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Valbiotis announces its roadmap for 2023: a pivotal year in the execution of its clinical, industrial and commercial strategy

- A decisive year in clinical terms with results expected in the first half of 2023 from the international Phase II/III REVERSE-IT study on TOTUM•63, a plant-based active substance that has already demonstrated metabolic benefits in prediabetic patients in a previous clinical study;
- Ramp-up of industrial and commercial operations with a view to supplying Nestlé Health Science with the first commercial batches of TOTUM•63 and marketing TOTUM•070 (LDL hypercholesterolemia) in France in the first half of 2024;
- Intensification of Business Development activities for the expected signature of a licensing and/or distribution partnership for TOTUM•070 internationally.

La Rochelle, January 10, 2023 (07:35 a.m CET) - **Valbiotis** (FR0013254851 – ALVAL, PEA / SME eligible), a commercially oriented Research and Development company committed to scientific innovation for preventing and combating metabolic and cardiovascular diseases, **announces its roadmap for 2023**. This year promises to be rich in strategic advances, with the completion of the clinical development of TOTUM•63 (prediabetes), the objective of signing a license and/or distribution agreement for TOTUM•070 (LDL hypercholesterolemia), and the preparation of commercial launches by 2024 for these two active substances.

On the R&D front, Valbiotis will continue its clinical development efforts for its plant-based active substances, to reinforce their scientific and medical value and obtain health claims. After the major success of the HEART Phase II clinical study in 2022, which demonstrated the efficacy of TOTUM•070 against excess LDL cholesterol in the blood ([press releases of June 13, 2022](#) and [October 3, 2022](#)), 2023 will be marked by expected clinical advances, in particular for TOTUM•63, against prediabetes:

- The first major milestone, before the end of the first half of the year, will be the clinical results of Phase II/III REVERSE-IT, a large pivotal study conducted on 600 people with the primary endpoint of reducing fasting blood glucose levels with TOTUM•63. These results will represent the final step before marketing and the filing of a health claim. In parallel, clinical results on the mode of action of TOTUM•63 will be obtained and communicated this year.
- For TOTUM•854, a major milestone should be reached at the end of the first half of the year with the completion of enrollment in the first Phase II/III clinical study (INSIGHT studies) for blood pressure reduction. The results of the clinical bioavailability and mode of action study will be known early in the year.
- The latest clinical advance announced for 2023 is the launch of a clinical study with TOTUM•448 against the early stages of metabolic liver disease, or "fatty liver disease", which is growing rapidly worldwide.



Alongside these R&D advances, Valbiotis will accelerate the commercialization strategy announced last October ([press release of October 7, 2022](#)), based on two main priorities:

- Structuring the Company to support the global strategic agreement signed with Nestlé Health Science for TOTUM•63 and to conclude future licensing and/or distribution partnerships for TOTUM•070, TOTUM•448 and TOTUM•854.
- Direct marketing in France of TOTUM products (except TOTUM•63) in pharmacies, drugstores and via a dedicated e-commerce site.

On the industrial and manufacturing processes front, which are essential for supporting strategic partnerships and marketing active substances in France, Valbiotis is continuing to develop galenic forms and to set up the supply chain, from the sourcing of plant raw materials to market launch, with the internalization of specific skills.

A dedicated team has been set up to look for new agreements worldwide (except in France), bringing together AEC Partners and Valbiotis' Business Development department. At the heart of the first partnership with Nestlé Health Science concluded in February 2020, AEC Partners has already identified a panel of global or regional players in the world of health and nutrition and initiated the first exchanges. The goal remains the signature of a partnership for TOTUM•070 by the second half of 2023.

With regard to direct marketing in France, the second major focus of the strategy, Valbiotis is gearing up for the launch of TOTUM•070 in the first half of 2024, to be followed by TOTUM•448 and TOTUM•854. Market research with healthcare professionals and consumers has helped establish the commercial strategy, combining medical recommendation and open access for consumers. This strategy is based on in-house medical promotion officers (MPOs), whose main focus is on key prescribers such as general practitioners, certain specialists and pharmacists, and on an e-commerce site that is scheduled to go online in the first half of 2024.

Valbiotis enters this new fiscal year with a strengthened financial position thanks to the success of the recently finalized fundraising ([press release of November 9, 2022](#)), for an amount of 9.7 million euros (€M).

Sébastien PELTIER, Chairman of the Valbiotis Board of Directors, states: *"After years devoted to R&D and the clinical advancement of our plant-based active substances, we are embarking on a new phase of development designed to make the most of our TOTUM products and rapidly generate sales. This goal is based on a two-pronged strategy: local, with our own revenues from direct marketing in France, and international, with worldwide revenues generated by partnerships. The year 2023 will bring us major clinical results for TOTUM•63, in particular for the Phase II/III REVERSE-IT study, the last step before market launch and health claim application. In 2023, we will also complete the first steps of our strategic acceleration with the signature of a license and/or distribution agreement for TOTUM•070, while we continue to structure the Company and ramp up our industrial operations to prepare for the launch of TOTUM•070 in France and the delivery of the first commercial batches of TOTUM•63 by the first half of 2024. With a consolidated financial situation thanks to the recent fundraising and a product portfolio with a high level of scientific evidence in the prevention of metabolic and cardiovascular diseases, Valbiotis is equipped to achieve its goals in the fast-growing food supplement market in France and abroad, estimated at €272 billion in 2028¹."*

About Valbiotis

Valbiotis is a commercially oriented Research & Development company committed to scientific innovation for preventing and combating metabolic and cardiovascular diseases in response to unmet medical needs.

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 and cardiovascular diseases, relying on a multi-target strategy enabled by the use of plant-based terrestrial and marine resources.

Its products are intended to be licensed to players in the health sector.

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 been awarded “Young Innovative Company” status and has 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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This press release contains forward-looking statements about Valbiotis' objectives. Valbiotis considers that these projections are based on rational hypotheses and the information available to Valbiotis at the present time. However, in no way does this constitute a guarantee of future performance, and these projections may be affected by changes in economic conditions and financial markets, as well as certain risks and uncertainties, including those described in the Valbiotis Universal Registration Document filed to the French Financial Markets Regulator (AMF) on May 19, 2022 and completed by an amendment on November 8, 2022. This document is available on the Company's website (www.valbiotis.com).

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