valbiotis®

Press release

Valbiotis publishes its annual accounts showing solid cash position of more than €25 million at the end of 2023

- **A financial year boosted by the highly successful Phase II/III study on TOTUM•63 (prediabetes/ type 2 diabetes);**
- **Accelerated industrial and commercial structuring in preparation for the first market launches of the dietary supplements in its portfolio;**
- **Commercial launch of Valbiotis®PRO Cholestérol: first revenues expected as early as May 2024;**
- **A cash position of over €25 million at the end of 2023 to secure financing for an ambitious roadmap;**

La Rochelle, April 26, 2024 (7:30 a.m. CEST) - **Valbiotis** (FR0013254851 – ALVAL, PEA/SME eligible), 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, **announces its results for fiscal year 2023, and takes this opportunity to review the Company's recent major milestones, as well as its clinical, industrial and commercial roadmap.**

Sébastien PELTIER, Chairman of the Executive Committee and Co-Founder of Valbiotis, comments: *'2023 was one of Valbiotis' most productive years since the Company was founded just ten years ago. It was characterized by a major scientific success in prediabetes and type 2 diabetes, with the positive results of the latest TOTUM•63 clinical phase. By accelerating its structuring, Valbiotis also laid the foundations for 2024, which promises to be particularly fruitful. Our sights are set on the first market launches of our 100% plant-based dietary supplements, starting with Valbiotis®PRO Cholestérol/Lipidrive® (ex-TOTUM•070) in France next month. With a cash position of over €25 million and a portfolio of products backed by a high level of scientific evidence, Valbiotis is now entering a new stage in its development, focused on revenue generation."*

The portfolio's key clinical advances in 2023

TOTUM•63, prediabetes and untreated type 2 diabetes (early stage)

TOTUM•63 successfully completed its entire clinical pathway in 2023, marked by the positive results of the Phase II/III REVERSE-IT study and then the mode of action study.

Co-designed with Nestlé Health Science as part of its global strategic partnership with Valbiotis, the randomized, placebo-controlled REVERSE-IT study was conducted in 52 clinical centers across 7 countries among a total population of 636 patients with impaired glucose metabolism, ranging from prediabetes to untreated (early stage) type 2 diabetes. The study achieved its primary endpoint of reducing fasting blood glucose levels, after 6 months of TOTUM•63 supplementation at 2 and 3 doses per day, with high statistical significance (press release of May 22, 2023).

Complementary results from REVERSE-IT (press release of September 11, 2023) showed remarkable efficacy on key markers of glucose metabolism, with efficacy levels comparable to those of some leading anti-diabetic drugs in a similar population. Key results *versus* placebo after 6 months of TOTUM•63 supplementation at 5 g/day in 2 doses include:

- Reduction in the main markers of prediabetes and type 2 diabetes: fasting blood glucose (-8.1 mg/dL), 2-hour blood glucose (-21.9 mg/dL), glycated hemoglobin (-0.18%) and HOMA-IR insulin resistance score (-1.04 pts).
- Significant reduction in progression to type 2 diabetes with a relative reduction of 40% in new cases of type 2 diabetes after 6 months.
- Attenuation of (low-grade) inflammatory processes at the root of insulin resistance.
- Confirmed efficacy in untreated early-stage type 2 diabetics.
- The study confirms TOTUM•63's excellent safety profile, with no hypoglycemic risk, very good tolerability, particularly digestive, and compliance in excess of 97%.

The mode-of-action clinical study on TOTUM•63, conducted on 19 volunteers by INAF at Université Laval in Quebec City, in partnership with Nestlé Health Science, confirmed the efficacy of the active substance (press release of November 7, 2023). In terms of mode of action, it revealed that TOTUM•63 has three main effects on the energy metabolism of at-risk subjects:

- Reduction of inflammation, a key mediator of insulin resistance.
- Modulation of the secretion of gastrointestinal hormones (incretins) involved in regulating metabolism and satiety.
- Increased efficacy of the metabolic response after meals.

These two studies rounded off the scientific development of TOTUM•63, which now benefits from unprecedented clinical proof of safety, efficacy and mode of action for a plant-based dietary supplement.

Valbiotis®PRO Cholestérol/Lipidrive® (ex-TOTUM•070), reduction of LDL hypercholesterolemia

2023 saw the start of the latest clinical phase for Lipidrive® (ex-TOTUM•070), with the launch of the Phase II/III HEART 2 trial, which will be completed in the first half of 2024. Conducted at three centers in Germany, this randomized, placebo-controlled study is being carried out in two arms on a total population of 180 people with mild to moderate hypercholesterolemia.

