packaging, and food lifecycles

High — **Hazardous substances**
Sensitively using and treating toxic products and waste, incl. chemical and technology pollutants

Biodiversity & Animal welfare
Protecting and enhancing natural ecosystems and living organisms; upholding animal welfare

Land and ocean use
Ensuring long-term sustainable land and ocean use, sound utilization practices

Air quality
Lowering pollutants impacting air quality and atmospheric integrity

S Social
Committing to equitable outcomes

Human rights
Upholding the corporate responsibility to respect universal rights (e.g., freedom of expression, no forced/child labour)

High — **Labour practices**
Decent and safe work, incl. equitable pay / benefits, upskilling / development, and hiring practices

Medium — **Consumer safety & engagement**
Safe offerings, clear labeling and non-abusive in marketing and pricing

Diversity, equity & inclusion
Practices and culture promoting diversity, equity, accessibility and inclusion inside company and beyond

Customer health & wellness
Products, services, and technologies that enhance customer / patient well-being

Digital rights and responsibilities
Secure and ethical technology systems, infrastructure, and data practices; duty of care to customer privacy; responsiveness to law enforcement

Community partnership
Aware and/or engaged members of the communities and broader society

G Governance
Demonstrating responsible conduct

Governance foundation
Norms and practices related to good governance, e.g., ownership & control, board diversity, accountability

Medium — **Business ethics**
Sound decision-making, ethical conduct; no anti-competitive practices, bribery, or corruption

National and intl. policy
Appropriately navigating complex domestic and international issues, incl. policy and lobbying stances

Transparency & risk management
Accurate accounting; appropriate risk disclosure and management; ESG transparency

Medium — **Third-party relationships**
Clear practices embedded in sourcing activities and investment and partnership decisions

Tax practices
Fair tax payment and practice

Indirect economic impacts
Sensitivity to indirect impacts on external populations of firm's economic activity

Materiality assessment

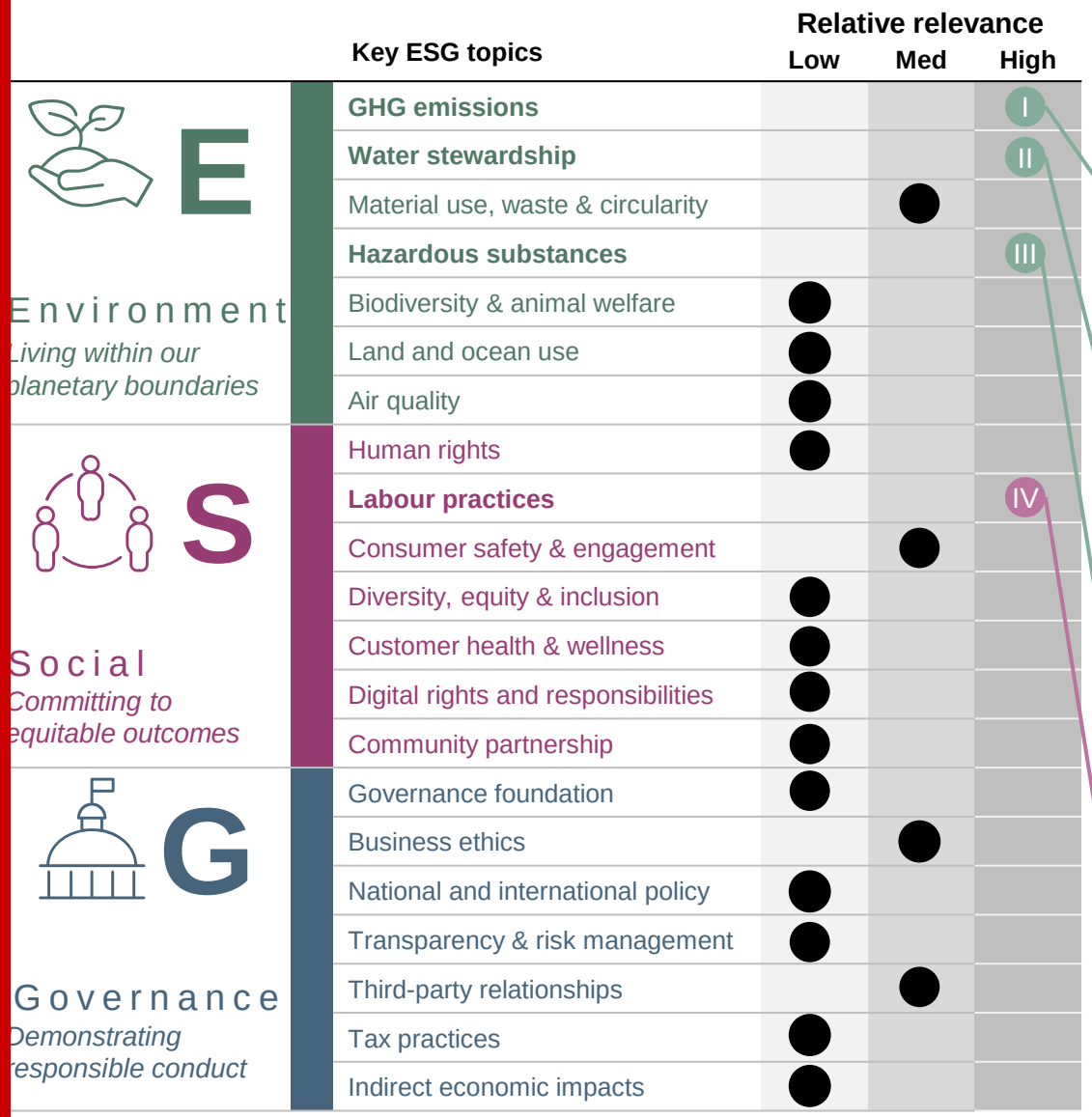
Topics with a high degree of materiality are of extreme importance to industry players to retain a license-to-operate from governmental and public standpoint, but are equally important to capture full commercial value from consumers and stay relevant vs. competitors

