ORPHAN DRUGS 2023-2028

A FLATTENING CURVE?

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Evaluate

Orphan Drugs 2023-2028: a flattening curve?

Orphan drugs continue to march ahead. They are the fastest-growing segment of the pharma market and dominate FDA approvals.

The top ten biggest orphans will be worth $64 billion globally in 2028, by which time orphans will comprise a **fifth** of all non-generic prescription drug sales ($1.5 trillion). Over a third of global drug sales at Johnson & Johnson and AstraZeneca in 2028 will come from orphans – mostly in oncology. Johnson & Johnson's multiple myeloma drug Darzalex holds onto the top-spot with $14.5 billion, and AstraZeneca's Lynparza and Calquence come in fourth and fifth with combined sales of $11 billion.

These trends are familiar. Orphan drugs have outgrown their non-orphan counterparts for each of the last ten years, apart from 2021 and 2022 which were boosted by Covid-19. Even a pandemic affecting the global population didn't fundamentally alter orphans' trajectory. These 'niche' treatments – for conditions affecting fewer than 200,000 in the US, or, in Europe, fewer than 5 in 10,000 – will grow two thirds faster (11.6% vs 7%) than non-orphan innovative drugs in the next five years according to Evaluate consensus, reaching an aggregate $300 billion sales in 2028.

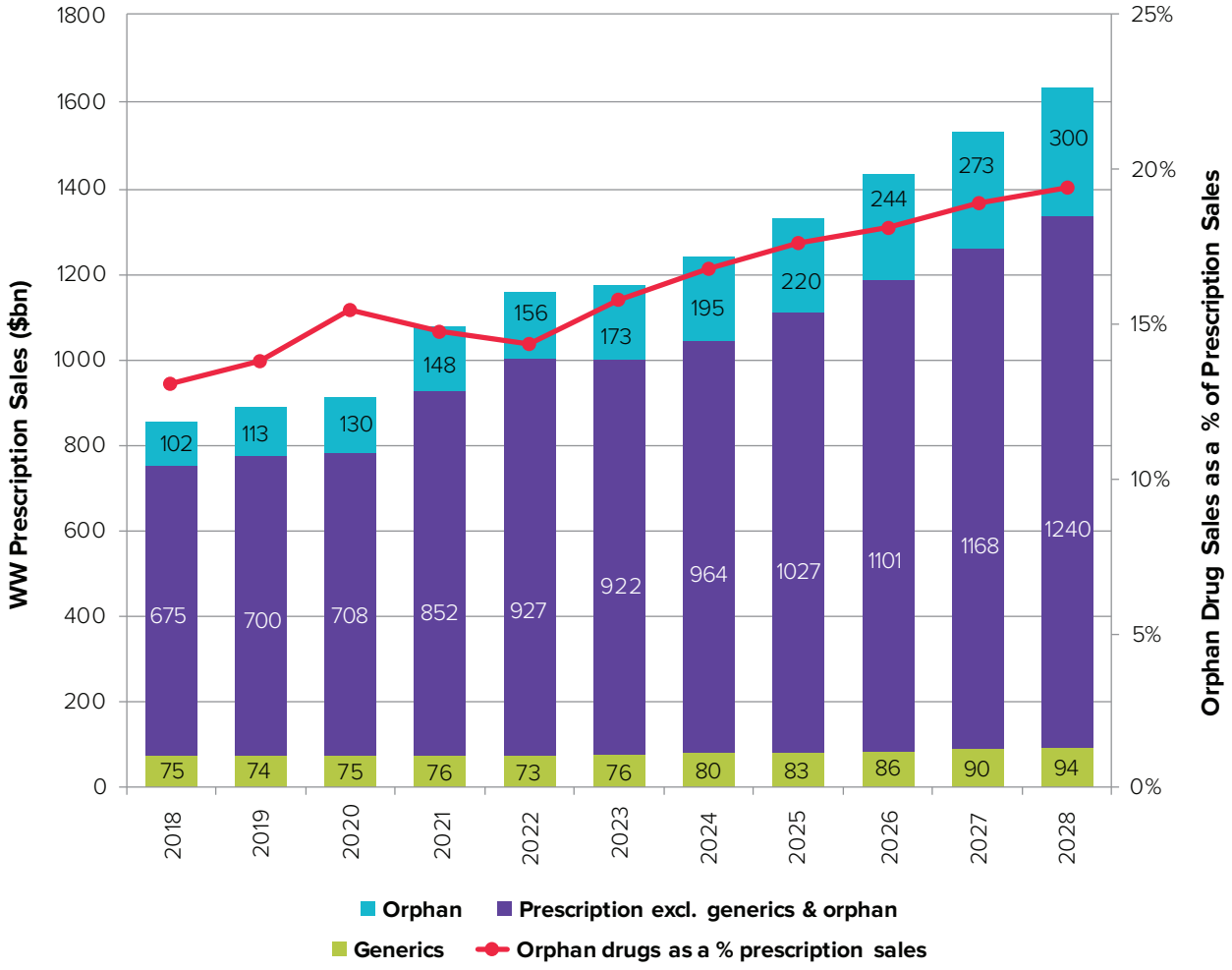
Will orphans' dominance endure? For now, there's little quantitative evidence of slowing growth (though orphans' share of the global pipeline may have peaked – see Figure 6). Several legislative and technological factors have come into play, however. The US Inflation Reduction Act (IRA), signed into law in August 2022, puts the costliest Medicare drugs on course for price cuts – including multi-indication orphans. (See Box p. 12) It has also prompted calls for further, orphan-specific reform. Meanwhile, commercial and/or development successes across more prevalent conditions such as migraine, obesity, cardiovascular diseases and non-alcoholic steatohepatitis (NASH) is drawing attention away from niche conditions. As new technologies mature, they find applications beyond their early testing-grounds.

