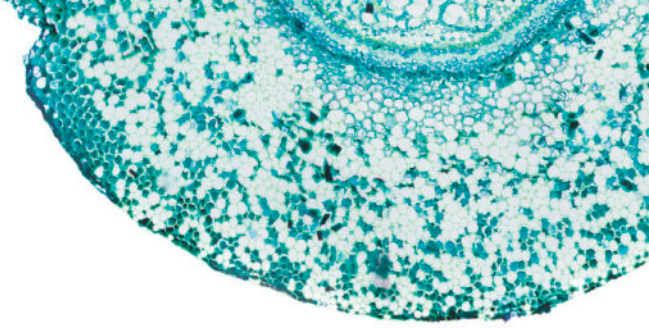

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# Valbiotis publishes its financial report for the first half of 2023 and confirms its strategic roadmap

- On the clinical front, the first half was marked by the resounding success of the Phase II/III REVERSE-IT study on TOTUM•63, and by the ongoing development of the portfolio's other active substances;

- The structuring of the Company is progressing, notably with a view to the direct commercial launch of TOTUM•070 in France in the first half of 2024;

- A cash position of €13.7 M as of June 30, 2023, giving Valbiotis financial visibility until the fourth quarter of 2024 (taking into account the lump-sum payment of 4 million Swiss Francs from Nestlé Health Science, receivable in the last half of 2023).

**La Rochelle, September 28, 2023** (5:40pm CEST) – **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 results for the first half of 2023 and reviews the progress made since the beginning of the year in terms of clinical development, the structuring of the Company, and Business Development.**

**Key clinical advances in the first half of 2023**

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

- A final clinical milestone is reached with the major success of REVERSE-IT
- Continuation of the mode of action clinical study conducted by INAF at Université Laval in Quebec City

The first half of 2023 was marked by the major success of the Phase II/III REVERSE-IT study. This major clinical milestone positions TOTUM•63 as an unrivaled non-drug innovation in the fight against the type 2 diabetes epidemic, potentially benefiting millions of people currently facing the risks associated with this debilitating chronic disease.

Co-designed with Nestlé Health Science as part of its global strategic partnership with Valbiotis, this randomized, placebo-controlled study was conducted in 52 clinical centers and 7 countries on a total population of 636 patients with impaired glucose metabolism, ranging from prediabetes to untreated (early stage) type 2 diabetes.

After a final patient visit early in the year (press release of March 13, 2023), REVERSE-IT's results on its primary endpoint were announced in spring 2023 (press release of May 22, 2023), in line with the schedule announced a year ago. The full efficacy results, also remarkable, were published this month (press release of September 11, 2023).

REVERSE-IT achieved its primary endpoint of reducing fasting blood glucose levels *versus* placebo with high statistical significance, after 6 months of supplementation with TOTUM•63 at a daily dose of 5 g, taken 3 times a day. The reduction in fasting blood glucose was also achieved with high statistical significance at a similar dose but taken twice daily, thereby confirming the efficacy of this optimal dosing regimen in real-world conditions.

Comprehensive results confirmed TOTUM•63's remarkable efficacy on glucose metabolism. Key results *versus* placebo after 6 months of TOTUM•63 supplementation at 5 g/day in 2 doses included:

- 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 40% relative reduction 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 over 97%.

The mode of action clinical study on TOTUM•63 in 19 volunteers at risk of developing type 2 diabetes, conducted by INAF at Université Laval in Quebec City in partnership with Nestlé Health Science, is on schedule. The results of this study are still expected in the second half of 2023.

The scientific publication plan of the data from the TOTUM•63 development program continued in the first half of the year, with a publication in the *International Journal of Molecular Sciences* in February and, in June 2023, the presentation of the characteristics of the REVERSE-IT study population at baseline, as part of the prestigious scientific sessions of the American Diabetes Association.

TOTUM•070, reduction in LDL hypercholesterolemia ("bad cholesterol")

- Preparing the final clinical stage (Phase II/III)

During the first half of the year, Valbiotis continued to prepare the Phase II/III study on TOTUM•070, which should confirm the very positive results of the Phase II HEART study (June and October 2022). These results demonstrated TOTUM•070's efficacy on blood levels of LDL cholesterol and triglycerides at as early as 3 months (-13.7% and -14.3% respectively *per protocol*) and at 6 months (-14.3% and -14.4% respectively), with an improvement in the overall lipid profile, in a population with mild to moderate hypercholesterolemia.

The final Phase II/III clinical stage on TOTUM•070 will be conducted in parallel with and independently of the product's commercial launch in France, which is scheduled for the first half of 2024.

