

# **Biotech Moat Overview**

Diversified, innovative portfolios support wide moats for Big Biotech. Single-product reliance and weaker pipelines can narrow a moat.

## Morningstar Equity Research

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## **Executive Summary**

We reviewed the qualitative strength of competitive advantages across much of our biotech coverage, and for each firm, compared our forecast 10-year returns on invested capital to our assumed weighted average cost of capital. We think most Big Biotech names continue to support wide moats, with excess returns more likely than not over the next 20 years. Strong innovation is countering headwinds from patent expirations, US drug pricing legislation, and pharmacy benefit managers negotiating leverage. Companies with more product concentration risk or weaker pipelines can still secure a narrow moat, with excess returns likely over the next 10 years. A combination of increasing product concentration, threats to the current portfolio, and a weak pipeline can warrant a no-moat rating.

#### **Key Takeaways**

- ► We see a median spread between ROIC and WACC of 10% for our wide-moat Big Biotechs, ranging from Novo Nordisk's strong profitability on its cardiometabolic portfolio to Gilead's slightly narrower spread on its dominant HIV portfolio and innovative oncology pipeline.
- We think Sobi's growing portfolio of hematology and immunology products now warrants an upgrade to a narrow moat, although we have downgraded Biogen to a narrow moat because of patent pressure and high-risk neurology programs. We also downgraded Grifols to no moat because of increasing competition and poor economics around the firm's plasma business.
- ▶ We see undervalued pipelines at top Big Biotech picks Gilead and Roche.

**Exhibit 1** Biotech Moat Summary: Intangible Assets—Largely Based on Patents—Support Moats

					Fair Value			10-Year Projected Ave.	
Company	Ticker	Star Rating	Sto	ock Price	Estimate	Moat Rating	Moat Source(s)	ROICs vs. WACC	Comment on Moat Rating
Amgen	AMGN	***	\$	304.73	\$ 31	7 Wide	Intangible Assets	16% vs. 7%	New blockbusters refresh a mid-sized patent cliff, even if maritide fails.
						Downgrade to			Biogen is adding lower-risk immunology, rare disease programs, but still
Biogen	BIIB	****	\$	225.98	\$ 30	3 Narrow	Intangible Assets	11% vs. 7%	overshadowed by MS drug patent pressure and Alzheimer's uncertainty.
							Intangible Assets		
BioMarin	BMRN	***	\$	82.94	\$ 8	7 Narrow	Efficient Scale	11% vs. 7%	Rare disease portfoliio finally supporting solid ROICs, but pipeline looks weak.
									HIV dominance and growing oncology pipeline support a steady competitive
Gilead	GILD	****	\$	65.25	\$ 9	7 Wide	Intangible Assets	15% vs. 7%	advantage.
						Downgrade to	Intangible Assets		Grifols may recover from Covid pressures and inefficiencies, but plasma market is
Grifols	GRFS	****	\$	7.10	\$ 11.8	0 None	Cost Advantage	6% vs. 7%	facing increased fundamental pressure.
							Intangible Assets		Stellar GLP-1 growth rests on a foundation of innovative cardiometabolic
Novo Nordisk	NV0	*	\$	143.63	\$ 8	6 Wide	Cost Advantage	39% vs. 7%	therapies and drug candidates.
									Eylea and Dupixent support strong ROICs, but pipeline beyond remains mostly
Regeneron	REGN	**	\$	1,002.55	\$ 75	0 Narrow	Intangible Assets	18% vs. 7%	centered on high-risk oncology.
									Steady, strong ROICs supported by diverse, innovative drug portfolio and leading
Roche	RHHBY	****	\$	33.46	\$ 5	5 Wide	Intangible Assets	17% vs. 7%	diagnostics platforms.
						Upgrade to			High ROICs as hemophilia revenue endures and the pipeline offers
Sobi	SOBI	****		SEK 273.20	SEK 3	13 Narrow	Intangible Assets	14% vs. 7%	diversification, even if innovation remains acquired.

Source: Morningstar. Data as of June 10, 2024

#### Big Biotech and Big Pharma Moats Have Similar, Strong Foundations

While biotechnology firms have a history of being the smaller, higher-risk cousins to the more stable and diversified Big Pharma firms, large-cap biotechs have a closer resemblance to Big Pharma. The main difference is that biotechs more frequently use biologic rather than chemical processes to design and manufacture new therapies, although today's biotechnology and pharmaceutical firms employ both methods. We think long-lived patents on innovative products will continue to form the basis of Big Biotech's intangible assets, allowing them to maintain strong pricing power despite continued policy headwinds. The 95%-plus gross margins for these firms allows them to produce returns on invested capital well above their cost of capital, even after allowing for ample investment in research and development as well as marketing costs.

For more background on industry and company specific patent/pipeline outlook, please see our report: Biopharma Pipeline Report. For a moat review of Big Pharma, please see our report: Big Pharma Moat Overview.

# Threat of Material Value Destruction Fades Following Inflation Reduction Act as Lawmakers Turn Attention to PBMs

The US market represents close to half of global pharmaceutical sales and well more than 50% of profits, giving it increased importance in assessing moats. Pharmacy benefit managers negotiate pricing with drug firms on behalf of most individuals in the US, whether they are covered by private insurance (typically through employers) or government programs (like Medicare and Medicaid). PBMs have gradually consolidated over the past 20 years, with the top three PBMs now representing nearly 80% of the market, giving them greater negotiating power for each contract. In addition, the 2022 Inflation Reduction Act made changes to Medicare (30% of the US market) that discourage price increases and allow Medicare to negotiate significant discounts on certain older drugs that still hold patent protection.

While we think the pricing power that drug firms can generate from their intangible assets has weakened, payers continue to support high prices for innovative therapies. In addition, as the Inflation Reduction Act should help reduce government Medicare spending as well as out-of-pocket costs for Medicare patients, we think significant additional policy pressures on drug firms (like international price benchmarking, or broader reform as part of a transition to a single-payer system) are becoming less likely. Attention has shifted toward the role of PBMs in perpetuating a market that can expose patients to high out-of-pocket costs despite back-end rebates that PBMs receive from drug firms.

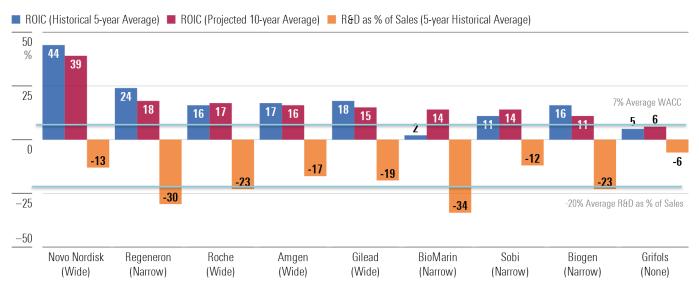
For more background on these trends and risk, please see our reports: How ESG Risk Affects Moats and Valuation in Pharma and Biotech and Biopharma ESG Risk: Introducing Our Capsule System for Assessing US Drug Pricing Risk With ICER Cost-Effectiveness Benchmark.

#### **Key Considerations for Evaluating Big Biotech Moats**

#### What Quantitative Metrics Can We Use to Evaluate Moats for Big Biotech?

The spread between ROIC and WACC is one of the clearest indicators of a firm's competitive advantage, and in biopharma in particular, investing in the pipeline (R&D expenses as a percentage of sales) is a sign of supporting the next generation of innovative products entering the portfolio. Firms with higher ROICs and a history of supporting R&D investment tend to be best positioned for long-term excess returns. Novo Nordisk is an outlier here, with strong ROICs despite lower R&D spending as a percentage of sales, as its very focused cardiometabolic business sees significant operating leverage from strong demand for GLP-1 therapies. At the opposite end of the spectrum, Biogen also stands as an outlier, as patent expirations on older multiple sclerosis drugs have weighed on profitability, but the firm continues to spend significantly on a variety of higher-risk neurology and lower-risk immunology and rare-disease pipeline programs.

Exhibit 2 Biopharma ROIC and R&D Trends: Investment in R&D Supports Long-Term Returns



Source: Morningstar, company reports.