These potential headwinds won't slow orphans this decade: the net present value (NPV) of the top 10 largest orphans in 2028 that are currently in Phase 3 or filed, is over $40 billion – *three quarters* of the equivalent figure ($54 billion) for non-orphans. But they may flatten the curve thereafter.

Orphan surge captures technological progress

Orphan drug sales will grow almost 12% between 2023 and 2028, significantly faster than the 7% expected for non-orphan innovative drugs. The estimated $300 billion total value in 2028 will account for almost a fifth of all non-generic prescription drug sales. That share has been climbing steadily over the last decade; in 2018 it was 13%.

FIGURE 1: Worldwide Orphan Drug Sales & Share of Prescription Drug Market (2018-28)

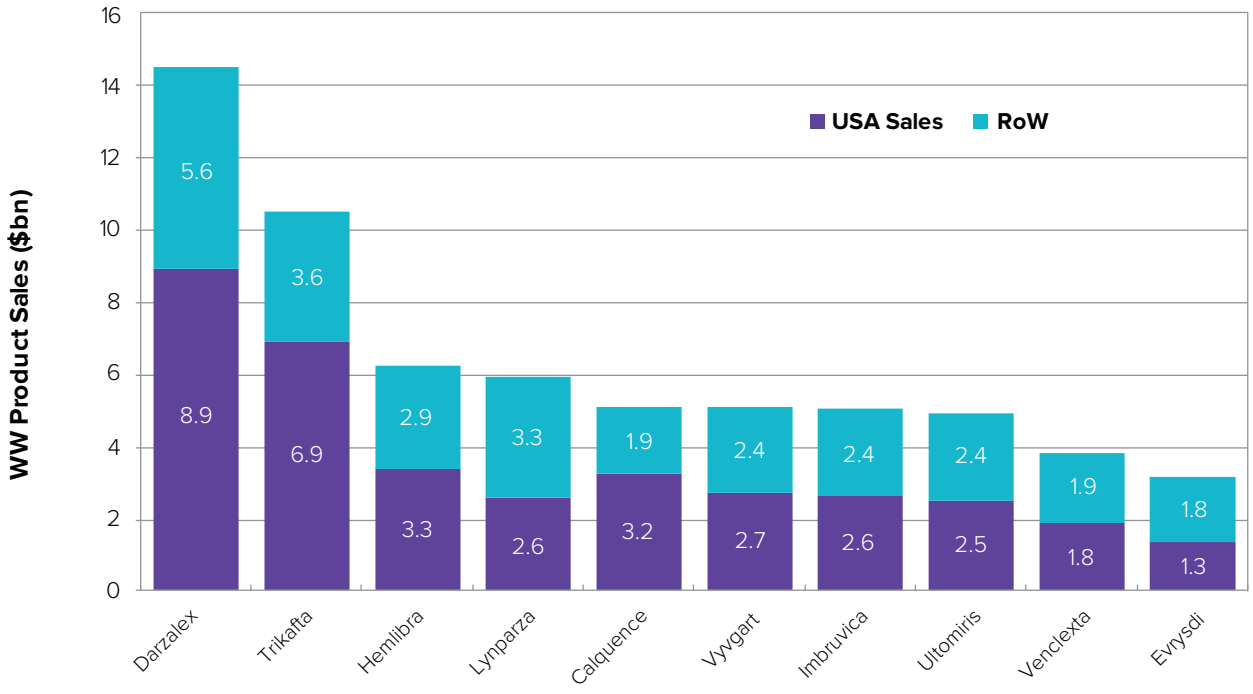


Source: EvaluatePharma® (February 2023)

This growth is reflected in approvals: in four of the last five years, FDA has approved more orphans than non-orphans. In 2022, the figure for FDA's Center for Drug Evaluation and Research (CDER) was 54%, the highest yet. (Ref: CDER report) Orphans' trajectory also captures technological progress: newer modalities such as cell and gene therapies, antibody-drug conjugates or bispecific antibodies are often tested in niche, well-defined conditions that make an orphan designation more likely. These new modalities made up a third of all 2022 CDER and Center for Biologics Evaluation and Research (CBER) approvals. In part as a result, 2022 was the first year ever that FDA biologics approvals (BLAs) outpaced those of small molecules (NMEs).

