



Valbiotis provides an update on its progress and publishes its financial report for the first half of 2022

- A cash position of €15.4 million at June 30, 2022.
- Financial visibility until the last quarter of 2023, excluding potential additional revenues.
- Continued execution of the strategic and operational roadmap for future commercialization.

La Rochelle, September 15, 2022 (7:35 am CEST) - Valbiotis (FR0013254851 – ALVAL, PEA/SME eligible), a Research and Development company committed to scientific innovation for preventing and combating metabolic and cardiovascular diseases, announces its results for the first half of 2022 and provides an update on its developments since the beginning of the year.

Sébastien PELTIER, Chairman of the Board of Directors at Valbiotis, comments: *"During the first half of 2022, Valbiotis achieved new milestones in the validation of the scientific interest of its products for preventing and combating metabolic and cardiovascular diseases. The Company has advanced on all fronts with the continued development of TOTUM•63 in prediabetes, the major success for TOTUM•070 in the Phase II HEART study, which achieved its goal of a significant reduction in "bad cholesterol", and the launch of three clinical studies for TOTUM•854: INSIGHT, INSIGHT 2 and the bioavailability and mode of action study. In parallel, Valbiotis conducted market studies with physicians (France, Germany, United States) and patients/consumers (France, United States) on TOTUM•070, TOTUM•854 and TOTUM•448 in order to have solid data for future commercialization. Finally, the Company has strengthened its CSR commitments by joining the United Nations Global Compact and applying the ISO 26000 standard. After these last few months, which have been rich in milestones, our teams remain fully mobilized to pursue a roadmap that will lead, in the near future, to the commercialization of products with proven scientific value."*

Main achievements since the beginning of 2022: advancing the clinical calendar, strengthening the company's structure and its CSR approach

TOTUM•63, prediabetes

- [Continuation of the last phase of clinical development with the completion of Phase II/III REVERSE-IT study recruitment](#)
- [New step for the mode of action study by the INAF at Laval University in Quebec City, in partnership with Nestlé Health Science](#)

A key milestone has been reached for the Phase II/III REVERSE-IT study, designed with Nestlé Health Science teams as part of the global strategic partnership signed in February 2020. In July 2022, Valbiotis announced the end of recruitment with the randomization of the last of the 600 participating volunteers ([press release of July 28, 2022](#)).

The study, conducted at more than 50 clinical centers worldwide, is among the most ambitious performed with non-drug approaches in early dysglycemia. Its primary objective is to confirm the positive Phase II results - published in summer 2019 - on fasting blood glucose, a well-established risk factor for type 2 diabetes.

Given the duration of the study (24 weeks) and the time required to finalize and analyze the data, the Company will now be in a position to communicate the main results at the latest before the end of the first half of 2023, which is a minor revision of the initial timetable (initial objective set at end of 2022).

In addition, the TOTUM•63 mode of action clinical study was officially launched following the necessary authorizations and the First Patient First Visit, announced in April 2022 ([press release of April 28, 2022](#)). This study conducted by the INAF (Institute of Nutrition and Functional Foods) at Laval University in Quebec City, as part of the global partnership with Nestlé Health Science, explores the mode of action of TOTUM•63 in 20 volunteers at risk of developing diabetes. It will provide additional data to support scientific communication and accompany the commercialization of TOTUM•63 in the prediabetes market. The results of the study are expected to be reported no later than the end of the first half of 2023. The First Patient First Visit resulted in a new lump sum payment from Nestlé Health Science of €487,000.

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

- [Major success of the Phase II HEART clinical study](#)
- [Positive results from the clinical bioavailability and mode of action study](#)

The results of the Phase II HEART clinical study, launched in February 2021, were reported in June 2022 ([press release of June 13, 2022](#)). The study was highly successful, achieving its objective of significantly reducing LDL cholesterol (primary endpoint) and confirming the very good tolerance of TOTUM•070. As early as three months of supplementation, the active substance significantly reduced the blood concentration of LDL cholesterol (-13% compared to placebo) and triglycerides (-14%). A raised LDL cholesterol blood level is a risk factor for cardiovascular diseases.

TOTUM•070 is thus positioned as a resolutely innovative product for the prevention of cardiovascular risk in a large population suffering from mild to moderate hypercholesterolemia. Based on the positive results of Phase II, Valbiotis has set the objective of marketing the product no later than the first half of 2024, in particular by intensifying its exchanges with major health and nutrition players. The Company is also preparing a final Phase II/III clinical stage in order to obtain a health claim that will further enhance the value of TOTUM•070.

Meanwhile, the study combining clinical evaluation, bioavailability study and metabolite identification produced positive results ([press release of March 29, 2022](#)). The data show that TOTUM•070 and its metabolites exert 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. They thus confirm the potential of TOTUM•070 to contribute to the regulation of cholesterol metabolism.

TOTUM•854, reduction of blood pressure

- [Acceleration of the program with the simultaneous launch of the Phase II/III INSIGHT and INSIGHT 2 studies](#)

This program has entered the final stage of development for the management of early-stage high blood pressure. In February 2022, Valbiotis received approval to initiate two Phase II/III clinical trials, INSIGHT and INSIGHT 2 ([press release of February 17, 2022](#)). The end of recruitment for each of the studies is scheduled for the first half of 2023. Valbiotis plans to commercialize the product as soon as the Phase II/III results are available, up to three years ahead of schedule. The market for mild to moderate high blood pressure in the United States and major European countries is estimated at €1.15 billion (study conducted in 2020 by AEC Partners).