## **How Much Product Concentration Does a Company Have?**

Firms with lower product concentration risk tend to be more likely to generate excess returns. The breadth of a firm's portfolio can be an indicator of the strength of intangible assets such as R&D productivity or business development success and generally provides a buffer against increased competitive threats to a single product. Returns from a single drug can be eroded by patent expiration, new branded competition, or unexpected safety issues that dramatically cut its sales potential. However, the impact to the portfolio is lessened if there are multiple drugs with strong sales to support excess returns.

We measure product concentration using an equation similar to the Herfindahl-Hirschman Index, focusing on individual product sales as a percentage of a firm's total sales, instead of industry concentration. Our forecast product concentration levels are highest for Grifols, which gets most of its sales from a handful of plasma-derived therapies. At the opposite end of the spectrum, wide-moat Big Pharma names like Pfizer and J&J give context for our Big Biopharma risk levels.

■ HHI 2023 ■ HHI 2028 Higher 4,000 3,000 Highly Concentrated Portfolio Concentration Risk 2,000 Moderately Concentrated Portfolio 1,000 Lower 0 Sanofi AbbVie Bristol Sobi Biogen Astra Novartis GSK Roche Pfizer BioMarin Lilly Amaen Merck REGN (Wide) (Narrow) (Narrow) (Wide) (Wide) (Wide) (Wide) (Wide) (Wide) (Narrow) (Narrow) (Wide) (Wide) (Wide) (Wide) (Wide) (Wide) (Wide)

Exhibit 3 Biopharma ROIC and R&D Trends: Investment in R&D Supports Long-Term Returns

Source: Morningstar, company reports.

#### How Much Patent Exposure Is There Over the Next Five Years?

Brand-name drugs enjoy 20 years of patent protection, but a significant portion of the protected period is eaten up by clinical trials because a patent application is usually filed as soon as a drug is identified. Many drugs enjoy only eight to 10 years of patent protection after they're launched, so it is crucial to identify the exclusivity period of each drug when assigning moats. Firms with higher exposure to patent losses will have less capital to allocate to the pipeline over the next several years, making it less likely to support long-term excess returns.

While biologic molecules are more complex to manufacture than most small-molecule (traditional pharmaceutical) drugs, generic and biosimilar manufacturers have had success with recent antibody launches. Unless a firm has a collection of biologics that are particularly complex (antibody-drug conjugates and CAR-T cell therapy, for example), we don't think a focus on biologic therapies provides significant protection from typical small-molecule patent exposure.

#### How Strong Is the Outlook for the Pipeline Over the Next Five Years?

Innovation in the pipeline is the key to pricing power and the translation of competitive advantages into excess returns. While we forecast pipeline sales over the next 10 years in our valuation models, we analyze pipeline strength for each company in this report over a five-year forecast period, as we tend to see higher uncertainty to our forecasts beyond this period.

#### Are There Any Major Acquisitions Over the Past Several Years That Dilute ROICs?

Biopharmaceutical firms make acquisitions to support pipelines, bring in new technologies, counter challenging periods of patent expiration, reduce their tax rates, and leverage their typically broad geographic reach. That said, firms with attractive pipelines likely face a competitive sale process, making it difficult for Big Biotech to improve ROICs even if they manage to close a deal on a firm with strong prospects. Large acquisitions increase a firm's invested capital (through a combination of intangible assets and goodwill) and can also pressure returns (amortization of intangible assets as well as upfront in-process research and development charges for asset acquisitions).

## What Trends Are Affecting Industry Productivity, and Do Any Firms Stand Out?

With less than 10% of drugs entering clinical studies likely to reach the market, improving industry R&D productivity would be key to securing a wider spread between returns on invested capital and the cost of capital.

New types of drugs, or new modalities, can help drug firms gain new tools for previously difficult-to-treat diseases. For example, biopharma firms like Merck (in partnership with Moderna) as well as Roche and Pfizer (in partnership with BioNTech) have access to mRNA technology to drive further innovation with vaccines as well as oncology and rare-disease treatments. Machine learning can help identify specific mRNA sequences to maximize the efficacy of vaccines and treatments. In oncology, cell therapy and novel antibody-based therapies (antibody drug conjugates and bispecific antibodies) are providing more durable responses to treatment, protecting healthy cells from the effects of chemotherapy, and activating and directing immune cells to help destroy cancer cells.

Researchers at GSK have estimated that having genetic support for drug targets could roughly double success rates of drug candidates. Firms like Amgen and Regeneron have large human genetic databases that they are using to better understand how diseases develop. For example, certain genetic mutations could predispose or protect individuals from a given disease, providing potential new targets for drug development. Combining these databases with advances in artificial intelligence could help to speed these discoveries.

<sup>1</sup> The support of human genetic evidence for approved drug indications; Nelson, Matthew R., et al.; Nature Genetics.

#### Amgen: We Maintain Our Wide Moat Rating for This Established Biotech

Despite a key patent loss in 2025, we think Amgen's newer portfolio and large late-stage pipeline put the firm in a solid position to maintain ROICs north of its cost of capital. Amgen's 2012 acquisition of deCODE genetics gave it access to a large human genetics database, which helps to identify or validate novel drug targets, supporting blockbuster therapies like cholesterol-lowering drug Repatha and osteoporosis drug Evenity, and obesity pipeline candidate MariTide. Amgen has also worked with Nvidia to accelerate drug development, not only using its large language models and generative Al service, but also building a data center platform to maximize the potential of its human genetics data. Amgen's Nvidia partnership has already increased the chances of an antibody drug candidate reaching clinical trials from 50% to 90% and shortened the research phase of a drug's R&D timeline from two years to less than one. Amgen also has a strong track record in biologic therapies, highlighted by recent innovation in cancer bispecifics such as Blincyto (leukemia) and Imdelltra (lung cancer).

While we see Amgen's history of acquisitions and collaborative deals as relatively neutral to ROICs, meaning that they do not appear to create or destroy significant economic value, we think they improve the firm's competitive positioning and moat sources. Amgen seems particularly good at finding assets that take advantage of its global infrastructure and established salesforces, such as tucking immunology drug Otezla into an Enbrel-driven immunology business or focusing on geographic and prescribing label expansion of Horizon's rare-disease portfolio.

Exhibit 4 Amgen: Key Product Overview

Patent Pressure		Inline Products		Pipeline Outlook	
Top Products (% of 2023 sales)	Patent Loss	Top Potential Drugs (% of 2028 sales)	Patent Loss	Top Products (Launch year)	Peak Annual Sales
Prolia (14%)	2025	Tepezza (8%)	2038	MariTide (2027)	>\$8 Billion
Enbrel (13%)	2028	Repatha (6%)	2029	olpasiran (2027)	>\$2 Billion
Xgeva (8%)	2025	Tezspire (6%)	2029	Imdelltra (2024)	>\$2 Billion

Source: Morningstar, company reports.

## **How Much Product Concentration Does Amgen Have?**

Amgen has one of the least concentrated portfolios among our large-cap biotech coverage, with obesity therapy MariTide standing out as the next potential drug candidate to achieve sales on par with immunology drug Enbrel or bone-forming drug denosumab (Prolia/Xgeva). Amgen's portfolio stretches across multiple therapeutic areas (immunology, cardiology, nephrology, oncology, rare diseases) and modalities (including RNA-based oligonucleotides and bispecific antibodies).

<sup>2</sup> Cash, chips and talent: Inside Nvidia's plan to dominate biotech's AI revolution; Dunn, Andrew; Endpoints News.

#### How Much Patent Exposure Relative to Growth Is There Over the Next Five Years?

Amgen's biggest upcoming patent expiration is in 2025 for denosumab, which accounted for more than 20% of sales in 2023 between osteoporosis drug Prolia and bone metastases drug Xgeva. Enbrel sales are already declining from branded competition, and the drug also faces upcoming Medicare negotiation in 2026, so its 2028 patent expiration is less of a headwind. This is more than offset by sales of approved products, a large late-stage pipeline, and growing sales of biosimilars.