The aim is to confirm the positive results obtained in 2022 by the Phase II HEART study, which demonstrated the efficacy of Lipidrive® with a significant reduction in blood LDL cholesterol ("bad cholesterol") levels in as little as 3 months of use, down by 16% in subjects whose LDL cholesterol was greater than 1.30 g/L, and by 22% in subjects whose LDL cholesterol was greater than 1.60 g/L.

The results of HEART 2 will be available in the first quarter of 2025. They will enable a proprietary health claim to be filed with the European Food Safety Authority (EFSA).

TOTUM•854, reduction of blood pressure

TOTUM•854's potential for reducing blood pressure in the early stages of hypertension, which affects 123 million people in the United States and Europe, was confirmed in early 2023 by the positive results of the bioavailability and mode of action study (press release of January 30, 2023). These results demonstrated that TOTUM•854 has a protective effect on vascular wall cells and promotes a reduction in angiotensin I-converting enzyme (ACE1) activity in humans.

At the same time, Valbiotis continued recruiting volunteers for the Phase II/III INSIGHT study, which was completed in early 2024 with the inclusion of the last of the 411 participants. This international, multicenter, randomized, placebo-controlled study is being conducted in a population with mild to moderate elevation of blood pressure. Its primary objective is to reduce systolic blood pressure after 3 months of supplementation (dose of 3.7 g/day). Results of the INSIGHT study are expected in the second half of 2024.

TOTUM•448, reduction of hepatic steatosis

The launch of TOTUM•448's scientific development will be the subject of a separate communication, detailing the final clinical strategy and associated academic partnerships. The non-drug treatment of metabolic liver diseases (MASLD, formerly NAFLD), the prevalence of which has doubled worldwide over the last 20 years, is generating strong expectations among doctors and patients faced with a limited choice of natural products.

Finally, the Company has received Food and Drug Administration (FDA) approval for New Dietary Ingredient (NDI) status for a plant extract present in all its TOTUM products (press release of December 11, 2023). Putting an end to a conventional authorization process, this approval enables Valbiotis to market all its TOTUM products in the United States - the world's leading market for dietary supplements - since all its other ingredients are already authorized there.

Accelerating the company's structuring in preparation for commercialization

Over the past year, major advances have been made in structuring the Company in preparation for its industrial and commercial expansion. This reorganization has a dual objective. Firstly, the direct marketing in France of Valbiotis®PRO Cholestérol (Lipidrive®), TOTUM•854 and TOTUM•448. Secondly, supporting the TOTUM•63 partnership with Nestlé Health Science – including a global supply agreement – as well as future international licensing agreements for the other three products.

In 2023, the Company continued to put the supply chain, IT infrastructure, e-commerce platform for France, and sales and marketing teams in place.

This structuring was fully completed ahead of the launch of Valbiotis®PRO Cholestérol, a dietary supplement composed exclusively of the active ingredient Lipidrive®, in France. In line with the announced timetable, this launch will take place in May (press release of April 3, 2024). In early April, an in-house team of 16 Medical Promotion Officers (MPOs) was deployed in high-potential geographical areas to promote Valbiotis®PRO Cholestérol to healthcare professionals (general practitioners, nutritionists and pharmacists). Valbiotis®PRO Cholestérol will be available in pharmacies as well as on the Company's dedicated e-commerce site as of May.

Finally, the platform will also provide exclusive access to the Valbiotis®PLUS range of natural food supplements, addressing health problems commonly associated with hypercholesterolemia. Six initial products will be launched: Omega 3, Vitamin D3, Antioxidant, Weight Management, Muscle Comfort, Sleep.

At the same time as preparing this commercial launch in France, Valbiotis has accelerated the structuring of its industrial activities with a view to honoring the exclusive worldwide TOTUM•63 supply agreement included in the global partnership with Nestlé Health Science. In particular, the constitution of strategic stocks and the validation of industrial processes have now been completed. As a result, Valbiotis has secured its TOTUM•63 production line.

Upcoming launches in France, international partnerships: a confirmed roadmap

The Company is also preparing to launch TOTUM•854 on the French market in 2025, followed by TOTUM•448. These launches will take place under the Valbiotis®PRO brand and will follow the same commercial strategy as that deployed for Valbiotis®PRO Cholestérol.
Internationally, for these three products (Valbiotis®PRO Cholestérol, TOTUM•854, TOTUM•448), the objective remains to sign one or more global or regional licensing agreements (outside France). Discussions along these lines are currently underway, notably for Valbiotis®PRO Cholestérol, with several players in the nutrition and health sectors. Bringing them to fruition will remain a priority for Valbiotis throughout 2024.