TOTUM•448, reduction of hepatic steatosis

- [Update of the development plan to meet the challenges posed by emerging pathologies](#)

TOTUM•448 is the fourth active substance in the portfolio and is being developed for the treatment of metabolic liver diseases such as non-alcoholic fatty liver disease (NASH). In view of the challenges posed by these emerging diseases, for which effective preventive and therapeutic strategies have yet to be developed, the development plan for TOTUM•448 has been updated ([press release of January 6, 2022](#)). Details of the plan will be announced at a later date.

New financial management and changes to the Board of Directors

On June 1, 2022, Frédéric PELONG took over as Chief Financial Officer from Jocelyn PINEAU. He brings to the Company over 20 years of experience in similar positions at major groups such as Pernod Ricard, Christofle and Audika. This experience has enabled him to acquire solid skills in growth management. Frédéric PELONG joined the Board of Directors on August 25, 2022 ([press release of September 6, 2022](#)).

Structuring of the CSR approach

Finally, Valbiotis strengthened its commitment to Corporate Social Responsibility (CSR) during the first half of the year by joining the United Nations Global Compact and applying the ISO 26000 standard ([press release of March 22, 2022](#)). In the first year of its membership, the Company has planned several initiatives including setting up CSR governance with the creation of a steering committee, structuring an ISO 26000-compliant approach, raising awareness of CSR issues among all employees, and assessing the impact of the Company's activities on the environment. Valbiotis, which two years ago joined the Gaia-Index (the French benchmark index for Small & MidCaps in terms of ESG), thus confirms its ambition to place CSR at the center of its long-term strategy.

Results: a financial position that is secured for the long term

The Company's interim financial statements, prepared in accordance with IFRS, were approved by the Board of Directors on September 7, 2022. They have been subject to a limited review by the Statutory Auditor and are available on the Valbiotis website: www.valbiotis.com (investors' section).

IFRS in €K, as of June 30	First half of 2022	First half of 2021
Operating income	1,514	748
<i>Including:</i>		
<i>Turnover</i>	635	148
<i>Grants</i>	101	28
<i>Research Tax Credit</i>	778	572
R&D expenditure	(4,055)	(2,355)
Sales & Marketing expenditure	(911)	(542)
Overhead expenditure	(768)	(549)
Share-based payment expenses	(693)	(632)
Other operating income and expenses	(16)	(56)
Operating profit for the period	(4,929)	(3,386)
Operating profit	(4,929)	(3,386)
Earnings before tax	(5,096)	(3,469)
Net income	(5,097)	(3,469)

IFRS in €K, as of June 30	First half of 2022	First half of 2021
Cash flow from operating activities	(5,745)	(3,706)
Cash flow from investing activities	(190)	76
Cash flow from financing activities	(442)	14,865
Net cash flow	(6,378)	11,235
Closing cash position	15,441	25,820

For the first half of 2022, Valbiotis posted a turnover of €635,000, including revenues from the partnership signed in February 2020 with Nestlé Health Science, resulting in the recognition of €148,000 for the upfront of €4,679,000 spread over the duration of the license agreement. To this amount should be added the milestone payment of €487,000 following the First Patient First Visit in the mode of action clinical study on TOTUM•63.

The research tax credit amounts to €778,000 and the grants to €101,000.

Total operating income for the first half of the year amounted to €1,514,000, compared with €748,000 for the first half of 2021.

Research and Development expenditure increased as a result of the continuation of clinical trials:

- Phase II/III clinical trial, REVERSE-IT, launched in July 2020, on TOTUM•63 (prediabetes),
- Phase II clinical trial of TOTUM•070, launched in February 2021 ("bad cholesterol"),
- Simultaneous launch of three clinical trials for TOTUM•854 (reduction of blood pressure).

They amounted to €4,055,000, compared with €2,355,000 in the first half of 2021.

Sales and marketing expenditure amounted to €911,000 compared with €542,000 in the first half of 2021. This increase in expenditure reflects the intensification of marketing efforts with a view to future commercialization, particularly in terms of market research.

Overhead expenditure amounted to €768,000 compared to €549,000 in the first half of 2021, mainly related to personnel costs.

Cash flow from operating activities amounted to €5,745,000 during the first half of the year, reflecting the intensification of research and development activities. Cash flow from investing activities was negative by €190,000. Cash flow from financing activities showed a negative impact of €442,000.

At the end of June 2022, Valbiotis thus has a cash position of €15,441,000. This cash position allows the Company to comfortably cover operational expenses related to the execution of its development plan and to meet the repayment schedule of its current financial debt, and thus to benefit from financial visibility until the last quarter of 2023, excluding potential additional revenues.

This cash horizon does not take into account additional milestone payments that may be received from Nestlé Health Science, nor additional revenues that may be received from new strategic partners.

Valbiotis is therefore looking forward to the coming months with confidence, with a view to continuing clinical studies on all the active substances in its portfolio and preparing for future marketing.

The annual financial report as of June 30, 2022 has been made available to the public and filed with the AMF (French Financial Markets Regulator). This document is available online at: www.valbiotis.com/investisseurs.

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 fewer 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).

About Valbiotis

Valbiotis is a 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 and cardiovascular diseases, relying on a multi-target strategy enabled by the use of plant-based terrestrial and marine resources.

Its products are intended to be licensed to players in the health sector.

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 May 19, 2022. This document is available on the Company's website (www.valbiotis.com).

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