

Valbiotis publishes its 2022 annual results and provides an update on its strategic roadmap

- A cash position of more than €20 million at the end of 2022, which provides the Company financial visibility until the end of the first half of 2024;
- A decisive year on the clinical front with the results of the Phase II/III REVERSE-IT study on TOTUM•63, expected before the end of the first half of 2023;
- Continued structuring of the Company towards the first commercial launches in early 2024, both in France and through international partnerships.

La Rochelle, March 15, 2023 (5:40 p.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 results for fiscal year 2022 and reviews its clinical and scientific news and recent strategic advances.**

Sébastien PELTIER, Chairman of the Board of Directors at Valbiotis, comments: *"During the year 2022, Valbiotis continued to pursue its R&D roadmap while providing itself with the means to accelerate its commercial strategy. On the clinical and scientific front, the year was marked by the positive results of the Phase II HEART study on the efficacy of TOTUM•070 against "bad cholesterol", the end of recruitment for the Phase II/III REVERSE-IT study on TOTUM•63, the launch of two Phase II/III studies (INSIGHT and INSIGHT 2) on TOTUM•854, as well as the first significant preclinical results for TOTUM•448 against metabolic liver diseases. On the strategic front, we announced a decisive new step with the marketing of our products through our own distribution network in France (excluding TOTUM•63), in parallel with their international launch through global or regional agreements. This dual lever will be the driving force behind Valbiotis' transition from an R&D model to a commercially oriented company, in order to optimize the value of our active substances and rapidly generate sales. At the same time, we have strengthened our commitment to CSR by joining the United Nations Global Compact and implementing the ISO 26000 standard. With a solid financial situation and a cash position of more than €20 million at the end of 2022, Valbiotis' teams are both confident and focused as we enter the pivotal year 2023."*

Key clinical advances for the year 2022

TOTUM•63, prediabetes

- Final phase of clinical development before decisive results
- New step for the mode of action study conducted by INAF at Laval University in Quebec City

Valbiotis completed enrollment last summer for the Phase II/III REVERSE-IT clinical study ([press release of July 28, 2022](#)) designed with Nestlé Health Science teams as part of the global strategic partnership signed in February 2020. This randomized, placebo-controlled study is being conducted in more than 50 clinical centers worldwide in a population with prediabetes or early, untreated Type 2 Diabetes (600 patients). It has the same primary endpoint (reduction in fasting blood glucose compared to placebo)

as the previous Phase II clinical study, which reported positive results in summer 2019.

The results of this Phase II/III REVERSE-IT will be a decisive milestone in finalization of the preparation for commercialization and in parallel of a health claim submission. Given the duration of the study (24 weeks) and the time required to analyze the data, Valbiotis will be in a position to communicate the main results at the latest before the end of the first half of 2023. This timetable is supported by the last visit of the last patient scheduled in the protocol ([press release of March 13, 2023](#)).

Regarding the clinical mode of action study on TOTUM•63 in 20 volunteers at risk of developing Type 2 Diabetes, which is being conducted by the Institute on Nutrition and Functional Foods (INAF) at Laval University in Quebec City in partnership with Nestlé Health Science, the First Patient First Visit was conducted in April 2022 ([press release of April 28, 2022](#)). This new milestone resulted in a payment from Nestlé Health Science of CHF 500,000, received in early July 2022. The results of the study are expected to be reported in 2023.

TOTUM•070, reduction of the blood concentration of LDL cholesterol ("bad cholesterol")

- Major success of the Phase II HEART clinical study
- Positive results from the bioavailability and mode of action study

The year 2022 was marked by the positive results of the Phase II HEART study, announced in June ([press release of June 13, 2022](#)). The study achieved its objective of significantly reducing LDL cholesterol, which is a cardiovascular risk factor, compared to placebo. It showed a significant lipid-lowering effect after 3 months of supplementation with TOTUM•070: blood LDL cholesterol levels were reduced by 13% compared to placebo, and triglyceride levels by 14%. The additional results of the study were also positive ([press release of October 3, 2022](#)), showing in particular a very high response rate (up to 100% saw results when LDL cholesterol levels at exceeded 160 mg/dL).