The new orphan class of 2022 includes Alnylam's small interfering RNA treatment Amvuttra (vutrisiran) for nerve damage in adults with hereditary transthyretin-mediated amyloidosis (ATTR). Amvuttra, also in Phase 3 trials for a more widespread form of ATTR, is expected to sell almost $3 billion by 2028. That puts it only narrowly outside the top ten orphan best-sellers. (Ref: **Alnylam's heart beats stronger**)

FIGURE 2: Top 10 Selling Orphan Drugs in 2028 by Worldwide Sales



Source: EvaluatePharma® (February 2023)

FIGURE 3: Worldwide Top 10 Selling Orphan Drugs in 2028

Product	Mechanism of Action	Therapeutic Category	Company
Darzalex	Anti-CD38 MAb for multiple myeloma	Oncology	Johnson & Johnson
Trikafta	CTFR potentiator/regulator for cystic fibrosis	Respiratory	Vertex Pharmaceuticals
Hemlibra	Coagulation factor bispecific for haemophilia	Blood	Roche & Chugai Pharmaceutical
Lynparza	Parp inhibitor for ovarian cancer	Oncology	AstraZeneca
Calquence	BTK inhibitor for lymphoma	Oncology	AstraZeneca
Vyvgart	FcRn antagonist for generalized myasthenia gravis	Immuno-modulator	Argenx & Zai Lab
Imbruvica	BTK inhibitor for lymphoma	Oncology	Abbvie & Johnson & Johnson

Product	Mechanism of Action	Therapeutic Category	Company
Ultomiris	C5 complement inhibitor for various autoimmune conditions	Immuno-modulator	AstraZeneca
Venclexta	BCL-2 inhibitor for leukaemia/lymphoma	Oncology	AbbVie
Evrysdi	SMN2 protein stimulant for spinal muscular atrophy	Central nervous system	Roche & Chugai Pharmaceutical

Note: Sales represent company reported sales where available, otherwise based on an average of equity analyst estimates. Worldwide sales represent sales for all indications. All sales analysis based on EvaluatePharma®'s 'Orphan' sub-set of products, as defined in the Appendix.

Source: EvaluatePharma® (February 2023)

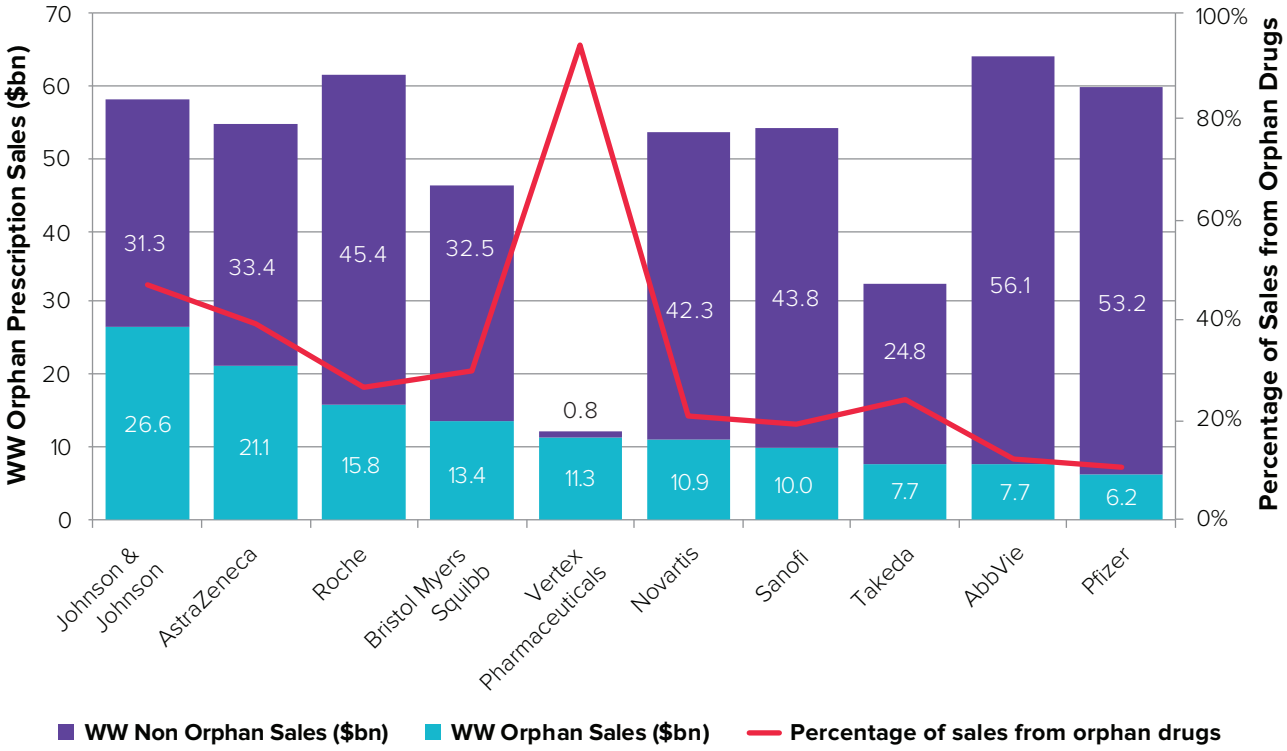
Two cancer-focused chimeric antigen receptor CAR-T cell therapies, Gilead's CD-19-directed Yescarta and Johnson & Johnson/Legend Biotech's anti-BCMA Carvykti also squeeze into 2028's top 20 best sellers, as manufacturing and administration hurdles facing this novel category are overcome. (There were no CAR-Ts in last year's top 20). Carvykti in 2022 became the sixth approved CAR-T in the US; its sales are expected to reach $2.4 billion globally by 2028. The swelling CAR-T therapy pipeline includes more convenient "off the shelf" versions that could one day reach many more people.

