

Valbiotis reaches an agreement to terminate its licensing and supply agreement with Nestlé Health Science

Valbiotis takes over all rights to TOTUM•63, its unique plant-based dietary supplement for the treatment of prediabetes and the early stages of type 2 diabetes

- Valbiotis takes back all intellectual property rights (patents, know-how and clinical data) pertaining to TOTUM•63, after receiving a total of 12.75 million Swiss francs in funding from Nestlé Health Science.
- TOTUM•63 is poised for direct launch in France in the first half of 2025 and will be launched internationally via new partnerships still to be finalized.
- Valbiotis had a cash position of €25 million at the end of December 2023, thereby ensures the Company's commercial objectives for its dietary supplement portfolio.

La Rochelle, June 4, 2024 (08:00 a.m CEST) - Valbiotis (FR0013254851 – ALVAL, PEA/PME eligible), a French scientific research laboratory specializing in the development and marketing of dietary supplements for preventing and combating metabolic disorders causing cardiovascular disease, **announces that it has reached an agreement with Nestlé Health Science to terminate the licensing and supply agreement binding the two companies. The agreement provides Valbiotis with full ownership of the TOTUM•63 intellectual property rights, giving it full strategic control over this active substance, which has been clinically approved for use in the treatment of diabetes (prediabetes and the early stages of type 2 diabetes).**

In February 2020, Valbiotis and Nestlé Health Science entered into a global contract including:

- 1) a worldwide license agreement granting Nestlé Health Science exclusive commercial rights to TOTUM•63.
- 2) a supply agreement with Nestlé Health Science for TOTUM•63.

Following changes at Nestlé Health Science and the company's shift in priorities in the health nutrition market, Valbiotis and Nestlé Health Science have come to an agreement to terminate this global contract.

Valbiotis holds the intellectual property rights to TOTUM•63, a substance with an outstanding clinical track record

The agreement stipulates that Valbiotis will take over all the intellectual property rights relating to the license on May 31, 2024: all patents pertaining to TOTUM•63 in France and around the world (62 countries), as well as ownership of the clinical data from the REVERSE-IT and mode of action studies.

Furthermore, the agreement excludes any reimbursement of payments made to Valbiotis by Nestlé Health Science. These payments, totaling 12.75 million Swiss francs (5 million upfront and 7.75 million in milestone payments) since February 2020, have been used to finance the final phases of the TOTUM•63 clinical program. This process was brought to a successful conclusion in 2023 with the positive results of the Phase II/III REVERSE-IT study, followed by the mode of action study. The results establish TOTUM•63 as the first plant-based non-drug active substance with such strong scientific evidence for the management of prediabetes and the early stages of type 2 diabetes.

Finally, as part of this agreement, Valbiotis will have total freedom to choose future licensing partners for TOTUM•63.

Valbiotis aims to bring its TOTUM•63 marketing strategy into line with that of the other three dietary supplements in the portfolio, leveraging growth through direct distribution in France and via licensing agreements worldwide.

Incorporating TOTUM•63 into Valbiotis' French strategy

In France, Valbiotis is targeting a market launch of TOTUM•63 in the first half of 2025; it should be noted that the structuring of the production chain (strategic stocks, industrial processes) was finalized at the start of 2024, ahead of Nestlé Health Science's anticipated supply of TOTUM•63 in powder form (prior to the final dosage form). The TOTUM•63 launch will draw on the experience gained from the launch of Valbiotis^{®PRO} Cholestérol - Lipidrive[®] (ex-TOTUM•070), which is running smoothly, in line with the Company's expectations.

The in-house team of 16 Medical Promotion Officers (MPOs) has registered strong interest in Valbiotis^{®PRO} Cholestérol from the healthcare professionals they have approached (over 2,500 visits to date). Meanwhile, the first orders for Valbiotis^{®PRO} Cholestérol have already been received on all available channels:

- Pharmacies (with or without a doctor's prescription);
- Wholesalers/distributors (currently listed with 5 of the 6 major wholesalers);
- Dedicated e-commerce website: <https://www.valbiotis-healthcare.com/fr-fr/>

Internationally, a development benefiting from a portfolio with enhanced attractiveness

In addition, Valbiotis confirms the commercial roadmap for TOTUM•854 (blood pressure) and TOTUM•448 (hepatic steatosis) as previously announced in the [press release of January 16, 2024](#).

The recovery of all intellectual property (including patents, know-how and clinical data) of TOTUM•63 offers Valbiotis the opportunity to accelerate its international development. Valbiotis pursues its strategic objective of marketing its TOTUM through licensing agreements. TOTUM•63, now marketable, reinforces the attractiveness of the Valbiotis portfolio, which continues its efforts in business development, including by fully internalizing this function.

Cash position of €25 million at end-December 2023

To successfully deploy this strategy over the coming years, Valbiotis is backed by a cash position of €25 million at the end of 2023, which will be assigned strictly to the company's strategic priorities.

About Valbiotis

Valbiotis is a French scientific research laboratory specializing in the development and marketing of dietary supplements to prevent and combat the metabolic disorders that cause cardiovascular disease.

Valbiotis has adopted an innovative approach, aiming to revolutionize healthcare by developing a new class of health nutrition products designed to reduce the risk of major metabolic diseases, relying on a multi-target strategy enabled by the use of plant-based terrestrial and marine resources.

Internationally, Valbiotis' products are the subject of licensing agreements with global and regional health and nutrition players. In France, Valbiotis is responsible for marketing its own products.

Created at the beginning of 2014 in La Rochelle, the Company has forged numerous partnerships with leading academic centers. The Company has established three sites in France – Périgny, La Rochelle (17) and Riom (63) – and a subsidiary in Quebec City (Canada).

Valbiotis is a member of the "BPI Excellence" network and has been recognized as an "Innovative Company" by the BPI label. Valbiotis has also received major financial support from the European Union for its research programs via the European Regional Development Fund (ERDF). Valbiotis is a PEA-SME eligible company.

For more information about Valbiotis, please visit: www.valbiotis.com

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