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Novartis Has A New Goal: $2bn Peak Sales Per Product

by Jessica Merrill

The company said during its R&D day that it has culled its pipeline to 103 clinical stage assets, choosing to focus on drugs that could be big blockbusters.

Novartis AG has reduced the number of drugs it has in clinical development by around 50 products as it looks to focus the pipeline on higher-value assets that can deliver blockbuster-sized returns. The company outlined an updated research and development strategy to investors during an R&D day in London on 27 November.

The strategy will position Novartis for steady growth into the next decade, CEO Vas Narasimhan said. The company simultaneously raised its mid-term sales guidance from 2022-2027 to a 5% compound annual growth rate (CAGR), from a 4% CAGR expectation set last year. (Also see "*New Pure Play Novartis Vows To Up Its Game – With Help From In-House Challenger Ronny Gal*" - Scrip, 22 Sep, 2022.) Novartis forecast mid-single-digit long-term sales growth after 2027.

The update comes amid a lot of change at the Swiss drug maker, which has put in place a new R&D leadership team over the last year, led by president-development and chief medical officer Shreeram Aradhye and president-

Key Takeaways

- Novartis outlined its pipeline priorities during an R&D day in London.
- The company has reduced its clinical-stage pipeline to 103 assets, hoping to invest more in fewer projects.
- The aspirational threshold the company has set is $2bn in peak sales per asset or $500m per indication.
- Novartis raised its mid-term guidance to a 5% CAGR from 2022-2027 from a prior 4% CAGR goal.

biomedical research Fiona Marshall. (Also see "*Novartis Changing Of The Guard Continues As R&D Chief Bradner Exits*" - Scrip, 1 Sep, 2022.) The company also brought on former industry analyst Ronny Gal last year as chief strategy and growth officer to help the company pick internal and external pipeline winners.

Along with the leadership changes, the company's spin-out of its generic drugs and established products business Sandoz in October has given Novartis another opportunity to reset as an innovative pure-play biopharma. (Also see "*Sandoz Stands Alone As It Completes Novartis Spinoff*" - Generics Bulletin, 4 Oct, 2023.)

The priority for R&D will be high-value assets that have the potential to be future blockbusters. The aspirational threshold the company has set is $2bn in peak sales per asset or $500m per indication.

"In general, our expectation is if we don't have a case for the asset to be over $2bn in peak sales than that's probably not an asset that will make sense for Novartis to grow given the size and scale of the company," Narasimhan said.

Fewer Oncology Drugs

Following the R&D review, the company now has 103 drugs in clinical development compared to 155 projects in the third quarter of 2021, with almost all of the projects focused in four primary therapeutic areas: cardiovascular-renal-metabolism, immunology, neuroscience and oncology.

The steepest cuts came from oncology, where 37 programs were cut. Earlier this year, Novartis detailed several programs that would be dropped, including several combination products with the company's internal PD-1 inhibitor spartalizumab. (Also see "*Novartis Culls Pipeline As 'Pure-Play' Drive Progresses*" - Scrip, 25 Apr, 2023.)

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Marshall, who joined Novartis from *Merck & Co., Inc.*, where she led drug discovery and stepped into the role previously filled by Jay Bradner, said the portfolio review involved her, Aradhye and Gal, with input from the commercial team, looking through each and every asset in the portfolio to determine where the high-value bets should be placed. The company also rationalized the early research portfolio.

As Narasimhan explained to investors, the reprioritization will allow the company to spend more on potential winners.

“When we benchmarked ourselves, as the new R&D leadership team, we were at the top of the chart in the number of assets, number of preclinical programs, number of trials, but that also meant we had some of the lowest resourcing per project, lowest number of chemists trying to drug a candidate, and so in making this shift, keeping resources growing in R&D but now dramatically reducing the pipeline size, we actually put more resources against our clinical-stage assets, against our early product portfolio, which we hope will then accelerate and help us find the assets that we really want to go after,” he said.

The company’s new pipeline now falls roughly within the median of the company’s peer group, which Narasimhan said is a “reasonable” place to be.

“We don’t necessarily want to go lower, but we no longer want to be the company that’s highlighted with the most of everything because that’s not the battle we want to win any longer,” he said.

But growing drugs into blockbusters isn’t always easy in the increasingly crowded commercial market, particularly in oncology, where drugs tend to grow through indication expansion over many years, and the cloud of Medicare drug price negotiations in the US now complicates the potential lifespan of a product.

Novartis had four commercial drugs that generated more than $2bn in 2022 – Cosentyx (secukinumab), Entresto (sacubitril/valsartan), Promacta (eltrombopag) and Gilenya (fingolimod) – but none of those are oncology therapeutics, which can take longer to grow. The breast cancer drug Kisqali (ribociclib), for example, launched in 2017 but took several years to gain commercial traction in a competitive market. The drug generated $1.23bn in 2022.

New drugs the company expects will help deliver growth as the company faces the expected loss of exclusivity of Entresto in the US in the 2025/2026 timeframe is the oral factor B inhibitor iptacopan, which the company has filed with the US Food and Drug Administration and European Medicines Agency for paroxysmal nocturnal hemoglobinuria (PNH) but has various opportunities for near-term indication expansion, including immunoglobulin A nephropathy (IgAN) and complement 3 glomerulopathy (C3G).

A second product for IgAN, atrasentan, is also a top priority; Novartis brought in the candidate through the $3.2bn acquisition of *Chinook Therapeutics Inc.* in June, and the endothelin A receptor inhibitor demonstrated positive Phase III data in October. (Also see "*Novartis Bookends October With Two IgAN Successes*" - Scrip, 30 Oct, 2023.)

The company’s oral BTK inhibitor remibrutinib is on track for regulatory filing for chronic spontaneous urticaria in 2024 and for multiple sclerosis in 2026. The drug has potential peak sales potential of $3bn across multiple indications in late-stage development, the company said.

Pelacarsen for elevated lipoprotein(a), or Lp(a), is in Phase III testing, with the goal of being the first to demonstrate Lp(a) lowering can benefit atherosclerotic cardiovascular disease (ASCVD).