

Ensuring API Supply Capacities for Europe and Beyond

EuroAPI: 150 Year of Heritage and Expertise, now Focused on Stand-alone Success

In early 2020 Sanofi announced plans to establish a new manufacturer of active pharmaceutical ingredients. The French drug-maker, in January 2021, named its new API company EuroAPI and in May 2022 listed it on the Euronext stock exchange in Paris. With around 3,350 employees, EuroAPI posted sales of about €900 million in 2021. The company is estimated to be the world's top manufacturer of small molecules and its second largest API maker in revenue terms. CHEManager asked Karl Rotthier, CEO of EuroAPI, about the start of the new CDMO, its vision for the future and current market trends in the API sector.

CHEManager: Mr. Rotthier, what was Sanofi's intent of spinning out its former Active Ingredient Solutions business and creating a stand-alone company?

Karl Rotthier: On February 24, 2020, Sanofi announced its plans to create a major leading European company dedicated to the production and marketing to third parties of active

pharmaceutical ingredients (APIs), which are the essential molecules responsible for the beneficial effects used in the composition of any drug. At that time, Sanofi said that with increasing medicine shortages that critically impact patient care, the new entity would contribute to supporting and securing API manufacturing as well as supply capacities for Europe and beyond.

Sanofi still holds a stake in EuroAPI and has established a long-term customer relationship. How independent is EuroAPI in working with and for other, external customers?

K. Rotthier: EuroAPI is now fully independent. We have been operating as a stand-alone player since our listing on Euronext Paris, which occurred on May 6. This listing marks an exciting milestone for the development of our company as it will enable us to consolidate our leadership in the dynamic API market. As an independent company, we will gain flexibility and growth opportunities and, as announced, Sanofi will remain a long-term strategic partner.

How is your portfolio made up, where do you see EuroAPI's core competence in terms of capabilities and technologies?

K. Rotthier: EuroAPI is the leading small molecules API company and the



Karl Rotthier, CEO, EuroAPI

second largest API producer in the world with around 200 APIs in our portfolio. Our business is focused on two activities: a wide offering of APIs in our API Solutions segment and custom innovative projects for clients in our CDMO Services segment

We have a broad range of technologies: the Haverhill facility in UK specializes in flow chemistry and spray drying. In France, Saint-Aubin-lès-Elbeuf focuses on fermentation and vitamin B12, and Vertolaye on corticosteroids and solid chemistry. Our Frankfurt site is mainly dedicated to oligonucleotides and peptides while our Budapest facility focuses on prostaglandins. Last but not least, in Italy, our Brindisi site specializes on anti-infectives.

How does your map of manufacturing facilities look like? Do you plan investments in new facilities or any of the existing?

K. Rotthier: As you can see, all of our plants are located in Europe and each of our production sites specializes in different technology. As far as investments are concerned, we announced in July the initiation of a €24 million investment for the construction of a state-of-the-art biomass boiler at our Elbeuf site. This investment should enable us to support our vitamin B12 production capacity increase program, reduce our CO₂ emissions by almost 76% in 2026, compared to





2020 and support our strategy towards greater energy autonomy. Among planned enhancements, we can mention the construction of a new production capacity for highly active hormones in Vertolaye.

As a CDMO you are a leader in small molecules APIs. What are your plans to develop the R&D and manufacturing capabilities to accelerate your activities in complex molecule segments?

K. Rotthier: The number of small molecule drug approvals continues to rise, and there is a long pipeline of small molecule drugs in various stages of clinical trials. In terms of complex chemistry, our approach is to use modern organic chemistry, biocatalysts and flow chemistry techniques. Our development is guided by green chemistry principles for both improved sustainability and lower cost. We already have 330 scientists spread across our six sites today and our plans are to almost double this capacity by 2025.

Through Sanofi's experience in the field of oligonucleotides and peptides, EuroAPI can provide different classes of Tides. Do you have plans to grow this capability?

K. Rotthier: Regarding peptides and oligonucleotides, our production capacities give us a hedge in the biologics space, and we do have projects to grow in that field. Our plans are for example to debottleneck the downstream process in Frankfurt, enabling us to reach a yearly production capacity of more than 100 kg by 2024.



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Overall, what do you think are the predominant trends in API/drug development?

K. Rotthier: The API market is dynamic, and I see three factors here: an increased access to medicine globally, consistent and sustainable outsourcing trends and favorable demographics due to an aging population. Excluding Covid years where the annual growth rate was approximately two percent, the growth rate is six to seven percent year over year and we are talking about a large, over €70 billion global market.

In terms of customer needs, where do you see market trends that you want to support and benefit from?

K. Rotthier: In our field, the quality of APIs and the reliability of supply are critical. At EuroAPI, all our offerings meet the latest regulatory and quality requirements through active monitoring and a reliable, high-performance supply chain. We have local regulatory expertise across Europe, the US and Japan and our industrial sites have health authority, GMP and ISO certifications.

Customers also require tailored solutions and that's what we are offering through our CDMO activity. The CDMO market is even more dynamic, benefitting from a seven to eight percent annual growth rate.

From the beginning of the pandemic on supply chain disruptions also af-

ected the pharmaceutical industry, revealing the shortcomings of globalization. What role will EuroAPI play in ensuring API supply capacities for Europe in the future?

K. Rotthier: Thanks to our strengths, we can play a role in the repatriation of essential activities for the healthcare sector. We are well positioned due to the wide range of technologies and know-how, along with large production capacities and industrial footprint across Europe. Do not get me wrong: the idea is not to bring back high-volume, low-cost products, but to repatriate some of the APIs that are complex to make, as our focus is on high added value solutions.

■ www.euroapi.com

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