Financial statements: a strengthened financial structure to support an ambitious roadmap

The Company's 2023 financial statements, drawn up in accordance with IFRS, were approved by the Board of Directors on April 23, 2024. They have been audited by the Statutory Auditor and are available on the Valbiotis website: www.valbiotis.com/en (investors section).

IFRS in €K, as of December 31	**2023**	**2022**
Operating Income	6,809	2,814
Including:		
- Turnover	4,733	785
- Grants	48	137
- Other	456	200
- Research Tax Credit	1,573	1,692
Sales Costs	-2,044	-
R&D Expenses	-7,150	-9,102
Sales & Marketing Expenses	-2,016	-1,703
Overheads	-2,161	-1,651
Share-Based Payment Expenses	-598	-2,344
Other Operating Income and Expenses	-20	-40
Operating Profit for the Period	**-7,180**	**-12,026**
Operating Profit	-7,180	-12,026
Earnings Before Tax	-7,368	-12,314
Net Income	**-7,368**	**-12,312**
IFRS in €K	**2023**	**2022**
Cash Flow from Operating Activities	-8,059	-9,192
Cash Flow from Investing Activities	-246	-197
Cash Flow from Financing Activities	12,494	8,401
Change in Cash Position	4,189	-988
Cash Flow	25,017	20,828

In 2023, Valbiotis' turnover increased more than sixfold, to €4,733,000. This figure includes:

- €298,000 for the deferred upfront payment under the partnership with Nestlé Health Science (€4,679,000 in total over the life of the contract).
- CHF 4.25 million in milestone payments from Nestlé Health Science, including i) CHF 4 million following the major success of the REVERSE-IT study, which demonstrated TOTUM•63's efficacy on the main risk factor for type 2 diabetes, and ii) CHF 0.25 million in connection with the success of the TOTUM•63 mode-of-action clinical study.

Other operating income includes a research tax credit of €1,573,000, compared with €1,692,000 in 2022.

It should be noted that the Company now accounts for its production costs under "sales costs", bringing together the production costs incurred over 2023 for the launch of Valbiotis®PRO Cholestérol (Lipidrive®) in France and TOTUM•63 by Nestlé Health Science. This development reflects the change in the nature of production, which is now dedicated to commercial rather than clinical batches. A portion of R&D expenses was therefore recorded under sales costs, explaining the drop in this item, which nevertheless remains very substantial: R&D expenses totaled €7,150,000 over 2023.

Sales and marketing expenses are up 18.4% to €2,016,000, reflecting the acceleration of the sales strategy and marketing efforts (market research in particular). Overheads came to €2,161,000 compared with €1,651,000 in 2022, in particular as a result of the creation of a Human Resources department in 2023, to support the Company's transformation.

Net income shows losses of €7,180,000 in 2023, compared with losses of €12,026,000 in 2022.

Cash flow from operating activities was –€8,059,000, compared with –€9,192,000 the previous year, reflecting ongoing R&D efforts and higher sales and marketing expenses.

Cash flow from financing activities was positive at €12,494,000. This figure was boosted by the capital increase carried out in December 2023, for an amount (net of expenses) of €12,973,000, as well as by two new bank loans totaling €1,000,000.

As of December 31, 2023, Valbiotis had a comfortable cash position of €25,017,000, an increase of €4,189,000 compared with the end of 2022. Given the anticipated ramp-up of its business, linked to in-house marketing and revenues from existing (Nestlé Health Science) and future licensing agreements, the Company believes it is in a position to fund its own growth within its current scope of activity.

The annual financial report to December 31, 2023 has been made available to the public and filed with the AMF. This document is available on the website: http://www.valbiotis.com/investors.

Valbiotis confirms that it complies with the PEA-SME eligibility criteria specified in Article D.221-113-5 of implementing decree no. 2014-283 of March 4, 2014, namely:

- Fewer than 5,000 employees.
- Sales of less than €1.5 billion or total assets of less than €2 billion.

As a result, Valbiotis shares continue to be included in PEA-SME accounts, which benefit from the same tax advantages as the traditional PEA share savings plan.

The Company's investor presentation is available at http://www.valbiotis.com/en.

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 will be the subject of licensing agreements with global and 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 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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