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Fresenius Kabi Takes Control Of mAbxience To Bolster Biosimilars

Also Announces Acquisition Of Ivenix To Strengthen Medtech Business

by David Wallace

Fresenius Kabi has made a major move to bolster its biosimilars business by acquiring a majority 55% stake in mAbxience, with the purchase price comprising €495m upfront as well as subsequent milestone payments. The deal offers Fresenius not only enhanced biosimilars capabilities but also access to the expanding biologics CDMO market.

Fresenius Kabi has taken a significant step to bolster its biosimilars business by striking a deal to take control of *mAbxience*. The transaction will see Fresenius Kabi acquire a majority 55% stake in the Insud Pharma biopharma unit, with a put/call option scheme for the remaining 45% retained by the current owners.

Expected to be financed by "cash flow and available liquidity," the deal involves an initial €495m ($550m) upfront payment as well as subsequent commercial and development milestones and is expected to close by mid-2022, subject to regulatory approvals and other customary closing conditions.

Founded in 2010, mAbxience currently employs around 600 staff and generated sales of around €255m in 2021.

Characterizing the acquisition agreement as one of the "first steps in executing Fresenius Kabi's 'Vision 2026' growth strategy" – announced last year (*see sidebar*) – the firm said the deal "significantly enhances Fresenius Kabi's

Fresenius Kabi Unveils 2026 Strategy With Focus On Business Not Region

presence in the high-growth biopharmaceuticals market."

Along with a simultaneously announced deal to acquire US specialized infusion therapy company Ivenix (*see below*), the moves will "meaningfully increase the company's scale over the next years and accelerate the group's growth," Fresenius said, with the mAbxience deal in particular providing "access to expertise and capabilities in one of the fastest-growing areas of healthcare, positioning Fresenius Kabi for accelerated medium- and long-term growth."

By Dean Rudge

05 Nov 2021
Fresenius Kabi has revealed a five-year strategic roadmap, driven by its fresh management team, including broadly to increase the injectables specialist's global competitiveness and advance organizational effectiveness.

Read the full article here

The mAbxience acquisition "follows a convincing industrial logic focused on a global, end-to-end vertically integrated biopharmaceuticals footprint," Fresenius insisted, creating "a strong partnership with excellent growth potential in the attractive biosimilars market."

> ***"With mAbxience, we are making a step-change in our biopharmaceuticals profile."***

Fresenius CEO Stephan Sturm had recently hinted at moves to strengthen Fresenius Kabi as the Fresenius group considered how best to make use of its capital. (Also see "*Fresenius Puts Kabi At The Top As It Ponders Best Use Of Cash*" - Generics Bulletin, 24 Feb, 2022.)

Commenting as the mAbxience and Ivenix deals were announced, Sturm said that "through these acquisitions we are further strengthening and leveraging Fresenius Kabi's position, as both perfectly complement the company's growth businesses in biopharmaceuticals and medical technology."

"We will continue allocating capital in a targeted manner to rigorously pursue the recently presented growth strategy of our health care group which has defined Fresenius Kabi as top priority," he confirmed. "In this way, we are creating even better conditions for providing ever better medicine to ever more people. At the same time, we create meaningful value for our

shareholders."

Meanwhile, Fresenius Kabi CEO Michael Sen indicated that "expanding our medtech business and broadening our presence in biopharmaceuticals are key to our Vision 2026 program. Today's announcements fit squarely into our plans," he said, including expanding along the value chain.

"With mAbxience, we are making a step-change in our biopharmaceuticals profile," Sen summarized. "This is a highly complementary transaction in terms of biologics pipeline, manufacturing capabilities and the business model."

'Two Businesses In One Company'

Sen suggested that "mAbxience is two businesses in one company," with the deal not only giving Fresenius Kabi access to a "highly cost competitive biologics manufacturing capacity with significant cost synergies expected for Fresenius Kabi's biosimilars portfolio," but also offering the firm a "strategic foothold" in the "high-growth biologics contract development and manufacturing market, with three state-of-the-art biologics manufacturing facilities in Spain and Argentina."

