

## **Valbiotis publishes its interim financial statements, showing a cash position of €18.5M, and confirms its attractive commercial roadmap**

- H1 marked by the French launch of Valbiotis<sup>@PRO</sup> Cholestérol, now sold in over 200 pharmacies and by all wholesaler-distributors.
- Confirmation of sales ramp up, starting with the launch of TOTUM•63 in the first half of 2025.
- New scientific successes including the results of the INSIGHT study on TOTUM•854, the 3<sup>rd</sup> Valbiotis product to obtain unequivocal proof of clinical efficacy.
- A cash position of €18.5M as of June 30, 2024, securing the financing of the Company's sales goals.

**La Rochelle, October 29, 2024** (5:40 PM CEST) – **Valbiotis** (FR0013254851 – ALVAL, PEA/PME 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 H1 2024 results today, and reviews the key events that have marked its progress.**

### **Valbiotis<sup>@PRO</sup> Cholésterol: A successful first commercial launch on the French market**

The Company reached a major strategic milestone in the first half of 2024 with the French launch of Valbiotis<sup>@PRO</sup> Cholésterol, a 100% natural dietary supplement composed exclusively of the active substance Lipidrive<sup>®</sup> (formerly known as TOTUM•070) for the treatment of mild to moderate hypercholesterolemia. This market launch, a first for the Company after ten years devoted to R&D, was carried out in two stages: 1) Provision of the product to pharmacies and most of their wholesaler-distributors ([Press Release of April 3, 2024](#)); 2) Opening of the valbiotis-healthcare.com e-commerce site ([Press Release of May 22, 2024](#)), enabling online purchases of Valbiotis<sup>@PRO</sup> Cholésterol, as well as Valbiotis<sup>@PLUS</sup>, an exclusive range of natural dietary supplements\*.

As of the end of September, the in-house team of 16 Medical Promotion Officers (MPO) promoting Valbiotis<sup>@PRO</sup> Cholestérol had made over 4,000 visits to general practitioners in high-potential areas. Valbiotis<sup>@PRO</sup> Cholestérol has been very well received by healthcare professionals and is now stocked and sold in over 200 pharmacies and by all wholesaler-distributors.

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\*The Valbiotis<sup>@PLUS</sup> range now includes Omega 3, Vitamin D3, Antioxidant, Immune Boost, Weight Management, Muscle Comfort, Serenity, Sleep, Multivitamins and Natural Acerola 1000.

## **Structuring for the launch of the three other TOTUMs in France and continuing international discussions**

In the first half of 2024, Valbiotis also continued to structure its business with a view to directly marketing the three other products in its portfolio, in France.

As a reminder, this sequence will begin with the launch of TOTUM•63 (pre-diabetes / type 2 diabetes), which has been scheduled for the first half of 2025 following the end of the partnership with Nestlé Health Science ([Press Release of June 4, 2024](#)). As part of the agreement formalizing the end of the worldwide contract between the two companies, Valbiotis has recovered all intellectual property (patents, know-how and clinical data) related to TOTUM•63, after receiving a total of 12.75 million Swiss francs in financing.

The launch of TOTUM•854 (blood pressure) in France, announced for 2025 as part of the commercial roadmap communicated earlier this year ([Press Release of January 16, 2024](#)), will take place in the first half of 2025. This will be followed by the launch of Valbiotis' fourth dietary supplement, TOTUM•448 (hepatic steatosis).

Finally, with regard to the international marketing of all four dietary supplements, Valbiotis intends to pursue a targeted strategy combining licensing and/or distribution agreements in the priority zones of Europe and North America.

## **A clinical pathway near to be finalized for most of the portfolio**

On the clinical front, the first six months of the year were marked by Lipidrive® (formerly known as TOTUM•070) entering its finish line, as enrollment of the 180 volunteers in the Phase II/III HEART 2 study was completed ([Press Release of June 13, 2024](#)). This randomized, placebo-controlled study is being carried out on a population with untreated moderate hypercholesterolemia. Its primary endpoint is the reduction of blood levels of LDL-cholesterol, a risk factor for cardiovascular disease and, in particular, atherosclerosis. The results of HEART 2 will be available in Q1 2025 and will enable the Company to submit a proprietary health claim to the European Food Safety Authority (EFSA).