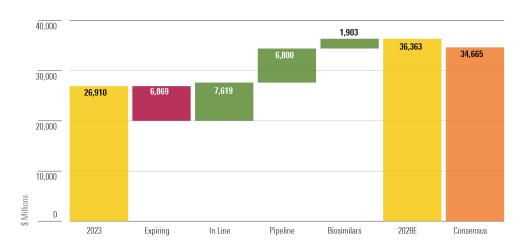


Exhibit 5 Amgen: Five-Year Sales Forecast (\$ Millions)

Source: Morningstar, company reports.

#### What Are the Key Points Against a Wide Moat Rating?

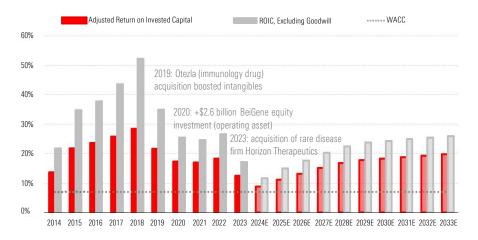
Amgen's acquisition of immunology drug Otezla in 2019 added \$13 billion in intangible assets to its balance sheet, and the 2023 acquisition of Horizon Therapeutics added intangible assets of around \$20 billion. Unless Amgen's newer in-house and acquired products and its late-stage pipeline can drive growth, Amgen could be forced to continue to acquire growth, placing additional pressure on ROICs. Obesity pipeline candidate MariTide is poised to enter phase 3 clinical studies and could easily generate peak sales north of \$10 billion or could fail to reach the market, adding uncertainty to growth prospects.

#### What Are the Key Factors to Consider Regarding ROICs?

Most of Amgen's goodwill (\$10 billion) dates back to the 2002 Immunex (Enbrel) acquisition, and it has been slowly building with smaller deals since then, with the 2023 Horizon Therapeutics acquisition adding \$3 billion. Intangible assets stem from the 2019 Otezla asset acquisition from Celgene as part of its sale to Bristol-Myers Squibb (\$13 billion) as well as the 2023 Horizon Therapeutics acquisition (\$20 billion).

## Exhibit 6 Amgen Historical and Projected Returns on Invested Capital

Horizon acquisition hits ROICs, but there is steady progress with an innovative, diverse portfolio and pipeline.



Biogen: Uncertain Alzheimer's Launch and Fading MS Portfolio Support Downgrade to Narrow Biogen's shrinking revenue in multiple sclerosis has created pressure on ROICs. Although the firm's significant investment in R&D and multiple collaborations could yield new products to keep excess returns intact, we are increasingly uncertain about Biogen's ability to improve ROICs.

Biogen has sunk substantial amounts of money into research and development, manufacturing, and commercialization preparation in Alzheimer's disease, only to see one failed launch with Aduhelm and a very slow launch of newer drug Leqembi. If the pathway to Alzheimer's diagnosis and treatment does not begin to rapidly improve, and if the phase 2 anti-tau candidate fails to reach the market, Biogen's high-risk investment in Alzheimer's disease may not pay off. Biogen does not have next-generation multiple sclerosis drugs to directly replace the several drugs going off patent that have supported its moat over the past two decades.

That said, cost-cutting programs and a focus on acquiring lower-risk programs in immunology and rare diseases are diversifying our revenue forecast, so success with these programs could move the firm back to a wide moat rating, regardless of Alzheimer's disease sales.

Exhibit 7 Biogen: Key Product Overview

Patent Pressure		Inline Products		Pipeline Outlook	
Top Products (% of 2023 sales)	Patent Loss	Top Potential Drugs (% of 2028 sales)	Patent Loss	Top Products (Launch year)	Peak Annual Sales
Tysabri (19%)	2023	Leqembi (17%)	2035	anti tau (2027)	>\$2 Billion
Avonex/Plegridy 11%)	2028	Spinraza (15%)	2030	LRRK2 (2026)	>\$1 Billion
Tecfidera (10%)	Expired/2025 EU	Skyclarys (7%)	2037	Lupus (2026)	>\$1 Billion

Source: Morningstar, company reports.

#### **How Much Product Concentration Does Biogen Have?**

Biogen has relatively low product concentration risk. Sales were historically more concentrated in multiple sclerosis but are poised to spread across multiple neurology, immunology, and rare-disease indications.

#### How Much Patent Exposure Relative to Growth Is There Over the Next Five Years?

Biogen's older multiple sclerosis drugs are in the process of losing patent protection, although sales of Avonex and Plegridy have been declining for years due to branded competition, and US Tecfidera sales have already been hit. We think newer approved drugs like rare-disease drugs Spinraza and Skyclarys and depression drug Zurzuvae will support growth despite patent exposure. We see more uncertainty around the firm's Alzheimer's drugs (approved drug Leqembi and phase 2 anti-tau pipeline candidate), as the launch of Leqembi has proceeded slowly despite Medicare reimbursement, but we think data supports increased uptake, and patient unmet need is very significant.

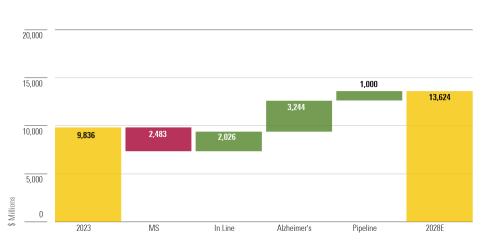


Exhibit 8 Biogen: Five-Year Sales Forecast (\$ Millions)

Source: Morningstar, company reports.

#### What Are the Key Points Against a Narrow Moat Rating?

Biogen is at a transitional point in its portfolio evolution, as old MS drugs lose patent protection, but newer products start their launches, so returns could improve to support a wide moat. Beyond Spinraza, which generates nearly \$2 billion in annual sales, Biogen is in the process of launching Leqembi as the first entrant in what we expect will evolve into a more-than \$10 billion market for Alzheimer's disease therapies. Differentiated therapies Skyclarys and Zurzuvae are also just launching and are poised to boost returns. Biogen's profit share from Roche for CD20-targeting drugs in MS and oncology, as well as sales of several biosimilar medicines, add further diversification to support its moat.

#### What Are the Key Factors to Consider Regarding ROICs?

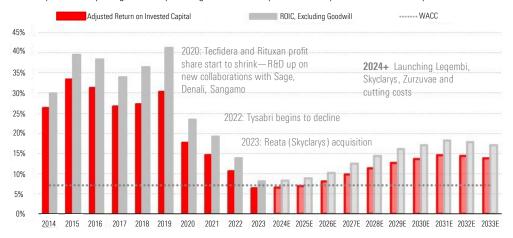
Biogen receives a significant profit share or royalty on several CD20-targeting products from Roche, and although sales of oncology drug Rituxan have already dwindled, next-generation oncology drug Gazyva is being tested in lupus, and two new drugs—Columvi and Lunsumio—were approved in 2022-23 and fall under the agreement. This expense-free revenue boosts Biogen's returns.

Significant pressure on Biogen's ROICs beginning in 2020 stems from multiple factors, including a stepup in collaboration activity, patent expirations pressuring sales on Tecfidera and profit share on Roche's Rituxan, as well as launch preparations for Alzheimer's disease drug Aduhelm (approved in 2021).

Biogen's ROICs could linger near its cost of capital, depending on its success in the high-risk, nascent Alzheimer's disease market. If we assume commercial failure of Leqembi and that the anti-tau program fails in development, it could take several years for ROICs to move significantly higher than Biogen's cost of capital.

**Exhibit 9** Biogen Historical and Projected Returns on Invested Capital

The firm is poised for improving ROICs despite being at a transitional point from multiple sclerosis to a newer portfolio.



# BioMarin: We Maintain Narrow Moat as Firm Reaches Critical Mass for Profitability, but Long-Term Pipeline View Is Fuzzier

We had attributed BioMarin's moat to both intangible assets and efficient scale, although as the firm's newer products drift from enzyme replacement therapies and enter larger markets, we think the efficient scale support is weakening.