"Fresenius Kabi's footprint in biopharmaceuticals will be significantly strengthened by broadening its biosimilars portfolio and by gaining access to the distinctive manufacturing capabilities of mAbxience," the firm said. "It will also allow Fresenius Kabi to provide end-to-end integrated biopharmaceutical solutions for customers from its state-of-the-art facilities."

With mAbxience already boasting two commercialized biosimilars in the form of rituximab and bevacizumab, the firm also expected "a mid-single-digit number of molecules across immunology and oncology" to be launched globally in the years 2024 to 2029, supported by internal R&D capabilities.

"In addition to highly competitive production costs for the internal programs," Fresenius noted, "the manufacturing platform allows mAbxience to offer third party biological CDMO services, including a recent contract with AstraZeneca to produce the drug substance for its COVID-19 vaccine in Latin America."

Mabxience Allies With Zentiva For European Bevacizumab Launch

By David Wallace

09 Apr 2021
Mabxience and Zentiva have partnered to launch the Alymsys bevacizumab biosimilar rival to Avastin that recently received a pan-European marketing authorization.

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Aiming To Capture 'Overproportionate Share' Of Biopharma Growth

As a result of the mAbxience deal, Fresenius Kabi said it expected "through its in-house biosimilars programs and through its investment in mAbxience to capture an overproportionate share of the underlying rapid growth in the biopharmaceutical market."

The three biologic drug substance facilities operated by mAbxience would address "a critical gap in Fresenius Kabi's value chain," the company indicated, "adding flexible, single-use biologic drug substance capacity that can be leveraged to provide competitive cost of production for the enlarged biosimilars portfolio."

"This manufacturing capability also offers end-to-end integrated biopharmaceutical solutions for customers and thus establishes a strategic foothold for Fresenius Kabi in the fast-growing biologic CDMO sector, complementing the existing small molecule active pharmaceutical ingredient and fill-and-finish operations."

Citing "material operating and cost synergies" from the deal, Fresenius these would be "primarily driven by leveraging mAbxience's manufacturing capabilities for Fresenius Kabi's existing biosimilars business."

This existing biosimilars business has previously grown more slowly than originally anticipated by the German firm, with an EBITDA breakeven date pushed back as the firm has seen delays in approval to certain key products, such as its proposed US biosimilar rival to Neulasta (pegfilgrastim).

However, positive moves have been seen in recent weeks, including a new licensing agreement, for Dr Reddy's proposed Rituxan/MabThera (rituximab) biosimilar (*see sidebar*), as well as a formal European Commission approval for Fresenius Kabi's Stimufend (pegfilgrastim) biosimilar following the European Medicines Agency's endorsement of the product earlier this year. (Also see "*Accord's Teriparatide And Fresenius Kabi's Pegfilgrastim Satisfy CHMP*" - Generics Bulletin, 31 Jan, 2022.)

Kabi Brings In Reddy's Rituximab As Biosimilar Breakeven Date Retreats

By Dean Rudge

23 Feb 2022

The Fresenius group had much to say of Fresenius Kabi's biosimilar business during the firm's Q4 and year-end results call, which disclosed a US in-licensing deal for Dr Reddy's proposed rituximab biosimilar and suggested additional biosimilar manufacturing is among its top priorities.

Read the full article here

Representing the firm's first oncology biosimilar – and its second biosimilar approval in Europe, after Idacio (adalimumab) in 2019 (Also see "*Fresenius Nod In EU Adds To Crowded Adalimumab Market*" - Generics Bulletin, 8 Feb, 2019.) – Stimufend has been approved for the same

indications as Neulasta, offering "an affordable, high quality treatment option in Europe for cancer patients receiving chemotherapy to decrease the incidence of infection as manifested by febrile neutropenia."

Fresenius Kabi chief operating officer Michael Schönhofen said that "with the approval of this new biosimilar product in Europe, we are leveraging our heritage in oncology and expanding our oncology portfolio to better support the treatment experience and clinical outcomes for patients with cancer."