Cancer, blood, CNS

Half of the top ten are oncology drugs, reflecting cancer's unwavering dominance of the orphan space. Gold medallist Darzalex also features in the top ten biggest new non-orphan sales generators for 2023. It's expected to add $1.6 billion this year, more than Novo's obesity drug Wegovy (beset by supply constraints) or AbbVie's immune-inflammatory duo Skyrizi and Rinvoq. (Ref. **Evaluate 2023 Preview Report**, p. 5) The last two are lining up to fill Humira's giant ($20.7 billion) shoes as **biosimilar competition arrives.**

The non-oncology top ten orphans include Vertex's cystic fibrosis blockbuster Trikafta and Roche's anti-coagulant Hemlibra. Roche's Evrysdi (risdiplan), for spinal muscular atrophy and Argenx's Vyvgart for a muscle weakening condition called myasthenia gravis are new to the list from 2026's iteration (See **Orphan Drug 2022 report**). They displace Novartis/Incyte's myelofibrosis drug Jakafi and Pfizer's first-mover ATTR drug Vyndaqel from the top ten. Jakafi falls to 11th place in 2028, despite a **forthcoming extended-release formulation and various combination trials**. Oral Vyndaqel and Vyndamax, a higher dose capsule, are expected to slip behind Amvuttra, given as a quarterly injection, in this increasingly competitive space.

FIGURE 4: Worldwide Orphan Prescription Drug Sales in 2028: Top 10 Companies



Source: EvaluatePharma® (February 2023)

FIGURE 5: Worldwide Orphan Drug Sales (2022/2028): Top 20 Companies & Total Market

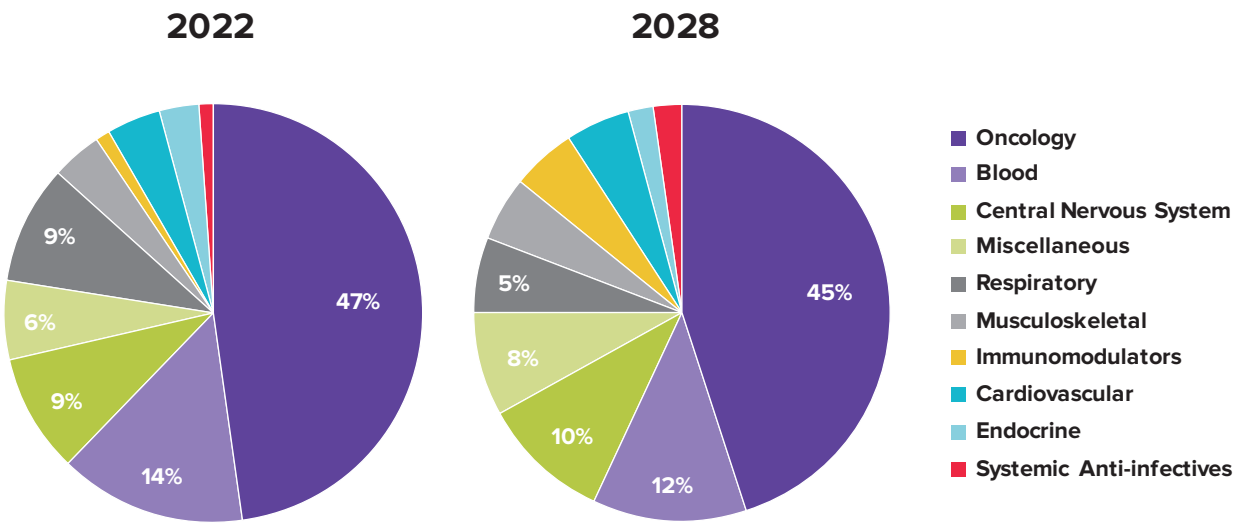
	Worldwide orphan sales ($bn)			WW non orphan sales ($bn)		Percentage of sales from orphan drugs	
Company	2022	2028	CAGR	2022	2028	2022	2028
Johnson & Johnson	13.7	26.6	+11.7%	37.2	31.3	27%	46%
AstraZeneca	11.9	21.1	+10.1%	31.1	33.4	28%	39%
Roche	7.3	15.8	+13.7%	40.6	45.4	15%	26%
Bristol Myers Squibb	21.3	13.4	-7.4%	25.6	32.5	45%	29%
Vertex Pharmaceuticals	8.6	11.3	+4.6%	0.0	0.8	100%	93%
Novartis	13.2	10.9	-3.1%	37.4	42.3	26%	20%
Sanofi	6.8	10.0	+6.7%	34.4	43.8	16%	19%
Takeda	6.0	7.7	+4.4%	24.2	24.8	20%	24%
AbbVie	5.9	7.7	+4.5%	49.1	56.1	11%	12%
Pfizer	5.5	6.2	+2.1%	90.5	53.2	6%	10%

Source: EvaluatePharma® (February 2023)

Johnson & Johnson will lead the company ranking by orphan sales in 2028, as star orphan Darzalex, plus Imbruvica and Carvykti, help it displace 2022's leader, Bristol-Myers Squibb. By then, Johnson & Johnson's $26.6 billion forecast orphan sales – largely in oncology – will represent nearly half (46%) of its overall pharma sales; its non-orphan revenues will decline by 16%, or $6 billion, between 2022 and 2028.