The scientific publication plan for TOTUM•070's development program has also gathered pace, with the first communication of the clinical results of the HEART study and the results of the bioavailability and mode of action study at an international congress, the European Atherosclerosis Society, in May 2023. These results were also published for the first time in a peer-reviewed international scientific journal, *Nutrients*, in April 2023.

TOTUM•854, reduction in blood pressure

- Positive results from bioavailability and mode of action study
- Recruitment underway for Phase II/III INSIGHT and INSIGHT 2 studies

Earlier this year, positive results were published from the TOTUM•854 bioavailability and mode of action clinical study, confirming the potential of this active substance to reduce blood pressure in the early stages (press release of January 30, 2023). This innovative study confirmed the presence of 10 metabolites of interest, mainly polyphenolic compounds, in the serum of volunteers after oral administration of TOTUM•854. *In vitro* analyses on human cell lines also demonstrated:

- a protective effect of TOTUM•854 on vascular wall cells, notably against inflammation and oxidative stress, a key bulwark against the worsening of arterial hypertension;
- a reduction in angiotensin I converting enzyme (ACE1) activity, one of the principal modes of action known to reduce blood pressure.

On the strength of these promising results for the clinical development of TOTUM•854, Valbiotis continued recruitment in the first half of the year for the Phase II/III INSIGHT and INSIGHT 2 studies, both of which have systolic blood pressure reduction as their primary endpoint. Completion of recruitment is now expected in the second half of 2023 for the INSIGHT study (400 volunteers) and later for the INSIGHT 2 study (press release of July 12, 2023).

TOTUM•448 for the reduction of hepatic steatosis as part of the management of metabolic liver disease, now known as MASLD (Metabolic dysfunction-associated steatotic liver disease)[1]

The Company has updated TOTUM•448's clinical development strategy to meet the challenges associated to these emerging pathologies, for which effective preventive and therapeutic strategies have yet to be developed. This strategy and the associated academic partnerships will be announced in the coming months, as announced on July 12, after the half-yearly financial closure (press release of July 12, 2023).

Presenting preclinical data at congresses and updating the clinical strategy

Following the significant preclinical results obtained at the end of 2022 with TOTUM•448 (press release of October 27, 2022), Valbiotis carried out a scientific communication plan for these data during the first half of the year, which were presented at the Keystone Symposium dedicated to the pathophysiology of metabolic liver disease (March 2023), then at the annual congress of the European Association for the Study of the Liver (June 2023).

**Further structuring of the company and business development activities**

At the same time as progress is being made in R&D, Valbiotis teams are engaged in structuring the Company with two objectives in sight. Firstly, preparing for direct commercial launch in France, with the first milestone being TOTUM•070 for hypercholesterolemia (first half of 2024). Secondly, supporting partnerships – the global agreement with Nestlé Health Science on TOTUM•63, as well as future partnerships (outside France) on the three other products (TOTUM•070 [hypercholesterolemia], TOTUM•854 [arterial hypertension], TOTUM•448 [MASLD, Metabolic dysfunction-associated steatotic liver disease]).

On the marketing front in France, digital projects, including the e-commerce platform, are now well advanced, thanks to the Digital Director, who was appointed at the end of 2022. The company has also begun drawing up the operational launch plan, including trade names, claims and benefits, finalizing eco-friendly packaging and product packaging graphics, and producing the first marketing tools for healthcare professionals.

Regarding the structuring of logistics, sales administration and information systems, a senior external project manager was appointed in early 2023 to support the company in its IT transformation project. A first decision was quickly made, confirming that the historical ERP would remain the cornerstone of the future IT structure.

From an industrial standpoint, operations are piloted by a dedicated, experienced in-house team, strengthened by the recruitment of a project manager in January 2023. This in-house team has already selected a number of industrial partners, all of whom are highly certified and subject to regular audits and visits. These partners have been chosen for their reliability and experience in the field. For the production of the 4 main active substances, the Company has confirmed the transposition of these processes to industrial scale with its partners, using stability studies and appropriate analytical data.

To support the structuring of the Company and its transition to a new commercial scale, Charlotte JEZEQUEL joined Valbiotis as Director of Human Relations last March, before joining the Executive Committee (press release of July 3, 2023). With a career spanning over 20 years in major international groups, Charlotte JESEQUEL's role will be to define an HR policy that supports growth, the attainment of strategic ambitions, talent management and CSR.

Finally, in recent months, the company has continued pursuing its business development activities with the support of AEC Partners, Valbiotis' long-standing partner and the firm behind the TOTUM•63 agreement with Nestlé Health Science. With a view to marketing TOTUM•070 internationally, discussions are underway with several global and regional players in the nutrition and health sectors.