BioMarin's ROICs are heavily driven by its ultra-rare-disease enzyme replacement therapy foundation (Vimizim, Aldurazyme, and Naglazyme) as well as the recent launch of growth disorder drug Voxzogo. Beyond Voxzogo, none of BioMarin's pipeline candidates have clinical data to support their potential, and we exclude them from the model. Voxzogo and the pipeline have potential in multiple new indications, although these drugs are generally targeting slightly larger rare-disease markets that could become competitive (BridgeBio could launch a Voxzogo competitor in 2027).

Exhibit 10 BioMarin: Key Product Overview

Patent Pressure		Inline Products		Pipeline Outlook	
Top Products (% of 2023 sales)	Patent Loss	Top Potential Drugs (% of 2028 sales)	Patent Loss	Top Products (Launch year)	Peak Annual Sales
Kuvan (7%)	Expired	Voxzogo (37%)	2035 US (est)	BMN 333	Not modeled
Naglazyme (17%)	Expired	Vimizim (21%)	2030 US/2029 EU	BMN 349	Not modeled
Aldurazyme (5%)	Expired	Roctavian (11%)	2037 US/EU (est)	BMN 351	Not modeled

Source: Morningstar, company reports.

## **How Much Product Concentration Does BioMarin Have?**

BioMarin has moderate product concentration risk, although risk is increasing as Voxzogo is likely to grow into the firm's top-selling drug.

#### How Much Patent Exposure Relative to Growth Is There Over the Next Five Years?

BioMarin's oral PKU drug Kuvan faces headwinds from generic competitors, but enzyme replacement therapies Aldurazyme and Naglazyme do not face biosimilar competition despite expired patents, which keeps patent exposure relatively minimal. Growth from these older enzyme replacement therapies as well as newer products Voxzogo and Roctavian far outweighs patent exposure.

Categorization by patent expirations, in-line products, and pipeline is less helpful for BioMarin than for other firms. Ultra-rare-disease drugs Aldurazyme or Naglazyme have efficient scale protections, as they serve very small populations that are well served by one product. We also expect gene therapies like Roctavian could face minimal biosimilar competition due to manufacturing challenges and complexity, although Roctavian's weak launch makes it a relatively small contributor to excess returns.

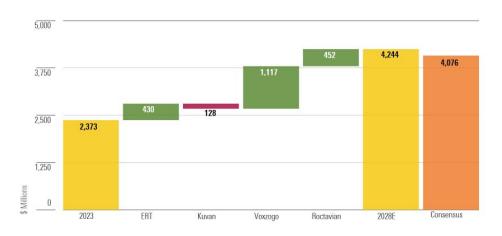


Exhibit 11 BioMarin: Five-Year Sales Outlook (\$ Millions)

Source: Morningstar, company reports.

#### What Are the Key Points Against a Narrow Moat Rating?

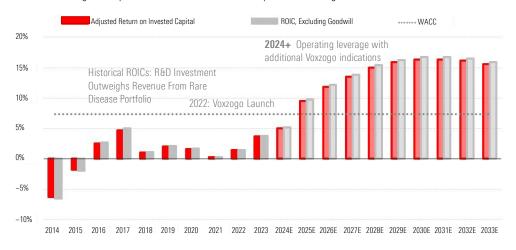
BioMarin's moat has some elements of a wide moat. BioMarin's rare-disease markets have historically been monopoly markets, allowing the firm to charge high-six-figure prices for chronic treatments. Biosimilar competition to the firm's older enzyme replacement therapies is still not on our radar despite expired patents, which we think is a signal of the stronger intangible assets surrounding these therapies. Patients trust BioMarin to provide life-saving therapy, and enrolling clinical trials for would-be biosimilars is difficult when there are only a couple-thousand patients globally with a given disease.

On the other hand, BioMarin's weak pipeline and reliance on Voxzogo for profitability are concerning and could signal a lack of a moat. BioMarin is just poised to see ROICs in excess of its cost of capital for the first time in 2025, after years of pouring money into its pipeline, despite sales from several rare-disease drugs. We think Voxzogo is a key part of this transition, with sales on track to reach 37% of BioMarin's total revenue by 2028. Voxzogo serves a larger market that has drawn a pipeline of competitors, and if these other products launch successfully, BioMarin could struggle to maintain market share. Reliance on Voxzogo has increased as BioMarin's gene therapy Roctavian has had a very slow launch, and management is considering licensing out the treatment unless sales pick up this year. This has ramifications for the firm's remaining earlier-stage gene therapy programs. Beyond gene therapy, the pipeline is thin, with a recent culling resulting in three remaining programs that are all too early to include in our valuation, and face competitive markets.

### What Are the Key Factors to Consider Regarding ROICs?

BioMarin's heavy research and development spending has historically kept ROICs below the cost of capital, despite several approved and successful rare-disease therapies. Voxzogo's strong launch is likely to move ROICs north of cost of capital in 2025. Despite strong ROICs in our 10-year forecast, we have doubts about BioMarin's ability to extend this track record, given the very early stage of its pipeline, cuts to R&D spending, and gene therapy platform setbacks.

**Exhibit 12** BioMarin Historical and Projected Returns on Invested Capital Investment in Voxzogo development adds to its foundation of steady rare-disease drug sales.



#### Gilead: Beyond Peak Hepatitis C Years, Core HIV and Oncology Business Support Wide Moat

Gilead's expertise in infectious diseases and single-pill formulations is a part of its research and development strategy, which we see as one of the strongest intangible assets supporting the firm's wide moat. We estimate that Gilead holds a more than 60% share of the nearly \$30 billion global branded HIV market, and the firm has a large pipeline of weekly orals and less-frequent injectables to continue to grow the market. While hepatitis C sales continue to shrink, recent acquisitions have brought other potential liver disease therapies to the firm's pipeline, including Hepcludex (hepatitis D) and seladelpar in primary biliary cholangitis (a rare liver disease). Progress expanding the firm's oncology franchise, led by CAR-T cell therapy Yescarta and antibody-drug conjugate Trodelvy, adds another pillar of support.

Exhibit 13 Gilead: Key Product Overview

Patent Pressure		Inline Products		Pipeline Outlook	
Top Products (% of 2023 sales)	Patent Loss	Top Potential Drugs (% of 2028 sales)	Patent Loss	Top Products (Launch year)	Peak Annual Sales
Genvoya (8%)	2029	Biktarvy (44%)	2033	Sunlenca (2025)	>\$2 Billion
		Trodelvy (10%)	2032	seladelpar (2024)	>\$1 Billion
		Yescarta/Tecartus (11%)	2031	domvanalimab (2027)	>\$1 Billion

Source: Morningstar, company reports.

#### **How Much Product Concentration Does Gilead Have?**

Gilead retains moderate product concentration risk, as its HIV sales are concentrated in the latest singletablet treatment regimen, Biktarvy.

### How Much Patent Exposure Relative to Growth Is There Over the Next Five Years?

Gilead's patent exposure is minimal over the next few years, as patients on HIV therapy Genvoya have been gradually making the transition to Biktarvy for years. Gilead does face pressure from continuing slowing sales of covid treatment Veklury as well as its hepatitis C therapies. Oncology is likely to be the biggest growth driver, as Yescarta (from Kite) and Trodelvy (from Immunomedics) expand their market share and approved indications. Pipeline opportunities include HIV prevention with Sunlenca, new liver disease markets with seladelpar, and entry into the immuno-oncology market with TIGIT-targeting domvanalimab.

40,000 30,000 217 30,196 1,685 1,019 26,938 27,307 654 20,000 10,000 0 2023 HIV HCV Covid Other Oncology 2028E Consensus

Exhibit 14 Gilead: Five-Year Sales Outlook (\$ Millions)

Source: Morningstar, company reports.

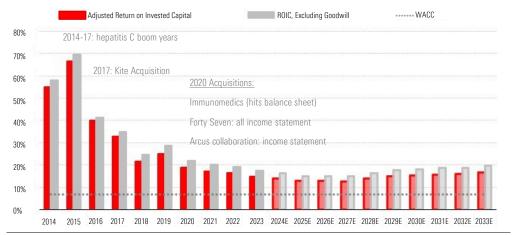
### What Are the Key Points Against a Wide Moat Rating?