Bristol-Myers Squibb will slip to fourth place by 2028, due to multiple myeloma drug Revlimid losing patent protection in the US and Europe this decade. But anti-anaemia drug Reblozyl and recently-approved cancer combo Opdualag (nivolumab/relatlimab) both make the top 20 that year, with forecast sales of $2.5 billion and $2.35 billion, respectively. AstraZeneca moves up to second place with over $21 billion of orphan sales in 2028, almost 40% of total sales. Despite its top-five cancer orphans Lynparza and Calquence (whose combined 2028 sales will reach almost $11 billion), AstraZeneca can't quite push Johnson & Johnson from the oncology top spot. (See Figure 4, p. 6).

FIGURE 6: Share of Worldwide Orphan Drug Sales by Therapy



Source: EvaluatePharma® (February 2023)

FIGURE 7: Worldwide Sales and Lead Company by Therapeutic Category

	WW Annual Sales ($bn)		2022		2028	
Therapeutic Category	2022	2028	Lead Company	WW Sales ($bn)	Lead Company	WW Sales ($bn)
Oncology	72.6	133.8	Bristol Myers Squibb	18.7	Johnson & Johnson	2.3
Blood	22.5	35.3	AstraZeneca	5.9	AstraZeneca	6.3
Central Nervous System	14.3	29.1	Biogen	2.7	Jazz Pharmaceuticals	3.1
Miscellaneous	9.2	24.0	Sanofi	3.9	Alnylam Pharmaceuticals	5.1
Respiratory	13.2	16.4	Vertex Pharmaceuticals	8.6	Vertex Pharmaceuticals	11
Musculoskeletal	7.0	15.1	Bristol Myers Squibb	1.7	Sarepta Therapeutics	3.2
Immunomodulators	2.1	13.8	Sanofi	1.0	Argenx	4.7
Cardiovascular	6.4	13.5	Johnson & Johnson	3.1	United Therapeutics	3.7
Endocrine	4.5	5.9	Novartis	1.6	Novo Nordisk	1.3
Systemic Anti-infectives	2.1	5.0	Merck & Co	0.7	AlloVir	0.7

Note: All sales analysis based on EvaluatePharma®'s 'Orphan' sub-set of products, as defined in the Appendix. Analysis excluded products categorised in the oncology therapeutic category to produce a non-oncology company list.

Source: EvaluatePharma® (February 2023)

Cancer's share of total orphan drug sales will remain in the mid-40% range through 2028, with blood disorder products retaining second place – if only just – as CNS drugs gain.

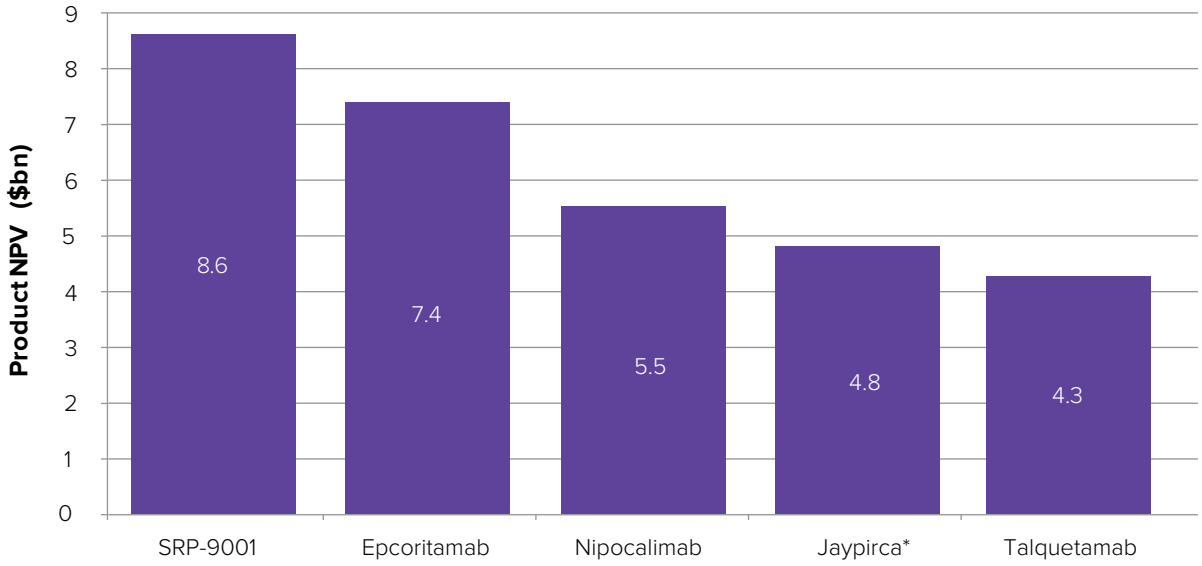
AstraZeneca leads in the blood category thanks to Ultomiris – the main prize from AstraZeneca's $39 billion Alexion acquisition. Ultomiris, currently approved for rare blood conditions paroxysmal nocturnal hemoglobinuria and atypical hemolytic uremic syndrome, is forecast to sell close to $5 billion by 2028, making it the eighth largest orphan that year.