In addition, results from the clinical bioavailability and mode of action study demonstrated that TOTUM•070 and its metabolites exerted a dual effect on human liver cells: inhibition of the *de novo* cholesterol synthesis pathway, a key mechanism against hypercholesterolemia, as well as inhibition of cholesterol storage in the liver ([press release of March 29, 2022](#)).

TOTUM•854, lowering blood pressure

- Simultaneous launch of the INSIGHT and INSIGHT 2 Phase II/III studies and a bioavailability and mode of action study

Regarding TOTUM•854, Valbiotis launched the Phase II/III INSIGHT and INSIGHT 2 clinical studies in early 2022 ([press release of February 17, 2022](#)). These randomized, placebo-controlled studies test the effect of a daily dose of 3.7 g and 2.6 g of TOTUM•854 for 3 months, respectively, with the primary endpoint being a reduction in systolic blood pressure compared to placebo. Enrollment is expected to end in the first half of 2023.

In parallel, the results of the clinical bioavailability and mode of action study have just confirmed the potential of TOTUM•854 for the reduction of early-stage elevated blood pressure ([press release of January 30, 2023](#)).

TOTUM•448, reduction of non-alcoholic fatty liver disease (NAFL)

- First significant preclinical results

At the beginning of 2022, Valbiotis updated the development strategy for TOTUM•448 ([press release of January 6, 2022](#)). In order to ensure that TOTUM•448 has the best possible place in the management of NAFL and NASH, the strategy is now based on a clinical efficacy study in healthcare centers and a clinical bioavailability and mode of action study currently being initiated. Last fall, Valbiotis presented the first significant preclinical results for TOTUM•448 against metabolic liver diseases (NAFL and NASH) at the annual meeting of the American Association for the Study of Liver Diseases (AASLD) ([press release of October 27, 2022](#)).

The latest step forward in the R&D field, Valbiotis signed a research partnership in intestinal microbiota at the end of the year with the MEDIS Unit at the University of Clermont Auvergne on its active substances TOTUM•070 and TOTUM•448 against dyslipidemia and metabolic liver disorders ([press release of December 14, 2022](#)). This project is partly funded by the French National Research Agency (ANR).



Strategic acceleration and securing of financial structure

In 2022, the Company's structural transformation continued on several fronts. First of all, Valbiotis strengthened its commitment to Corporate Social Responsibility (CSR), by joining the United Nations Global Compact and applying the ISO 26000 standard ([press release of March 22, 2022](#)). In terms of governance, the Board of Directors was bolstered by the arrival of Frédéric PELONG ([press release of September 6, 2022](#)), who joined Valbiotis on June 1 as the Company's Chief Financial Officer.

From a strategic point of view, the year was marked by the announcement of a new phase in commercial development designed to make the most of the TOTUM products and to rapidly generate turnover ([press release of October 7, 2022](#)). Valbiotis has thus opted for a two-tier commercial strategy with, in France, the internalization of commercial operations for direct distribution and, internationally, the signing of licensing and/or distribution partnerships with major nutrition and health players.

In order to finance this strategic acceleration, the Company raised €9.7 million last November through the issuing of 2,681,059 new shares, of which 200,674 were purchased by individuals, at a unit price of €3.60 ([press release of November 9, 2022](#)). Valbiotis has thus secured its cash flow while initiating the ramp-up of industrial and commercial operations ([press release of January 10, 2023](#)).

In this way, Valbiotis is putting itself in a strong position to prepare, by the first half of 2024, the direct launch of TOTUM•070 on the French market, as well as the delivery of the first commercial batches of TOTUM•63 to partner Nestlé Health Science. The Company's structuring also aims to support future international licensing agreements, with the first signature expected for TOTUM•070, by the second half of 2023.