Gilead has a moderately concentrated portfolio, largely due to reliance on HIV drug Biktarvy, which accounts for 44% of our 2028 sales forecast. HIV treatments are already considered safe and effective, making it harder for Gilead to continue raising the bar with new therapies. If pipeline efforts to create weekly oral or every-six-month injectable therapies fail, Gilead faces a significant patent cliff in 2033. Gilead's new every-six-month injectable for HIV prevention could launch in 2025, but we're still waiting for key phase 3 data to determine its potential. Gilead is relatively new to the field of oncology and has already faced setbacks with acquired therapies from Kite, Immunomedics, Forty-Seven, and the Arcus collaboration.

## What Are the Key Factors to Consider Regarding ROICs?

Very high ROICs between 2014-17 were heavily driven by the firm's hepatitis C portfolio, as the launch of new therapies led to average annual sales for Gilead's treatments of \$14 billion over this period, followed by dramatic declines due to lower pricing and the curative nature of treatment. Gilead's Kite and Immunomedics acquisitions both contribute to goodwill and intangible assets, and Gilead has impaired some of these assets from both acquisitions, due to setbacks in extending sales to new products and indications.

**Exhibit 15** Gilead Historical and Projected Returns on Invested Capital ROICs remain above WACC despite recent acquisitions.



#### Grifols: Downgrade to No Moat Due to Poor Execution, Innovative Threats to Plasma Therapies

Grifols is one of the three key companies dominating the roughly \$30 billion plasma-derived therapy market, along with CSL and Takeda. Grifols has long been admired for its engineering expertise at its fractionation and purification centers, but poorly run and sprawling collection centers have weighed on returns, and we don't think pipeline innovation will allow it keep up with peer CSL, which maintains a mix of plasma-derived and innovative products. While Grifols is rebounding from temporary pandemic pressures, we think more fundamental changes to the competitive landscape are finally becoming clearer, and we see significant pressure on Grifols' ability to improve returns despite recent cost control efforts.

Exhibit 16 Grifols: Key Product Overview

Top Products	% of sales 2023	% of sales 2028E	Key Competitors
Biopharma	84%	89%	
Immunoglobulin (IVIG, SCIG)	46%	51%	Plasma-based (CSL, Takeda) Innovators (ArgenX, J&J, Immunovant, UCB)
A1P (alpha-1 antitrypsin)	15%	12%	Plasma-based (CSL, Takeda) Innovators (Sanofi, Intellia)
Specialty Proteins	11%	14%	Plasma-based (CSL, Takeda) Innovators (Roche, Sobi, Sanofi)
Albumin	13%	13%	Plasma-based (CSL, Takeda)
Diagnostics	10%	10%	Roche (blood typing, molecular infectious disease diagnostics)

Source: Morningstar, company reports.

#### What Is the Outlook for Plasma Market Growth?

Grifols collects roughly 25% of global plasma volume and has a 30% share of plasma collection centers in the US and EU. The market remains poised to grow at a high-single-digit level over the next several years due to strong demand for plasma-derived products. The plasma market is not governed by patent expirations, but by expertise in collection, fractionation, purification, and branding. Grifols generally sees much stronger pricing in the US, although recent pricing trends have been positive in both geographies. Innovative medicines already compete with some plasma-derived therapies and are well-established in the hemophilia market. Newer entrants are likely to compete in alpha-1 and immunoglobulin markets.

#### **How Much Product Concentration Does Grifols Have?**

Strong pricing and demand across multiple indications gives Grifols the highest reliance on its immunoglobulin business, which is nearly 50% of the firm's revenue. We consider Grifols to have high product concentration. In the plasma business, gross margins are dramatically impacted by the number of products sold from the collected plasma, so diversification would improve both sales and margins. Grifols also sees 60% of revenue from North America, making it vulnerable to any US pricing pressure.

#### Will Innovators Eventually Compete Away the Plasma Market?

We still think the plasma market will grow in the long run, but profitability could suffer as some markets (alpha-1) could be overtaken by innovators and others (immunoglobulin) could see narrower demand. In hemophilia, innovators dominate, with plasma-derived products now reserved mostly for tender markets in less developed countries. In immunoglobulin, multiple FcRn-targeting competitors are already launching in one autoimmune indication (myasthenia gravis), and argenX is likely to extend its launch this year to CIDP (the biggest autoimmune market for Grifols and 20-25% of immunoglobulin demand). The autoimmune indications (40% of immunoglobulin sales) appear much more vulnerable to competition than the immunodeficiency markets (40%-50% of immunoglobulin sales). In the alpha-1 market, Sanofi/Inhibrx have a recombinant (not plasma derived) product that could have phase 3 data later this year, and Intellia has a Crispr-based gene editing program entering early development this year.

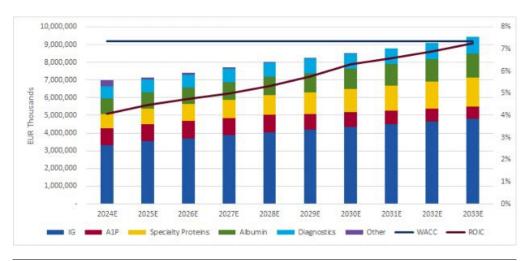


Exhibit 17 Grifols: 10-Year Forecast for Sales (Left Axis) and ROICs (Right Axis)

Source: Morningstar, company reports.

## What Are the Key Points for a Narrow Moat Rating?

Barriers to entry for other would-be plasma competitors are high, including the capital-intensive nature of plasma fractionation, the five- to seven-year lead time to build this capacity, and the intangibles such as high-yielding manufacturing processes and brands.

In addition, immunodeficiency indications for immunoglobulin have room to continue growing, particularly oncology indications, given the number of immune-depleting cancer treatments on the market.

Grifols could counter new competition with new launches. Grifols does invest in R&D (albeit at a rate of roughly 6% of sales, well below biopharma counterparts). This helps support next-generation versions of its plasma-derived products (subcutaneous dosing, less frequent dosing, and so on), new indications (like immunodeficient cancer patients), and also potential new plasma-derived launches (like Biotest's

fibrinogen product, likely to launch in 2026, or one of the thousands of other plasma proteins identified with the Alkahest acquisition). In the long run, Grifols could also launch recombinant versions of its immunoglobulin via its GigaGen-acquired technology.

#### What Are the Key Factors to Consider Regarding ROICs?

Returns have faced headwinds related to the effects of the pandemic. Fewer plasma donations led to a decline in product supply after a 10-month production lag, weighing on revenue. At the same time, payments to donors increased, weighing on margins. Grifols has also faced inefficiencies in existing collection centers and is working to cut costs and improve productivity. Grifols' continued acquisitions of plasma collection centers (to gain more plasma supply) have weighed on invested capital.

While beyond the ROIC metric, the firm's heavy debt load also weighs on net income, and we assign Grifols and Morningstar Uncertainty Rating of Very High to account for this financial leverage and complexity/controversy around the firm's debt ratio calculations, although we think the June sale of Grifols' stake in Shanghai RAAS (China plasma firm) and improving business fundamentals will help Grifols refinance 2025 debt and reduce leverage.

ROIC, Excluding Goodwill ----- WACC Adjusted Return on Invested Capital 40% 2014-17: 2024+: 35% Solid returns but expanding Cost-cutting programs and return of capital base from acquisitions 30% plasma supply Expanding competition in autoimmune 2020-2023 25% diseases (IG) and alpha-1 businesses Pandemic weighs on returns 20% Incremental pipeline advancements Invested capital growing as 15% plasma collection center 10% acquisitions continue 5% 2015 2016 2017 2018 2019 2020 2021 2022 2023 2024F 2025F 2026F 2027F

**Exhibit 18** Grifols Historical and Projected Returns on Invested Capital ROICs are likely to remain below WACC because of the competitive landscape, despite cost controls.

#### Novo: GLP-1 Innovation and Management's Long-Term Focus on Innovation Secure a Wide Moat

Novo Nordisk's leading position in the diabetes market with insulin and GLP-1 therapies has supported its move into the rapidly growing obesity market, which we think secures very strong ROICs over the next 10 years. Novo Nordisk accounts for 34% of the global diabetes market, including roughly half of both the \$15 billion insulin therapy market and the nearly \$40 billion GLP-1 market. We think Novo will remain a leader (at least 30% share) in a potential \$200 billion global GLP-1 market despite new competition. Reliance on the semaglutide molecule is high, although we think Novo's track record for innovation and a solid pipeline in cardiometabolic indications could help diversify away from semaglutide to some extent ahead of the 2032 patent expiration.

