

Valbiotis sets out its commercial and clinical roadmap for 2024

- **A new phase of development is opening up for the Company, with at least one product due for launch this year.**
- **French market launch of TOTUM•070 (hypercholesterolemia) confirmed for the first half of 2024.**
- **Structuring of industrial activities soon to be finalized with a view to Nestlé Health Science's first order for TOTUM•63 (prediabetes / type 2 diabetes), followed by future worldwide or regional licensing and/or distribution partnerships for other TOTUM products.**
- **In terms of clinical development, Valbiotis announces the launch of the HEART 2 study on TOTUM•070 (hypercholesterolemia) and the end of recruitment for the INSIGHT study on TOTUM•854 (arterial hypertension).**
- **Continued clinical development of the Company's portfolio to consolidate its scientific value.**

La Rochelle, January 16, 2024 (05:40 pm CET) – Valbiotis (FR0013254851 – ALVAL, PEA / PME eligible), a commercially-oriented company, specializing in dietary supplements, committed to scientific innovation for preventing and combating metabolic and cardiovascular diseases, **sets out its roadmap for 2024. This year will be marked by several major strategic milestones, with the launch of TOTUM•070 for hypercholesterolemia in the first half of the year, and Nestlé Health Science's first order for TOTUM•63. While the Company plans to finalize a new licensing and/or distribution agreement over the course of the year, and to pursue the clinical development of its portfolio, this new development phase, focused on generating sales, should enable Valbiotis to rapidly establish itself as one of Europe's leaders in 100% plant-based dietary supplements.**

A strategic roadmap built around marketing challenges

The Company enters this new year rich in strategic ambitions and in a stronger financial position thanks to the resounding success of the capital increase finalized last December, for a net amount of 13 million euros ([press release of December 22, 2023](#)).

These new resources will enable Valbiotis to achieve several major milestones, starting with the preparation of the commercialization of TOTUM•63 alongside Nestlé Health Science, Valbiotis' global strategic partner since February 2020 in prediabetes and the early stages of type 2 diabetes. Commercialization is the next step for TOTUM•63, which has an exemplary clinical track record, culminating recently in the positive full results of the Phase II/III REVERSE-IT study ([press release of September 11, 2023](#)) followed by the success of the mode of action study ([press release of November 7, 2023](#)).

Under this partnership with Nestlé Health Science, which includes an exclusive supply agreement, Valbiotis expects to receive its first TOTUM•63 order in the first half of 2024. In order to be able to deliver on this order and secure the TOTUM•63 production chain over the long term, industrial activities are already up and running, with the production of the first strategic stocks, the qualification of industrial partners with high-level, controlled certifications, and the validation of processes on an industrial scale.

These structuring efforts will be stepped up in 2024 to support future licensing and/or distribution partnerships for the international marketing - outside France - of other dietary supplements: TOTUM•070 (hypercholesterolemia), TOTUM•854 (arterial hypertension) and TOTUM•448 (metabolic liver disease). For these three products, the objective remains the signature of one or more global or regional agreements. Business Development activities are also continuing at this early stage of the year. Among the 68 prospects identified, discussions are underway with several major players in the nutrition and healthcare sectors.

Valbiotis' latest strategic milestone is the direct marketing of its products in France (excluding TOTUM•63), which will begin in the first half of 2024 with the launch of TOTUM•070. Preparations for this launch are already well advanced, in terms of industrial processes, IT infrastructure (ERP expansion, e-commerce platform project) and sales and marketing policy. The latter will be supported by a dedicated team of Medical Promotion Officers (MPOs), whose recruitment has already begun, targeting prescribers and key pharmacies, and will be complemented by a direct approach to patients via an adapted digital strategy.

Enhancing the clinical value of the portfolio: launch of the HEART 2 study (TOTUM•070, hypercholesterolemia) and completion of recruitment for INSIGHT (TOTUM•854, arterial hypertension)

In 2024, Valbiotis will also continue its R&D efforts to consolidate the high level of scientific proof of its portfolio in the prevention of metabolic and cardiovascular diseases, and to prepare tomorrow's pipeline. Following the successful completion of TOTUM•63, the Company's goal remains to complete the clinical processes for the other three products and to obtain health claims – these steps not necessarily representing a prerequisite for their commercialization. On this scientific front, several key milestones are also expected in 2024.

TOTUM•070 is now entering its final clinical phase: after obtaining the necessary approvals, the Phase II/III HEART 2 study is underway. Carried out in three centers in Germany, this randomized, placebo-controlled study is being conducted in two arms on a total population of 180 people with mild to moderate hypercholesterolemia (72 subjects recruited to date), with 3 months of TOTUM•070 supplementation. The aim is to confirm the positive results obtained in 2022 by the Phase II HEART study, which demonstrated TOTUM•070's efficacy, from three months, on blood LDL cholesterol and triglyceride levels (-13.7% and -14.3% respectively on target population). HEART 2 should pave the way for TOTUM•070 to be granted a health claim.

Regarding TOTUM•854, enrollment in the Phase II/III INSIGHT study has just been completed, with the inclusion of the last of the 411 participating volunteers. This international, multicenter, randomized, placebo-controlled study is being conducted in a population with mild to moderate arterial hypertension. Its primary objective is to reduce systolic blood pressure between the TOTUM•854 group (dose of 3.7 g/day) and the placebo group, after 3 months of supplementation. Results from the INSIGHT study are expected in the second half of 2024.

With regard to the INSIGHT 2 study, which is also underway, recruitment is now scheduled to end in time for the marketing of TOTUM•854 in France, still scheduled for 2025. Designed with a different dose (2.6 g/day), this international, multicenter, placebo-controlled Phase II/III study (400 volunteers) will bolster TOTUM•854's health claim files.

Finally, Valbiotis plans to announce the clinical strategy for TOTUM•448 and associated academic partnerships in the non-drug treatment of metabolic liver disease (MASLD, formerly NAFLD) shortly.

Sébastien PELTIER, Chairman of the Board, and co-founder of Valbiotis, concludes: *"After a landmark year 2023 in scientific terms, featuring the very good results of TOTUM•63 in its latest clinical phase, 2024 opens a new chapter in the history of Valbiotis with the launch of marketing, which will be conducted both alongside international partners and directly in France. With 100% natural plant-based dietary supplements backed by a high level of scientific proof, our value proposition is unique and will enable us to meet the immediate preventive needs of millions of patients. The potential markets are growing fast and are already significant: today, 30% of the adult population is affected by prediabetes, almost 40% by "bad cholesterol", 25% by arterial hypertension and 18% by metabolic liver disease – all public health challenges targeted by our innovations."*

About Valbiotis

Valbiotis is a commercially-oriented company, specializing in dietary supplements, 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.

Internationally, its products are intended to be the subject of licensing and/or distribution agreements with global or regional health and nutrition players. In France, Valbiotis will be 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 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.

↳ Contacts

Corporate communication

Valbiotis

+33 5 46 28 62 58

media@valbiotis.com

Media relations

Monet Agency

Victoire BEAU

Alexandra DUNANT

Mélanie DA RUI PONS

+33 1 45 63 12 43

valbiotis@monet-rp.com

Financial communication

Seitosei Actifin

Marianne PY

+33 1 80 48 25 31

marianne.py@seitosei-actifin.fr



Name: Valbiotis
ISIN code: FR0013254851
Ticker symbol: ALVAL
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