Annual accounts: a financial situation tailored to the new roadmap

The 2022 financial statements of the Company, prepared in accordance with IFRS, were approved by the Board of Directors on March 13, 2023. They have been audited by the Statutory Auditor and are available on the Valbiotis website: www.valbiotis.com (investors section).

IFRS in €K, as of December 31	2022	2021
Operating income	2,814	2,693
Including:		
- Turnover	785	298
- Grants	137	645
- Other	200	
- Research Tax Credit	1,692	1,750
R&D expenditure	-9,102	-7,028
Sales & Marketing expenditure	-1,703	-1,509
Overhead expenditure	-1,651	-1,115
Share-based payment expenses	-2,344	-1,447
Other operating income and expenses	-40	-70
Operating profit for the period	-12,026	-8,475
Operating profit	-12,026	-8,475
Earnings before tax	-12,314	-8,681
Net income	-12,312	-8,681
IFRS in €K		
Cash flow from operating activities	-9,192	-7,156
Cash flow from investing activities	-197	-7
Cash flow from financing activities	8,401	14,398
Net cash flow	-988	7,235
Closing cash position	20,828	21,819

In 2022, Valbiotis' turnover more than doubled to €785,000. This amount includes €298,000 for the upfront payment under the partnership with Nestlé Health Science (€4,679,000 in total over the duration of the contract) and €487,000 for the milestone payment following the First Patient First Visit in the TOTUM•63 mode of action clinical study.



Other operating income includes €1,692,000 in research tax credit, virtually unchanged from the previous year, and €137,000 in grants.

As expected, Research and Development expenditure increased (+29.5%) due to the continuation of both the Phase II/III REVERSE-IT clinical study on TOTUM•63 and the TOTUM•854 studies, with the launch of the TOTUM•63 mode of action clinical study (in the first quarter of 2022), and with the completion of the TOTUM•070 Phase II clinical study. In total, R&D expenditure amounted to €9,102,000 in 2022, compared to €7,028,000 in 2021.

Sales and marketing expenditure is up 12.8% to €1,703,000, reflecting the efforts required to accelerate the marketing strategy, including expenses related to market research. Overheads amounted to €1,651,000 in 2022 compared to €1,115,000 in 2021, mainly due to the increase in personnel costs.

Cash flow from operating activities amounted to €(9,192,000) for the year, compared to €(7,156,000) in 2021, reflecting the intensification of R&D activities and the increase in sales and marketing expenses. Cash flow from financing activities was positive at €8,401,000, fueled by the November 2022 fundraising (an amount of €9,004,000 net of fees); a new Bpifrance innovation loan was also obtained, for €700,000.

As of December 31, 2022, Valbiotis had a cash position of €20,828,000, close to its level at the end of 2021 (€21,819,000). This enables the Company to finance its operating expenses and to meet its financial debt repayment schedule, with an estimated end-of-cash horizon at the end of the first half of 2024. This horizon does not take into account in particular the milestone payments expected during 2023 in the context of the global partnership with Nestlé Health Science for TOTUM•63, as well as potential revenues from a licensing and/or international distribution partnership for TOTUM•070, which is still expected to be signed in the second half of 2023.

The annual financial report as of December 31, 2022, has been made available to the public and filed with the AMF. This document is available online: www.valbiotis.com/en/investors.

Valbiotis confirms that it complies with the PEA-SME eligibility criteria specified in Article D.221-113-5 of the implementing decree n°2014-283 of March 4, 2014, namely:

- a total workforce of less than 5,000 employees;
- a turnover of less than 1.5 billion euros or a balance sheet total of less than 2 billion euros.

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

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 or distribution 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 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). This press release and the information it contains do not constitute an offer to sell or subscribe, or a solicitation to purchase or subscribe to Valbiotis' shares or financial securities in any country.