Exhibit 19 Novo Nordisk: Key Product Overview

Patent Pressure		Inline Products		Pipeline Outlook	
Top Products (% of 2023 sales)	Patent Loss	Top Potential Drugs (% of 2028 sales)	Patent Loss	Top Products (Launch year)	Peak Annual Sales
NovoRapid (6%)	expired	Ozempic (25%)	2032/31 US/EU	Cagrisema (2025)	>\$20 Billion
Victoza (4%)	expired	Wegovy (20%)	2032/31 US/EU	Icodec (2024)	>\$4 Billion
Saxenda (4%)	expired	Rybelsus (22%)	2032/31 US/EU	Mim8 (2025)	>\$2 Billion

Source: Morningstar, company reports.

#### How Much Product Concentration Does Novo Nordisk Have?

We think Novo Nordisk has moderate to high product concentration risk, as it is heavily reliant on one GLP-1 targeting therapy, semaglutide, across several brands in diabetes and in obesity. The firm's pipeline in cardiometabolic indications, including weekly insulin icodec, combination GLP-1/amylin drug CagriSema, and hemophilia drug Mim8 could all help diversify revenue, although stellar growth for GLP-1 therapies will make this difficult to achieve.

#### How Much Patent Exposure Relative to Growth Is There Over the Next Five Years?

Novo faces relatively minimal patent exposure over the next few years. Older GLP-1 therapy Victoza/Saxenda is facing generic competition in 2024, although most patients have transitioned to newer semaglutide-based therapies like Ozempic, Rybelsus, and Wegovy. Rapid-acting insulin NovoRapid is already off-patent, but approval of a biosimilar version has been significantly delayed, and prices of Novo and Lilly's competing rapid-acting insulin products are already heavily discounted, which could make it difficult for a new entrant to compete.

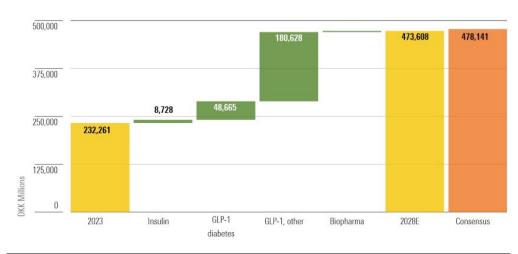


Exhibit 20 Novo Nordisk: Five-Year Sales Outlook (DKK Millions)

Source: Morningstar, company reports.

#### Does Novo Nordisk Have a Cost Advantage That Supports Its Wide Moat?

Novo Nordisk has a dominant position in the global market for insulin, with a 45% share of insulin volumes sold globally as of February 2024. Novo has faced intense price competition for tender contracts in international markets for its older insulins, as well as pricing pressure in the US from Eli Lilly and Sanofi as the top firms all vie for top positions in PBM formularies. Novo can maintain strong profitability despite price concessions partly due to its manufacturing scale and expertise specifically in manufacturing complex biologics with modern injection devices.

However, Novo's foundation has rapidly shifted from insulin (20% of 2023 sales) to GLP-1 therapies (70% of 2023 sales). Novo's heavy investment in manufacturing its GLP-1 therapies and productivity improvements could offer a similar advantage in the GLP-1 market (Novo already holds a 55% share of the diabetes GLP-1 market), although we see more uncertainty ahead. If peptide-based GLP-1 therapies continue to remain the standard of care for the next 10 years, we expect Novo could hold a minor cost advantage in this market as well. However, the massive potential of GLP-1 therapies beyond diabetes—particularly in obesity—has drawn multiple competitors. Several of these pipeline drugs are manufactured differently, either as antibodies or small molecules, and could launch in the 2026-28 timeframe. If a pill version of a GLP-1 therapy is able to achieve similar efficacy and tolerability, or Amgen's antibody is able to do the same but with much less frequent dosing, Novo's expertise in peptide manufacturing would be less relevant (and potentially burdensome) to maintaining a competitive advantage in the market.

#### What Are the Key Points Against a Wide Moat Rating?

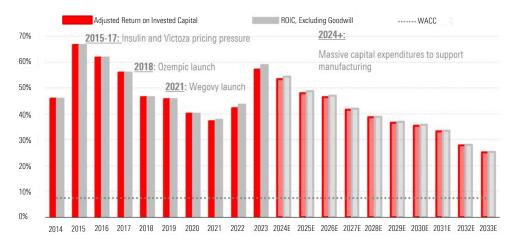
Novo's product concentration risk is decreasing as its GLP-1 launches extend to new brands and formulations, but it remains very reliant on the success of semaglutide-based drugs for its strong ROICs. This creates a potentially massive patent cliff in 2032 when semaglutide patents expire across indications, assuming generic drug manufacturers can handle the manufacturing of this complex

peptide. Novo's solid track record of innovation and expertise in cardiometabolic markets have produced a pipeline beyond semaglutide, largely amylin-based combination products like CagriSema (potential launch in 2025) and amycretin, but also novel acquired drug candidates like monlunabant from Inversago. However, by 2032, we expect significant competition from other firms could make it more difficult to transition semaglutide sales to new branded Novo Nordisk products, unless Novo can significantly improve convenience, tolerability, or efficacy.

## What Are the Key Factors to Consider Regarding ROICs?

Novo faced pressure on ROICs from declining insulin pricing power and sales ahead of its launches of Ozempic and Wegovy. Increasing supply of these newer GLP-1 therapies led to strong growth in 2023, although massive increases in capital investment (likely in the low-double-digits as a percentage of sales over the next several years) and the acquisition of key Catalent contract manufacturing sites are boosting its capital base. Patent expirations for Ozempic and Wegovy in 2032 will be a key hurdle for the firm.

**Exhibit 21** Novo Nordisk Historical and Projected Returns on Invested Capital ROICs are well above the cost of capital, despite semaglutide reliance and significant forecast capital expenditures.



#### Regeneron: Maintain Narrow Moat as Heavy R&D Investment Attempts to Counter Eylea Reliance

We assign a narrow moat rating to Regeneron based on the intangible assets that underlie the commercial potential of Eylea (including high-dose Eylea) and the productivity of its monoclonal antibody research and development platform, which has led to blockbuster sales of immunology drug Dupixent. Much of the pipeline potential rests on combinations of foundational immuno-oncology drug Libtayo with bispecific antibodies, although progress with gene-based therapies in broader indications beyond oncology could help contribute to a wide moat down the road.

**Exhibit 22** Regeneron: Key Product Overview

Patent Pressure		Inline Products		Pipeline Outlook	
Top Products (% of 2023 sales)	Patent Loss	Top Potential Drugs (% of 2028 sales)	Patent Loss	Top Products (Launch year)	Peak Annual Sales
Eylea (56%)	2027 (high dose 2039)	Dupixent (34%)	2031/32 US/EU	odronextamab (2024)	\$2 Billion
		Libtayo (8%)	2035	linvoseltamab (2024)	\$2 Billion
				PSMA bispecifics (2026)	\$2 Billion

Source: Morningstar, company reports.

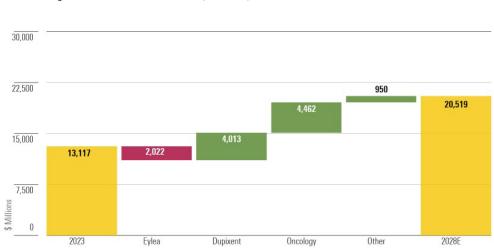
## **How Much Product Concentration Does Regeneron Have?**

Regeneron has high product concentration risk, but we see the firm's highly concentrated current portfolio (56% Eylea) diversifying somewhat over the next several years as Dupixent and Libtayo grow to a larger share of revenue. Eylea and Dupixent together comprise 80% of 2023 revenue, falling below 60% of revenue by 2028.