Roche will see the strongest growth in orphan sales among its top ten peers between 2022-2028 (13.7%), climbing from sixth to third place over the period. Despite the Swiss group's oncology focus, its two biggest orphan drivers are in blood disorders and CNS: Hemlibra (emicizumab) for hemophilia A, and Evrysdi for spinal muscular dystrophy.

Orphan R&D pipeline – broader applications, new formulations

Gene therapies, monoclonal antibodies and fusion proteins dominate the top ten orphan pipeline products in 2028 by NPV. Most follow the orphan blockbuster template and are in development for multiple cancer sub-types: Eli Lilly's Jaypirca, a Bruton's tyrosine kinase (BTK) inhibitor, is chasing several B-cell malignancies and was approved in January as Jaypirca for mantle cell lymphoma, a rare form of Non-Hodgkin's lymphoma (NHL); AbbVie/Genmab's bispecific antibody epcoritamab may also address several types of NHL.

FIGURE 8: Top 5 Orphan Drugs in 2028 (Phase III/ Filed) by NPV



Source: EvaluatePharma® (February 2023)

FIGURE 9: Worldwide Top 5 Orphan R&D Products based on NPV (Sales, NPV)

Product	Description	Therapeutic Category	Company	Sales ($bn)	WW NPV
SRP-9001	Gene therapy for Duchenne muscular dystrophy (filed with regulators)	Musculoskeletal	Sarepta/Roche	2.2	8.6
Epcoritamab	CD3xCD20 bispecific for lymphoma (filed with regulators)	Oncology	Abbvie/Genmab	1.3	7.4
Nipocalimab	FcRn antagonist for various autoimmune conditions (phase 3)	Immuno-modulator	Johnson & Johnson	1.5	5.5
Jaypirca*	BTK inhibitor for mantle cell lymphoma (approved Jan 2023)	Oncology	Eli Lilly	1.0	4.8
Talquetamab	CD3xGPRC5D bispecific for multiple myeloma	Oncology	Johnson & Johnson	1.0	4.3

*Jaypirca approved January 2023.

Note: Consensus figures may include 'best-case' estimates; not fully adjusted for development risk.

Source: EvaluatePharma® (February 2023)

Not all are in oncology. Sarepta's gene therapy for Duchenne's Muscular Dystrophy, SRP-9001, tops the pipeline league with forecast 2028 sales of over $2 billion and an NPV of more than $8 billion. FDA's approval decision is expected in May 2023.

Gene therapies' high price tags help explain Sarepta's top-spot. The $1 million-per-shot mark is long surpassed: three of the gene therapies FDA approved in 2022 cost $2.8 million or more. Bluebird's Zynteglo for beta-thalassamia is $2.8 million; Skysona for CALD, a rare neurological disorder costs $3 million, and CSL Behring/UniQure's hemophilia B therapy Hemgenix is listed at $3.5 million. These therapies challenge payers, who must invest heavily upfront, yet are unlikely to recuperate downstream savings unlocked via displaced treatment costs.

Johnson & Johnson's fourth-place nipocalimab is being tested across a suite of non-cancer rare diseases, from muscle disorder myasthenia gravis to various anaemias. The molecule, from Johnson & Johnson's $6.5 billion Momenta acquisition in 2020, binds to FcRn, a protein involved in recycling antibodies, including unwanted autoantibodies. This mechanism may open the door to more common auto-immune disorders such as rheumatoid arthritis.