The company said it "intends to launch the biosimilar in a pre-filled syringe in several European markets over the coming months."

Insud: mAbxience Will Maintain Identity And Brand

Commenting as the deal with Fresenius was announced, mAbxience parent Insud said the agreement "will bring new business to the biotech company, which is expanding its manufacturing capabilities and maintains its identity, brand, and complete team."

"With this strategic transaction, the Spanish group Insud will also have resources to increase its current growth investments worldwide," the company observed.

"As a result of this agreement, mAbxience will continue its ambitious growth plans and will keep its well-defined corporate identity, and team of around 600 professionals, ensuring continuity of its current business strategy," Insud indicated.

Mabxience Expands Biosimilar Capacity

By David Wallace

24 Mar 2021

Mabxience has announced plans to bolster its biosimilar manufacturing capacity as well as giving a boost to its CDMO business by expanding its facility in León, Spain.

Read the full article here

"With this alliance, Insud Pharma plans to accelerate its biotech unit, bringing new and exciting opportunities to mAbxience customers and increasing its research activities," including the expected inauguration in early May of a new R&D facility in Spain.

Insud Pharma CEO Lucas Sigman insisted that the collaboration with Fresenius Kabi "recognizes mAbxience's capabilities in biopharmaceuticals and our strong team of dedicated employees," representing "a tremendous opportunity to add further value to the industry, to make mAbxience bigger and stronger and to collaborate and work together."

Suggesting that the deal "will give our company the chance to continue investing more and to

open the door to faster expansion into new areas and opportunities," Sigman summarized that "as joint partners with Fresenius Kabi, we fully expect to further accelerate our mission to deliver affordable medicines to patients worldwide."

Meanwhile, mAbxience CEO Emmanuelle Lepine said the deal with Fresenius Kabi "represents the best possible next step in line with mAbxience's strategic growth plan."

"This partnership will allow the further progression of our development pipeline and will enable the acceleration of our capacity expansion, both of which will benefit patients, customers, and health systems," Lepine emphasized.

"This new stage in the evolution of our company will bolster opportunities to grow our biopharmaceutical platform in key areas of high technological development and manufacturing, as well as accelerate access in strategic markets, adding a key collaboration to our already strong global partnership base."

Ivenix Acquisition Strengthens Medtech Business

Meanwhile, Fresenius Kabi's acquisition of Ivenix is set to provide the German firm with a "next-generation infusion therapy platform for the US market," complementing the firm's global infusion therapy offering and providing it with "key capabilities in hospital connectivity."

With the purchase price combining a $240m upfront payment and milestone payments linked to commercial and operating targets, Fresenius said that "significant scale and growth synergies" were expected from the transaction, which is expected to close by mid-2022, subject to regulatory approvals and other customary closing conditions.

"The company has developed the technologically most advanced infusion system including a large volume pump with administration sets, infusion management software tools, applications and analytics to inform care and advance efficiency," Fresenius observed.

After receiving US Food and Drug Administration approval, the Ivenix Infusion System was launched in late 2021.

"The Ivenix Infusion System's innovative design and architecture sets a new standard in infusion safety, simplicity and interoperability," Fresenius said. "The system is centered around the patient and clinician and is designed to reduce infusion-related errors and drive down the total cost of ownership."

Setting out its rationale for the deal, Fresenius explained that the acquisition offered "attractive growth potential for Fresenius Kabi in the large and growing infusion therapy market."

“The combination of Ivenix’ leading hardware and software products with Fresenius Kabi’s offerings in intravenous fluids and infusion devices will create a comprehensive and leading portfolio of premium products,” the company indicated, “forming a strong basis to enable sustainable growth in the high-value Medtech space.”

“With the acquisition of Ivenix,” said Fresenius Kabi CEO Michael Sen, “we add the next generation infusion therapy platform; we complement and strengthen our existing infusion therapy offering and we create a superior portfolio for the US market.”

Summing up the transactions, he concluded: “mAbxience and Ivenix as portfolio advancements are good for patients, good for healthcare providers and our company.”