After the close of H1, Valbiotis also announced the resounding success of the Phase II/III INSIGHT study on TOTUM•854 ([Press Release of October 15, 2024](#)). This randomized, multi-center, international study carried out on 410 participants met its primary endpoint as a significant difference (vs. placebo) in the reduction of systolic blood pressure (SBP). This difference was demonstrated unambiguously in individuals with untreated mild to moderate hypertension. The full results of this study will be released at a later date and would position TOTUM•854 as a highly promising non-drug solution for reducing SBP and preventing the risk of associated cardiovascular diseases.

With regard to TOTUM•448, at the beginning of 2024, Valbiotis launched an innovative research chair on hepatic steatosis in partnership with Laval University (Quebec). The aim is to assess TOTUM•448's effects and mechanisms of action on the microbiota-liver axis, as well as the associated cardiometabolic risks in the context of hepatic steatosis. This chair, financed by Valbiotis, will run for 5 years.

Lastly, after completing its clinical pathway at the end of 2023, with an exemplary track record, TOTUM•63 has been continuing to accumulate accolades from the scientific community. Valbiotis has been selected for an oral presentation of Phase II/III REVERSE-IT results at the ADA (American Diabetes Association) and the EASD (European Association for the Study of Diabetes), the world's two largest diabetes congresses ([Press Releases of June 17, 2024](#), and [September 5, 2024](#)).

## **Governance: A new CFO to support the strategic pivot**

Stanislas Sordet joined Valbiotis and its Board of Directors as Chief Financial Officer in May, to support the Company's transformation from an R&D laboratory to a Company focused entirely on sales generation. Having spent 6 years with Laboratoires Uργο as Financial Controller for the Consumer Business Unit, and 10 years with Sanofi-Pasteur-MSD, notably as Business Controller and Chief Financial Officer, Stanislas Sordet also gained 5 years of entrepreneurial experience with Acting Executive, working with start-ups and SMEs (structuring finance departments, building business plans, raising funds and seeking non-dilutive funding), before joining Mablink Biosciences as CFO, where he played an key role in

financing and M&A operations (acquired by Eli Lilly). His extensive financial expertise, forged in both large groups and smaller structures, is a valuable asset for Valbiotis. Stanislas Sordet joined the Board of Directors this July.

### Interim Financial Statements: A solid financial structure with a €18.5M cash position

The Company's interim financial statements, prepared in accordance with IFRS, were approved by the Board of Directors on October 25, 2024. They have been reviewed by the Statutory Auditor and are available on the Valbiotis website: [www.valbiotis.com](http://www.valbiotis.com) (investors section).

In K€	H1 2024 IFRS	H1 2023 IFRS
<b>Operating Revenues</b>		
Turnover	35	4 241
Others operating revenues	4 143	995
<b>Total Revenues</b>	<b>4 179</b>	<b>5 236</b>
<b>Operating Expenses</b>	<b>(7 889)</b>	<b>(7 056)</b>
Cost of good sold	(960)	
Research & Development	(3 186)	(5 006)
Sales & Marketing	(1 743)	(873)
General Expenses	(1 403)	(923)
Share-based payment expenses	(596)	(236)
Other operating profit		
Other operating expenses		(18)
<b>Current Operating result</b>	<b>(3 710)</b>	<b>(1 820)</b>
<b>Operating result</b>	<b>(3 710)</b>	<b>(1 820)</b>
<b>Operating result before tax</b>	<b>(3 503)</b>	<b>(1 920)</b>
<b>Net result</b>	<b>(3 503)</b>	<b>(1 927)</b>
<b>Operating cashflow</b>	<b>(5 748)</b>	<b>(6 389)</b>
<b>Investment cashflow</b>	<b>24</b>	<b>(93)</b>
<b>Financial cashflow</b>	<b>(747)</b>	<b>(599)</b>
<b>Change in cash position</b>	<b>(6 471)</b>	<b>(7 082)</b>
<b>Closing cash</b>	<b>18 545</b>	<b>13 744</b>

#### Income:

For H1 2024, operating income was comprised primarily of the following items:

- Sales: Following the launch in pharmacies in May 2024 and on the e-commerce site on May 22, 2024, the Company invoiced €35K to pharmacies and website customers that had ordered since launch, over the last two months of the first half.
- Research Tax Credit in the amount of €531K.
- Following the termination of the NHS contract, €3,514K was recognized under other operating income, corresponding to the carryover of deferred income (under IFRS) not recognized as of 12/31/2023.

