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\$10bn Sandoz Business May Be Sold Or Spun As Novartis Weighs Options

Novartis Aims To Provide Update 'Towards End Of 2022'

by Dean Rudge

Novartis finally has confirmed plans to begin a strategic review for its Sandoz generics and biosimilars business, following years of conjecture and suggestions from the market. However, the originator stressed that it will take its time with a decision, while underlining that keeping Sandoz is among its choices.

<u>Novartis</u> has announced plans to commence a strategic review of its \$10bn <u>Sandoz</u> generics and biosimilars business, including for a potential divestment, following dedicated moves towards greater autonomy for Sandoz and much speculation around its long-term future as a subsidiary of the Novartis group.

"The review will explore all options, ranging from retaining the business to separation, in order to determine how to best maximize value for our shareholders," Novartis announced, as the Swiss originator published third-quarter financial results.

"This will take time," acknowledged Novartis CEO Vas Narasimhan, "and we will aim to provide an update on the progress of the review towards the end of 2022."

Queried whether Novartis had received interest from prospective buyers at this early stage, Narasimhan was understandably non-committal.

"We would explore all options," he said. "I think it would be premature at this point to really describe any of the options that are in the very early stages of this review."

Sandoz Autonomy Progress Led To Announcement

As Narasimhan made clear, Novartis had always "wanted to create a more autonomous Sandoz within Novartis, particularly [in] creating a separate manufacturing unit, as well as some of the other support functions that enable Sandoz to perform."

The establishment of the Sandoz Technical Operations division, following the creation of Novartis' centralized Technical Operations unit in 2016, provided Sandoz with "far more control over site utilization, investment and strategy," the company noted a year ago. (Also see "*Sandoz Keeps Tabs On Teva Skinny Label Ruling*" - Generics Bulletin, 28 Oct, 2020.)

According to Narasimhan, the drive towards autonomy for Sandoz has "really progressed now to a point where we think it's the right moment to think, 'What is the right longer term strategic positioning of Sandoz?'"

A Sandoz spokesperson reiterated to *Generics Bulletin* that Novartis had always prioritized making Sandoz more autonomous before considering strategic options.

"Now is the right moment to start a process to bring clarity to our associates and the market," Sandoz underlined.

No 'Big Shifts' For Sandoz' Margins

Novartis' long-term outlook for Sandoz has cast a large shadow for investors in recent years, with the suggestion that Novartis could achieve greater success as an innovator without a huge generic and biosimilar business under its command.

From an operational standpoint, Sandoz' significant Retail Generics business has struggled, particularly in the US, amid longstanding pricing and volume challenges for the sector.

Sandoz has also been setback by price erosion in Europe, where it manages a \$5bn operation, noting earlier this year a negative 10% impact on its financial results from falling prices "across Europe and the US."

With softer Retail Generics sales exacerbated by the COVID-19 pandemic, alongside lower sales of the company's core Anti-Infectives portfolio, Sandoz' margins have come under pressure and presented material challenges for management.

"In the coming years you're not going to see big shifts in the margin or the operating leverage," Narasimhan conceded to investors during Novartis' Q2 call in July.

Driving "very strong efficiency gains across all the relevant P&L items," alongside "important pipeline deliveries in biosimilars, in respiratory and in oral solids" led Novartis to expect the margin in the midterm would be accretive, before moving up to Sandoz' goal of mid- to high-20s.

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"The shape is going to be stable for the next few years, and then we expect the acceleration in margin improvement for Sandoz as that portfolio ultimately comes through," he forecast.

Sandoz Q3 US Sales Slump By 20%

Last year, Sandoz was forced to reconfigure in the US after its \$1bn agreement with Aurobindo for Sandoz' US generic oral solids and dermatology businesses collapsed, more than 18 months after the deal was first announced. (Also see "*Sandoz And Aurobindo Cancel US Deal*" - Generics Bulletin, 2 Apr, 2020.)

In response to challenges in the US, Sandoz performed a major reshuffle of its management in North America that saw regional head Carol Lynch move on to become the Novartis unit's global chief business officer, with her position being taken by Keren Haruvi, the former Novartis head of mergers and acquisitions. (Also see "*Haruvi Takes Charge Of Sandoz North America*" - Generics Bulletin, 14 Jan, 2021.)

Evidence of weakness in the US for Sandoz has persisted, however, evidenced in the company's financial third quarter. Sales in the US tumbled by 20%, pushing net sales down by 1% as reported and 2% in constant currencies to roughly \$2.4bn.

Novartis To Host Q3 Call Today

With the strategic review likely a hot topic for investors, Novartis will hold its third-quarter earnings call at 14:00 Central European Time.

On the Q2 call in July, one investor demonstrated seeming prescience, pointing out that management comments around Sandoz' strategic vision and "the long term seemed almost like setting the narrative for a 2022 decision on the longer-term outlook for Sandoz." (*see sidebar*)

Was this, the investor asked, "the timeframe in which we should expect a broad decision on whether Sandoz is a part of Novartis or not in the longer term?"