Topics with a medium degree of materiality are important as they receive attention from regulation and the public, and provide opportunities to enhance commercial success, however they are not essential to retain license-to-operate

Materiality | In the CDMO industry, GHG emissions, water stewardship, hazardous substances, and labour practices are highly material (2/2)

BCN: Updated 21st Oct

PRELIMINARY



Highest material topics rationale

GHG Emissions

- Biologics manufacturing in the CDMO industry is highly **energy-intensive**, involving processes like **fermentation, purification, refrigeration, sterilization**, etc. which require constant energy input for **precise conditions** (e.g., temp. control, air quality control, etc.)
- EU Green Deal (2020) mandates **55% GHG reduction by 2030** and the EU ETS[1] has **2.2%** annual emissions reduction target for the overall manufacturing industry
- Biologics CDMOs face pressure from **customers** (e.g., pharmaceutical companies like GSK, Merck, etc.) who have scope 3 emission reduction targets for upstream activities

Water Stewardship

- Biologics manufacturing involves **water-intensive processes** (e.g., cell culture, purification, cleaning, and sterilization) which require **large quantities of freshwater** impacting water-stressed areas; additionally, it risks **contaminating water bodies** with **heavy chemicals** (e.g., fluorine) and **micropollutants** (e.g., anti-microbial resistance)
- The **EU Drinking Water Directive (2021)** requires manufacturers **to reduce pollution of surface and groundwater** sources and protect **vital drinking water** sources
- Peers like Lonza target to reduce industrial **water usage intensity** by **50% by 2030**

Hazardous Substances

- Biologics production uses **hazardous, infectious or toxic** substances (e.g., solvents, bioreactor additives, cleaning agents) which require **specialized handling and disposal**, and pose significant risks to the environment, human health, and product quality and safety
- **Regulatory bodies** (e.g., FDA[2], EMA[3]), regulate the use and management of hazardous substances, and monitor the safety and efficacy of pharmaceutical products; EU has set frameworks (e.g., REACH[4], Waste Framework Directive (2008), Directive 2008/68/EC) to ensure **management**, **transportation**, & **storage** of hazardous waste by manufacturers
- Peers like WuXi have made efforts towards achieving a **23% decrease** in **hazardous waste intensity** in 2023 vs 2022

Labour Practices

- Employees in biologics manufacturing handle **biohazardous substances** (live cultures, genetically modified organisms, etc.), risking **pathogen exposure**; additionally, toxic chemicals and heavy equipment pose risks of **chemical exposure** and **physical injury**
- EU enforces **guidelines** (e.g., PPE Regulation (2016), Chemical Agents Directive (1998), etc.) **to prevent occupational exposure** to chemicals, including adopting **common minimum standards**, providing personal protective equipment, etc.
- Peers like WuXi focus on **extensive OHS training** (incl. routine safety training, first aid training, fire drills, etc.) with **100%** of employees receiving these trainings

Note: (1) EU Emissions Trading System; (2) Food and Drug Administration; (3) European Medicines Agency; (4) Registration, Evaluation, Authorization and Restriction of Chemicals | Source: Company Reports; Lit. Search

BAIN & COMPANY