## How Much Patent Exposure Relative to Growth Is There Over the Next Five Years?

We think Eylea will face some pressure from biosimilar entrants by 2028, although this should be somewhat limited by a new high-dose version. Dupixent, Libtayo, and novel bispecific antibodies in oncology should help drive significant sales growth over the next five years. Blood cancer bispecifics linvoseltamab and odronextamab could be the next oncology approvals. Regeneron is also testing Libtayo in combination with LAG-3 antibody fianlimab in melanoma and lung cancer, and in combination with a long list of bispecific antibodies.

Exhibit 23 Regeneron: Five-Year Sales Outlook (\$ Millions)



Source: Morningstar, company reports.

#### What Are the Key Points Against a Narrow Moat Rating?

Regeneron's expertise in antibody research and development and a massive genetics research center could help it build a wide moat.

If Regeneron can find novel bispecific antibodies to combine with Libtayo that thread the needle of significant efficacy but acceptable safety, it could launch a wide portfolio of novel combination regimens over the next several years.

Beyond oncology, Regeneron could build a critical mass of new therapies using gene-based technologies, partly driven by the Regeneron Genetics Center, which is helping to find new drug targets in areas from obesity to liver disease. Regeneron's collaborations with firms such as Alnylam (RNA interference) and Intellia (Crispr-based therapies) are moving into phase 3 trials, which could further diversify Regeneron's portfolio.

Regeneron is also moving two antibody programs into phase 2 in obesity in combination with Novo Nordisk's semaglutide, hoping to improve the quality of weight loss and reduce muscle loss. This could be particularly helpful for older patients and help the firm develop a niche in this massive market.

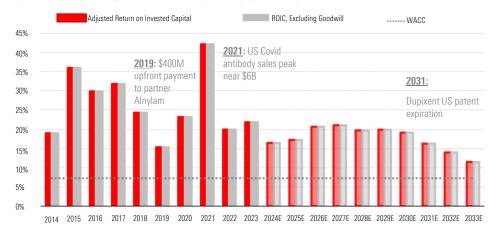
### What Are the Key Factors to Consider Regarding ROICs?

A large upfront payment to new RNA-based drug partner Alnylam in 2019 weighed on ROICs, and sales of Covid antibody cocktail Ronapreve boosted ROICs in 2020-23. We expect relatively steady ROICs over our forecast period, although Dupixent's patent expiration in 2031 could hit ROICs if Regeneron's highrisk oncology pipeline doesn't produce blockbusters by this time.

The timing of declines in Eylea/Eylea HD sales is more uncertain but could begin in 2027-28, depending on biosimilar uptake and Medicare negotiation. We think biosimilar Eylea could launch in the US in 2027, although a high-dose version (Eylea HD) is poised to replace this drug and appears to have some

patent protection (formulation patents) extending through our 10-year forecast period. Eylea and Eylea HD could be subject to Medicare negotiation beginning in 2028, depending on the timing and success of the biosimilar launches and whether Medicare views Eylea HD as a different formulation or a novel product (Medicare covers 70% of Eylea usage in the US).

**Exhibit 24** Regeneron Historical and Projected Returns on Invested Capital They are above the cost of capital but are still heavily driven by Eylea and Dupixent.



#### Roche: ROICs Staying Solidly Above WACC; Maintaining Wide Moat

Roche's wide moat arises from its status as the leader in oncology therapeutics and in vitro diagnostics, and the firm has a promising strategy of combining its expertise in both areas to generate a growing personalized medicine pipeline, making use of companion diagnostics.

Roche has one of the largest pipelines among its peers, and recent efforts have focused the pipeline on products with first or best-in-class potential. Roche has also embraced artificial intelligence and machine learning; its Genentech arm has a "lab in a loop" system that uses AI to discover new targets, predict outcomes, and increase speed of development, when combined with more traditional biological methods of studying diseases.

Exhibit 25 Roche: Key Product Overview

Patent Pressure		Inline Products		Pipeline Outlook	
Top Products (% of 2023 sales)	Patent Loss	Top Potential Drugs (% of 2028 sales)	Patent Loss	Top Products (Launch year)	Peak Annual Sales
Perjeta (6%)	2025	Ocrevus (11%)	2029	TL1A (2027)	>\$2 Billion
Actemra (4%)	2024	Hemlibra (8%)	2030+	CT-388 (2028)	>\$4 Billion
Xolair (4%)	2025	Vabysmo (8%)	2030+	zilebesiran (2028)	>\$2 Billion

Source: Morningstar, company reports.

#### **How Much Product Concentration Does Roche Have?**

Roche has low product concentration risk, with a large portfolio that extends across multiple indications.

### How Much Patent Exposure Relative to Growth Is There Over the Next Five Years?

Biosimilar pressure on sales of older oncology therapies Rituxan, Avastin, and Herceptin led to significant erosion of their sales in 2020-21, although pressure has declined significantly in recent years. We expect biosimilar competition to immunology drugs Actemra and Xolair as well as oncology drug Perjeta through 2025, although together these only composed 14% of 2023 sales, and Perjeta sales are partly defended by Phesgo, a more convenient co-formulation of Herceptin and Perjeta. In-line products like MS drug Ocrevus, hemophilia drug Hemlibra, and eye disease drug Vabysmo should contribute to significant growth over the next five years, potentially supplemented by pipeline programs such as obesity drug CT-388 and a TL1A-targeting immunology drug.

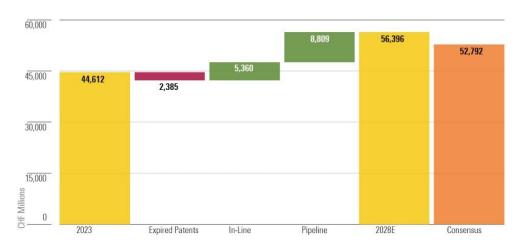


Exhibit 26 Roche: Five-Year Sales Outlook (CHF Millions)

Source: Morningstar, company reports.

#### What Are the Key Points Against a Wide Moat Rating?

An analysis shared at Roche's pharma day in September 2023 pointed to a solid overall success rate for Roche's pipeline, but with a recent below-industry success rate in the largest, most expensive phase 3 trials. Roche faces significant competition to its biggest products like Ocrevus (Novartis' Kesimpta), Hemlibra (Sanofi's Altuviiio and Novo's Mim8), and Vabysmo (Regeneron's Eylea). If current phase 3 trials don't see improving success rates, Roche could struggle to increase its pharma sales.

## How Does Roche's Diagnostics Business Affect Its Moat?

Although we think Roche's diagnostics expertise supports the firm's innovation in drug discovery and its intangible asset moat source, we don't think the switching costs for Roche's diagnostics platforms are significant enough to support an additional moat source at the firm level. Roche's diagnostics arm (25% of sales, 15% of operating profit) is the leading global diagnostics firm, with a number-one position in its biggest Core Lab division as well as molecular lab and pathology (tissue diagnostics). Roche's overall share of the in vitro diagnostics market remains ahead of peers including Abbott, Danaher, Siemens, and bioMerieux. Roche's molecular lab and pathology divisions are complementary to the firm's oncology portfolio, as Roche's companion diagnostics help guide therapy choices, such as the FoundationOne genomic sequencing test. In the future, connections could extend to the core lab (a blood test for Alzheimer's and drug candidate trontinemab) and to the point-of-care business (continuous glucose monitor and cardiometabolic drug candidate CT-388). Roche has a massive installed base of diagnostic testing platforms that only grew further during the pandemic, and improvements to its systems (additional automation, broader testing menus, and new types of machines like mass spectroscopy) are further entrenching Roche as the leader in the market.

#### What Are the Key Factors to Consider Regarding ROICs?

Roche tends to rely more on internal drug discovery and development, as well as collaborations, instead of large acquisitions, so there is less discrepancy between ROICs including and excluding goodwill.

Roche's key investments over the years include the acquisition of biotech firm Genentech (1990 and 1999 deals), tissue diagnostic firm Ventana (2008), and companion diagnostic firm Foundation Medicine (2015). We think recent deals, like the \$7.1 billion acquisition of US and Japan rights to Roivant's bowel disease drug RVT-3101 and the \$2.7 billion acquisition of obesity firm Carmot Therapeutics, bring best-in-class potential and support Roche's immunology and cardiometabolic expansion.