[1]Metabolic diseases of the liver related to metabolic dysfunction, new international denomination adopted in June 2023, replacing the appellation NAFLD (Non-alcoholic fatty liver diseases): Rinella ME et al. A multi-society Delphi consensus statement on new fatty liver disease nomenclature, Hepatology, 2023.

**Half-year financial statements: cash position of nearly €14 million**

The company's interim financial statements, prepared in accordance with IFRS, were approved by the Board of Directors on September 15, 2022. They have been subject to a limited review by the Statutory Auditors and are available on the Valbiotis website: www.valbiotis.com (investors section).

| Consolidated, IFRS in €K, as of June 30 | H1 2023 | H1 2022 |
|---|---|---|
| Operating income | 5,236 | 1,514 |
| Including: | | |
| - Turnover | 4,241 | 635 |
| - Grants | 24 | 101 |
| - Other | 154 | - |
| - Research tax credit | 816 | 778 |
| R&D expenses | (5,006) | (4,055) |
| Sales & Marketing expenses | (873) | (911) |
| Overheads | (923) | (768) |
| Share-based payment expenses | (236) | (693) |
| Other operating income and expenses | (18) | (16) |
| Operating profit for the period | **(1,820)** | **(4,929)** |
| Operating profit | (1,820) | (4,929) |
| Earnings before tax | (1,920) | (5,096) |
| Net income | **(1,927)** | **(5,097)** |
| IFRS in €K, as of June 30 | | |
| Cash flow from operating activities | (6,389) | (5,745) |
| Cash flow from investing activities | (93) | (190) |
| Cash flow from financing activities | (599) | (442) |
| Change in cash position | (7,081) | (6,377) |
| Cash flow | **13,744** | **15,441** |

In the first half of 2023, operating income more than tripled to €5,236,000, in line with the sharp rise in turnover, which reached €4,241,000 compared with €635,000 a year earlier.

This turnover includes two revenue streams from the partnership with Nestlé Health Science:

- €4,094,000 milestone payment for TOTUM•63's demonstrated efficacy on the primary endpoint in the REVERSE-IT Phase II/III clinical trial;
- €148,000 upfront payment spread over the term of the license agreement (€4,679,000 in total).

Other operating income includes €816,000 in research tax credit, a slight increase on the €778,000 figure for the first half of 2022.

Research and Development expenses came to €5,006,000, up 23.5% in view of the sustained level of clinical trials carried out over the period. They reflect the finalization of the Phase II/III REVERSE-IT study (TOTUM•63), the continuation of the two clinical studies INSIGHT and INSIGHT 2 (TOTUM•854) and the mode of action study on TOTUM•63, as well as the finalization of the Phase II HEART study (TOTUM•070). Sales and marketing expenses were relatively stable (-4.2%) at €873,000, while overheads rose to €923,000 from €768,000 a year earlier, mainly as a result of higher personnel costs linked to structuring efforts.

Cash flow from operating activities amounted to €(6,389,000) in the first half of 2023, compared with €(5,745,000) for the same period in 2022. This reflects the increase in WCR linked to the level of receivables, notably the milestone payment from Nestlé Health Science relating to the success of REVERSE-IT (to be collected in the second half of 2023) and the tax credits due in respect of 2022 – and not yet collected. Cash flow from financing activities amounted to €(599,000), consisting mainly of loan repayments and advances.

As of June 30, 2023, Valbiotis had cash and cash equivalents of €13,744,000, close to its level of €15,441,000 a year earlier. These amounts enable the Company to finance its operating expenses and meet its financial debt repayment schedule, with an estimated end-of-cash horizon set for Q4 2024. It should be noted that this horizon:

- includes the receipt in the second half of 2023 of a lump-sum payment of 4 million Swiss Francs relating to the success of the REVERSE-IT study as part of the global partnership with Nestlé Health Science on TOTUM•63,
- does not include any potential partnership revenues for TOTUM•070, for which the ambition remains to sign one or more licensing and/or distribution agreements worldwide (excluding France).

The half-yearly financial report to June 30 has been made available to the public and filed with the AMF. This document is available on the following website: www.valbiotis.com/en/investors.

Valbiotis confirms that it complies with the PEA-PME 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;
- turnover of less than 1.5 billion Euros or total assets of less than 2 billion Euros.

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

The company's corporate profile is available at: www.valbiotis.com.

## 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 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 and regional health or 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 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 April 26, 2023. This document is available on the Company's website (www.valbiotis.com).
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