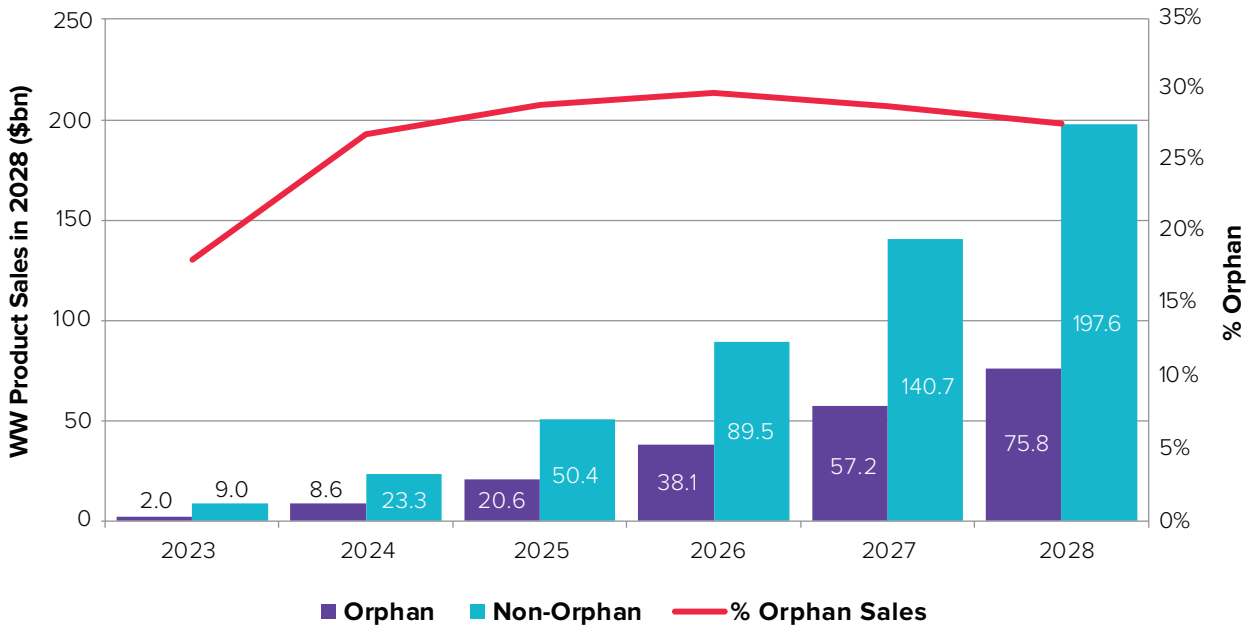
Tomorrow's biggest orphans may include novel formulations, as well as new molecules – mirroring non-orphan drugs' lifecycle management efforts. Sanofi's efanesoctocog alfa, for instance, is a once-weekly Factor VIII for haemophilia A, designed to be more convenient than other Factor VIII replacement therapies (many of which are given every 48 hours). It will go up against **Roche's orphan blockbuster** Hemlibra which is also dosed once-weekly, or less, after an initial loading dose period. Hemlibra doesn't replace Factor VIII, but instead binds to other clotting factors to help them work better.

As the orphan landscape crowds, and as treatments expand into more diseases – including more prevalent ones – the affordability question becomes more urgent.

Orphans' share of global pipeline: close to peak?

Orphans will drive significant growth at several big pharma for the rest of the decade. The category is expected to make up 28% of the global pipeline in 2028. In absolute terms, that's $75.8 billion in combined projected sales – almost double the figure for 2026.

FIGURE 10: Worldwide Pipeline to 2028: Orphan vs. Non-Orphan



Source: EvaluatePharma® (February 2023)

FIGURE 11: Worldwide: Pipeline of Orphan vs. Non-Orphan Drugs to 2028

	WW Sales ($bn)					
R&D Pipeline	2023	2024	2025	2026	2027	2028
Orphan	2.0	8.6	20.6	38.1	57.2	75.8
Non-Orphan	9.0	23.3	50.4	89.5	140.7	197.6
% Orphan Sales	18%	27%	29%	30%	29%	28%
Total	11.0	31.9	71.0	127.6	198.0	273.4
Cumulative Orphan	2.0	10.6	31.2	69.3	126.6	202.4
Cumulative Non-Orphan	9.0	32.2	82.6	172.1	312.8	510.4

Note: Sales represent sales for all indications. All sales analysis based on EvaluatePharma®'s'Orphan' sub-set of products, as defined in the Appendix.

Source: EvaluatePharma® (February 2023)

But, as questions around orphans' 'special status' get louder, due to price-tags and global sales hauls, there are early signs that orphans' share of global R&D pipeline value may soon peak.

The 28% forecast share in 2028 marks a small slide from the 30% in 2026. It is too early to call a definite plateau in orphans' pipeline share, let alone a reversal. But legislative and technological factors have come into play.

The US Inflation Reduction Act, signed into law in August 2022, puts all high-spend Medicare drugs on course for price cuts – including multi-indication orphans. It has also prompted calls for further, orphan-specific reform. *(See Box: Orphan Drug Act 2.0?)* Meanwhile, as new technologies mature, they're finding applications beyond their early, often niche, testing grounds. Development and/or commercial successes across more prevalent conditions such as migraine, obesity or cardiovascular disease are drawing some attention away from rare conditions.

Alnylam, for instance, with four approved rare diseases drugs, is now taking its siRNA platform into hypertension, NASH, Alzheimer's and diabetes. Alynlam discovered Leqvio (inclisiran), marketed by Novartis for certain stubborn forms of high cholesterol; the safety profile of that drug "opened the door [for us] to go into more prevalent conditions," says Alnylam CMO Pushkal Garg.

With several big pharma facing multi-billion dollar patent cliffs this decade, big drugs for big diseases may continue their comeback. (See Article: **The patent winter is coming**). AbbVie is relying on (non-orphan) auto-immune disease drugs Skyrizi and Rinvoq to help fill the $20 billion Humira-sized gap, though Johnson & Johnson will be looking to Darzalex, plus newer cancer orphans Carvykti and Tecvayli, to plug immunosuppressant drug Stelara's $6.5 billion hole.