### **Expenditure:**

Expenses incurred in H1 2024 totaled €7,889K, compared with €7,056K for the same period in 2023.

Research and development expenditure fell by €1,820K due to the end of clinical trials, mainly on TOTUM•63.

The cost of sales (€960K) reflects the Company's change of focus from producing batches for clinical use (accounted for under R&D in the second half of 2023) to producing batches for commercial use (accounted for under cost of sales starting December 31, 2023).

At the same time, sales and marketing expenses rose by €870K due to the recruitment of sales force staff (16 Medical Promotion Officers and 1 Regional Director), and the creation of the Marketing, Digital and Customer Service Department, which mainly took place in the first half of 2024.

Overheads were up by €480K, mainly due to restructuring and development costs (expenses related to the Collective Contractual Termination (*Rupture Conventionnelle Collective*) and recruitment costs), as well as an €80K loss on the valuation of treasury shares.

Share-based payment expenses amounted to €596K in H1 2024, compared with €236K over the same period in 2023. Prepared in accordance with IFRS2, they include the costs, over the period concerned, of the old BSPCE plans and the new free share plan issued during this period.

Overall, in H1 2024, financial resources (excluding share-based payment expenses) were allocated as follows: 13% to Cost of Sales, 44% to Research & Development, 19% to Overheads and 24% to Sales & Marketing. For H1 2023, the breakdown was 0% for Cost of Sales, 73% for Research & Development, 14% for Overheads and 13% for Sales & Marketing.

### **Results:**

Operating income was a loss of €3,710K for the period, compared with a loss of €1,820K in H1 2023. After a period of investing resources in the development of a portfolio of 4 marketable products, this operating loss is mainly due to Company efforts in sales development, marketing activities and in company structuring.

Net income for H1 was a loss of €3,503K, compared with a loss of €1,927K the previous year.

### **Cash Position:**

The Company's net amount of cash and cash equivalents was €18,545K as of June 30, 2024, compared with €25,017K as of December 31, 2023, and €13,744K as of June 30, 2023. This level of cash flow enables the Company to finance its operating expenses and meet its financial debt repayment schedule, with estimated cash depletion in 2026.

H1 2024 ended with a net cash outflow of €6,471K mainly attributable to net cash flow from operating activities, compared with a net cash outflow of €7,082K in H1 2023, also mainly attributable to operating activities.

Valbiotis' interim financial statements for H1 2024, ending on June 30, were made available to the public and filed with the AMF. This document is available on our website: [www.valbiotis.com/investisseurs](http://www.valbiotis.com/investisseurs).

## **Introduction of a new strategy in Q1 2025**

Over the second half of the current financial year, Valbiotis intends to accelerate its efforts to adapt its organization and cost structure to its new business model, focused on marketing and revenue generation. In particular, the Company plans to close its preclinical research platform in Riom, and to adapt the organization of other R&D-related activities (notably Quality and Clinical Operations). This reorganization concerns 19 positions and is almost complete (14 have left the Company as of October 29, 2024, and 5 more plan to leave by April 2025).

This closure will generate significant recurrent savings, estimated at €2.2M over a full year. It will enable the Company to align R&D resources with the now rather advanced, scientific maturity of its portfolio, with two active substances having completed a full clinical pathway (TOTUM•63 and TOTUM•854) and a third in Phase II/III (Lipidrive®).

Beyond this, Valbiotis intends to hold on to its R&D DNA through its three founding partnerships (with La Rochelle University, the CNRS and Université Clermont Auvergne) and university research agreement with Laval University in Quebec.

Valbiotis will detail its strategic and financial goals to investors when it unveils its medium-term roadmap in Q1 2025.

## **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 natural dietary supplements designed to reduce the risk of the metabolic diseases and cardiovascular risk factors, relying on a multi-target strategy enabled by the use of plants.

In France, Valbiotis is responsible for marketing its own products. Internationally, its products are the subject of licensing agreements.

Created at the beginning of 2014 in La Rochelle, the Company has forged numerous partnerships with leading academic centers.

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](http://www.valbiotis.com)

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