From 2013 through 2023, Roche has gradually impaired various investments by a total of roughly CHF 12 billion. Without these impairments, its investment capital in 2023 could be 10% higher—but then the numerator (returns) would have been slightly lower each year because of the effect of writedowns on the income statement.

Adjusted Return on Invested Capital ROIC, Excluding Goodwill WACC

25%

ROIC, Excluding Goodwill WACC

20%

15%

2014 2015 2016 2017 2018 2019 2020 2021 2022 2023 2024E 2025E 2026E 2027E 2028E 2029E 2030E 2031E 2032E 2033E

Exhibit 27 Roche Historical and Projected Returns on Invested Capital: Steadily Above Cost of Capital

#### Sobi: Growing Diversification and Enduring Hemophilia Potential Support a Narrow Moat

Dating back to Biovitrum's 2009 acquisition of Swedish Orphan, Sobi has built its portfolio with acquisitions, beginning in hemophilia, and adding orphan (rare-disease) drugs and a portfolio of immunology and hematology drugs. Sobi's low product concentration risk offers important diversification, making it less likely that a single patent loss or competitor could bring ROICs below the cost of capital. New products like long-acting hemophilia drug Altuviiio (launching in Europe in 2024), gout drug SEL-212 (launching in 2025) and myelofibrosis drug Vonjo should help drive sales and profit growth over the next several years.

Exhibit 28 Sobi: Key Product Overview

Patent Pressure		Inline Products		Pipeline Outlook	
Top Products (% of 2023 sales)	Patent Loss	Top Potential Drugs (% of 2028 sales)	Patent Loss	Top Products (Launch year)	Peak Annual Sales
Gamifant (7%)	2027/26 US/EU	Vonjo (9%)	2033	Beyfortus (2024)	< \$1 Billion
Doptelet (14%)	2027/28 US/EU	Elocta (9%)	2029	Altuviiio (2024)	>\$1 Billion
		Aspaveli (8%)	2037	SEL-212 (2025)	< \$1 Billion

Source: Morningstar, company reports.

#### **How Much Product Concentration Does Sobi Have?**

Sobi has low product concentration risk, as the firm is building a portfolio beyond hemophilia therapies extending into other hematology indications as well as immunology. We think Sobi's exposure to hemophilia peaked in 2018 at around 60% of revenue and will remain below 40% in the future, due to a combination of older products and newer acquisitions that help diversify into immunology and hematology.

How Much Patent Exposure Relative to Growth Is There Over the Next Five Years? Sobi has relatively mild patent exposure through 2028, with roughly 20% of 2023 sales vulnerable to generics in key US and Europe markets over the next five years.

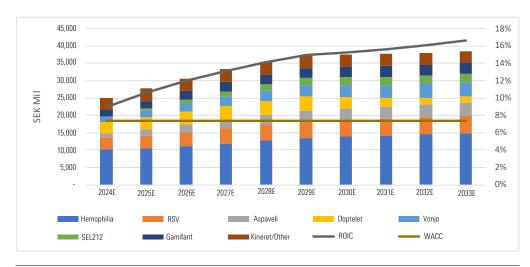


Exhibit 29 Sobi: 10-Year Forecast for Sales (Left Axis) and ROICs (Right Axis)

Source: Morningstar, company reports.

#### What Are the Key Points Against a Narrow Moat Rating?

Sobi does face significant branded competition, as all the firm's key products and pipeline candidates face entrenched alternative treatments. The firm's lack of in-house innovation makes it difficult to define intangible assets that could form a foundation for a narrow moat, despite that a growing portfolio could generate returns well above the cost of capital in the future. Sobi's ability to secure a moat will depend on the quality of future acquisitions and the evolving competitive landscape.

#### What Are the Key Factors to Consider Regarding ROICs?

Sobi has been very acquisitive in recent years, with average acquisitions over the past five years amounting to roughly 57% of sales. Big acquisitions in 2019 and 2023 raised its capital base (intangible assets), but invested capital is declining over our 10-year forecast period because of amortization of intangibles and minimal capital expenditure requirements.

Because Sobi does not have in-house drug discovery, the firm will likely continue to acquire new pipeline candidates, which could put some pressure on ROICs. That said, the firm's light capital base makes ROICs fairly resilient, as we would require annual \$1 billion acquisitions that fail to generate revenue in order to push Sobi's ROIC below its cost of capital by the end of our 10-year forecast period.

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Exhibit 30 Sobi Historical and Projected Returns on Invested Capital

ROICs are above the cost of capital despite acquisitions.



#### **Research Methodology for Valuing Companies**

#### Overview

At the heart of our valuation system is a detailed projection of a company's future cash flows, resulting from our analysts' research. Analysts create custom industry and company assumptions to feed income statement, balance sheet, and capital investment assumptions into our globally standardized, proprietary discounted cash flow, or DCF, modeling templates. We use scenario analysis, in-depth competitive advantage analysis, and a variety of other analytical tools to augment this process. We think analyzing valuation through discounted cash flows presents a better lens for viewing cyclical companies, high-growth firms, businesses with finite lives (mines, for example), or companies expected to generate negative earnings over the next few years. That said, we don't dismiss multiples altogether but rather use them as supporting cross-checks for our DCF-based fair value estimates. We also acknowledge that DCF models offer their own challenges (including a potential proliferation of estimated inputs and the possibility that the method may miss short-term market-price movements), but we believe these negatives are mitigated by deep analysis and our long-term approach.

Morningstar's Equity Research Group ("we," "our") believes that a company's intrinsic worth results from the future cash flows it can generate. The Morningstar Rating for stocks identifies stocks trading at a discount or premium to their intrinsic worth—or fair value estimate in Morningstar terminology. Five-star stocks sell for the biggest risk-adjusted discount to their fair values, whereas 1-star stocks trade at premiums to their intrinsic worth.

Four key components drive the Morningstar rating:

- our assessment of the firm's economic moat.
- our estimate of the stock's fair value.
- our uncertainty around that fair value estimate.
- ▶ the current market price.

This process ultimately culminates in our single-point star rating.

#### **Economic Moat**

The Morningstar Economic Moat Rating is a structural feature that Morningstar believes positions a firm to earn durable excess profits over a long period of time, with excess profits defined as returns on invested capital above our estimate of a firm's cost of capital. The economic moat rating is not an indicator of the investment performance of the investment highlighted in this report. Narrow-moat companies are those that Morningstar believes are more likely than not to achieve normalized excess returns for at least the next 10 years. Wide-moat companies are those that Morningstar believes will earn excess returns for 10 years, with excess returns more likely than not to remain for at least 20 years. Firms without a moat, including those that have a substantial threat of value destruction-related risks related to environmental, social, and governance; industry disruption; financial health; or other idiosyncratic issues, are more susceptible to competition. Morningstar has identified five sources of economic moats: intangible assets, switching costs, network effect, cost advantage, and efficient scale.

#### **Fair Value Estimate**

Each stock's fair value is estimated by using a proprietary discounted cash flow model, which assumes that the stock's value is equal to the total of the free cash flows of the company is expected to generate in the future, discounted back to the present at the rate commensurate with the riskiness of the cash flows. As with any DCF model, the ending value is highly sensitive to Morningstar's projections of future growth.

#### Fair Value Uncertainty

The Morningstar Uncertainty Rating represents the analysts' ability to bound the estimated value of the shares in a company around the fair value estimate, based on the characteristics of the business underlying the stock, including operating and financial leverage, sales sensitivity to the overall economy, product concentration, pricing power, exposure to material ESG risks, and other company-specific factors. Based on these factors, analysts classify the stock into one of several uncertainty levels: Low, Medium, High, Very High, or Extreme. Our recommended margin of safety—the discount to fair value demanded before we'd recommend buying or selling the stock—widens as our uncertainty of the estimated value of the equity increases.

#### **Market Price**

The market prices used in this analysis and noted in the report come from exchanges on which the stock is listed, which we believe is a reliable source.

#### Morningstar Rating for Stocks

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