Meanwhile, pipeline clear-outs underway across the industry include rare diseases assets as well as non-rare, reflecting growing competitive and commercial pressures across the board. Pfizer, for instance, in early January **announced it was cutting in-house R&D in rare neurology and cardiology indications**.

Orphan Drug Act 2.0?

Calls to update the 1983 US Orphan Drug Act (ODA) had begun before the Inflation Reduction Act (IRA) arrived. The ODA granted R&D tax credits and extended market exclusivity for orphans at a time when only a handful of such products were available. Since then, FDA has approved over 600 orphan drugs. As biologics and other new technologies commanded higher prices, and genomics sliced big diseases into orphan-sized pieces, the ODA incentives started to appear over-generous.

Pushback started in 2017, when R&D tax credits were cut by 50%. Yet developers still could recoup 25% of R&D costs, and longer exclusivities remained. Meanwhile, average prices for orphans were multiples of those for non-orphans.

The IRA, then, is a second attempt to clip the ODA's wings – and a rather blunt one. More tailored reform may be possible: a potential "Orphan Drug Act 2.0" could include tiered incentives (more support for drugs in smaller populations, and no support once a certain sales threshold is reached) and higher tax credits for ultra-rare orphan drugs, notes Jeremy Levin, Chairman and CEO of rare diseases player Ovid Therapeutics, also on the board of US advocacy group Biotechnology Innovation Organisation (BIO). As for oncology orphans, they'd need to be handled separately, Levin says. "ODA was never constructed for oncology."

It's unclear whether there is appetite for further legislation.

IRA singles out orphans

A single sentence in the 274-page Inflation Reduction Act exempts orphans with just one approved indication from the price controls that will hit other high-cost Medicare drugs. Those with multiple indications – which include orphan blockbusters like AstraZeneca's Lynparza or AbbVie's Imbruvica, used across various cancers – will eventually be subject to the same price controls as their non-orphan counterparts. If they're among the costliest medicines for Medicare (ten outpatient drugs will be selected in 2026, rising to 60 inpatient and outpatient drugs by 2029), and have no generic competition, they may be eligible for price negotiations. It's unclear how far prices may fall, but there are stiff penalties for failing to engage with the process. The negotiated prices are limited to Medicare, but commercial payers may take advantage of those lower prices to win better deals themselves.

The IRA is already influencing development decisions. Alnylam has halted tests of Amvuttra in Stargardt, a second, smaller rare disease, to avoid losing a single-indication exemption. With its $2.9 billion 2028 sales forecast, Amvuttra would almost certainly otherwise be vulnerable to price cuts.

The decision is bad news for patients with Stargardt disease. It's also one of several unintended consequences of the law. By differentiating single versus multi-indication orphans – a clear aim at the promiscuous oncology orphans – the IRA discourages development of *all* orphans across a wider range of disease settings where they may offer benefit.

Orphan growth will continue, despite headwinds

These potential headwinds won't slow orphans this decade. Alongside approved orphans with a strong forecast sales trajectory are almost 500 more in Phase 3 or filed. Of those, 30 are forecast to each sell $500 million or more by 2028; many will grow much bigger still. (Among non-orphans in Phase 3 or filed, the equivalent figure is 43). Nor will the IRA smother either orphan or non-orphan R&D: its provisions pale in relation to Europe's at-entry price restrictions. Instead, shorter monopolies and greater commercial pressures will compel faster, more efficient R&D of only the best new medicines – rare or otherwise.

Yet as the payer landscape continues to tighten, and if calls for ODA 2.0 endure, orphan drug R&D may lose some of its sparkle. The economics that pulled larger players into the sector over the last two decades may start to look less compelling.

Appendix

An orphan drug is a pharmaceutical product that treats a rare condition or disease. The development of orphan drugs has been financially incentivised through US law via the Orphan Drug Act of 1983. The National Organization for Rare Disorders (NORD), which was instrumental in establishing the Act, currently estimates that there are as many as 7,000 rare diseases and that up to 30 million Americans suffer from a rare disease. Prior to the 1983 Act, 38 orphan drugs were approved in the United States. The success of the original Orphan Drug Act in the US led to it being adopted in other key markets, most notably in Japan in 1993 and in the European Union in 2000.

Orphan drug classification methodology

Using publicly available sources, EvaluatePharma® identify products that have been granted orphan drug designations in the US, EU or Japan. These products are then classified as 'EvaluatePharma® orphan drugs' if:

- The product is approved only for use in the indication/s for which it was awarded orphan designation and these indications are covered by Evaluate Pharma®.
- Approximately one-fifth of products have designations in orphan and non-orphan indications. Products that have orphan and non-orphan drug designations and are expected to generate less than 50% of their sales in 2015 and 2028 from their orphan-designated indication/s, are excluded from this analysis. This has led to the exclusion of therapies such as Avastin, Opdivo, Enbrel, Herceptin, Humira and Remicade.
- EvaluatePharma® may also classify R&D products as 'orphan drugs – prior to the products receiving this status from regulatory bodies – in the following cases:
  - The product is being developed in an indication that is classified by regulatory bodies as an orphan disease, and other products for this disease were granted orphan drug designation.
  - The company developing the product states it is seeking orphan drug designation for the product's lead indication.

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