Sandoz Champions Stability As It Returns To Growth In Q2

By Dean Rudge

22 Jul 2021

Sandoz enjoyed both top- and bottom-line growth in the second quarter, as the Novartis company rebounded from a challenging Q1 and explained how it would reach its financial targets in the longer term.

Read the full article here

"Our goal right now is to put Sandoz in a strong position, invest in the business so that it can be on a track to be the leading generics company in the world, which we think it can be from a financial as well as impact standpoint," Narasimhan reasoned at the time.

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"If and when we take any decisions or start a process, we'll of course let you know," he added.

"But right now, our focus is on the operational performance of Sandoz...and driving the midsingle-digit growth and margin expansion that we've outlined."

Sandoz Details Core Strategic Goals Amid Review

Notwithstanding the strategic review, the spokesperson reiterated, Novartis' "highest priority and focus is on getting Sandoz back to growth as quickly as possible."

Sandoz experienced a tough start to 2021 as pandemic-related pressures combined to drive down sales and profit in what management described as a "challenging" first quarter. (Also see "<u>'Challenging' Times For Sandoz As COVID Bites</u>" - Generics Bulletin, 27 Apr, 2021.)

In particular, Sandoz told investors during its April Q1 earnings call, on a global basis the company had seen a negative 10% impact on its first-quarter results from price erosion "across Europe and the US."

But on the Q2 earnings call Sandoz announced that it was "now beginning to stabilize," with net sales and core operating profit returning to growth. Nevertheless, Novartis continued to expect disruptions related to COVID-19 for Sandoz during 2021.

"Bringing back the US to a position of strength, continuing to build and support our biosimilars, antibiotics and oncology leadership positions, and maintaining our market leadership in several markets including Europe," were core strategic goals outlined by Sandoz to *Generics Bulletin*.

With an overall strategic priority of bolstering its revenues and growing margins, Sandoz has prioritized investment in costly higher-margin hospital drugs and biosimilars, as well as complex generics across its geographies.

Amid ambitions to achieve \$6bn in sales from biosimilars by 2030, however, failing to bring US biosimilars to market has been a source of frustration for the company. (Also see "*Sandoz Aims For \$6bn Biosimilar Business By 2030*" - Generics Bulletin, 27 Nov, 2020.)

Narasimhan Asked Repeatedly Of Sandoz Plans

Less than a year ago, Narasimhan had underlined to investors that there had been "no change on our perspective on Sandoz as part of Novartis," as rumors continued to swirl. (Also see "*Novartis Emphasizes Message On Spinning Off Sandoz*" - Generics Bulletin, 1 Dec, 2020.)

"Our goal is, as I have said, to build a very strong Sandoz business," Narasimhan maintained speaking at the 2020 virtual Meet Novartis Management event.

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"We have, with Richard [Sandoz CEO Richard Saynor] and his team, a very strong focus in being a leading generics player."

With one investor pointing out at the time that Novartis appeared to be sharing much more data on Sandoz than previously seen, pondering whether this precluded a strategic transaction, Narasimhan maintained that this was merely the result of Novartis now having "a lot of clarity on the strategy."

"Vas and I both talk about 'pragmatic autonomy'," Saynor told investors during the four-hour meeting last year, repeating the phrase he used during an exclusive interview with *Generics Bulletin* last year, shortly after taking charge of Sandoz. (Also see "*Saynor Seeks To Take Sandoz Back To Basics*" - Generics Bulletin, 4 Nov, 2019.)

"There's a number of areas across the business that Sandoz has the decision rights in terms of where it needs to make its own call," Saynor said, noting that the supply chain was a "very good example," as well as "things like tech, IT and digital platforms and, clearly, our pipeline decisions."

"But equally, we're part of a global organization, and there's many parts of that that still we can leverage, whether it's talent development, compliance, framework quality. The list is long," Sandoz' CEO remarked.

"I think what we try to do is be very clear about what we need to make decisions to run this business effectively and compete at a global scale," Saynor commented. "And I think the business is moving in that right direction."

Saynor: Sandoz Unique In Pure Play Generics

Sandoz would pursue future growth by focusing on a "pure" generics and biosimilars model that is unique among its peer group of the off-patent industry's biggest companies, Saynor told *Generics Bulletin* during another exclusive interview held at the beginning of this year. (Also see "*Sandoz' Saynor Insists On Value Of 'Pure Play' Approach*" - Generics Bulletin, 28 Jan, 2021.)

"Of the three big generics companies, we are the only one that is effectively a pure-play generics business," Saynor pointed out.

"Teva clearly is focused on more specialty pharma now to replace its Copaxone (glatiramer acetate) business; Mylan no longer exists, it's now a hybrid generics/mature brands business. Whereas we are a pure generics company."

Further details of the Novartis' plans to commence a strategic review for Sandoz, as well as analysis of Sandoz' third-quarter earnings, will be covered by Generics Bulletin in a later piece.