



Valbiotis reviews its activities and publishes its financial report for the first half of 2021

TOTUM•63, prediabetes

- Obtaining of the patent in China;
- Scientific publications validating the R&D work performed;
- Announcement of the implementation of a clinical mode of action study by INAF at Laval University in Quebec City, in partnership with Nestlé Health Science.

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

- Launch of the HEART Phase II clinical study;
- Completion of recruitment confirmed in September.

TOTUM•854, reduction of blood pressure

- Acceleration of the development program following the presentation of preclinical data at the annual congress of the European Society of Hypertension and the International Society of Hypertension;
- Launch of three clinical studies that could lead to commercialization up to 3 years ahead of the initial plan.

Strengthening the organization

- Obtaining of ISO-9001:2015 certification for all the Company's activities;
- Appointment of Sébastien BESSY as Chief Operating Marketing and Business Officer.

A long-term secure financial situation

- Cash flow of €25.8 million as of June 30, 2021;
- Financial visibility until the first half of 2024, excluding potential additional revenues.

La Rochelle, September 30, 2021 (7:35 am CEST) - Valbiotis (FR0013254851 – ALVAL, PEA/SME eligible), a French research and development company committed to scientific innovation for preventing and combating metabolic diseases, **publishes its financial report for the first half of 2021 and provides an update on the Company's progress.**

Sébastien PELTIER, Chairman of the Board of Directors at Valbiotis, comments: "2020 was a pivotal year for Valbiotis with the conclusion of our strategic global partnership with Nestlé Health Science for TOTUM•63, our flagship product dedicated to the reduction of risk factors for type 2 diabetes. This partnership has decisively strengthened our visibility on an international scale. It has opened up promising marketing prospects for us as we enter the final phase of development of this active substance, which has already been scientifically proven to be effective. And, above all, it has strengthened our resolve to pursue our strategic roadmap. This is what 2021 is all about: redoubling our efforts to reach new milestones with TOTUM•63, as well as with the other products in our portfolio. In the first half of the year, we were on target. In addition to achieving new scientific milestones and strengthening our organization, we also secured our financial resources on a long-term basis. All of these achievements enable us to approach our next challenges with confidence, backed by the commitment of our employees and the crucial support of our shareholders."

Main achievements since the beginning of 2021: start of the year perfectly in line with the roadmap

TOTUM•63, prediabetes

- **Obtaining of Chinese patent**

In the area of intellectual property, further progress was made in the first half of the year, with the granting of a patent in China for TOTUM•63. Announced in May 2021 ([press release of May 19, 2021](#)), this patent grants broad protection for the composition and use of this substance. It also confers a monopoly on exploitation in this strategic country, one of the most affected by metabolic diseases, where the prevalence of prediabetes in the adult population is estimated at 35%¹, i.e. 390 million people, and that of overweight and obesity at 50%². This is a concrete example of the Society's global protection strategy, with patents having now been acquired in nearly 50 countries, including across Europe, the United States and China.

- **First publications of scientific articles in three international journals**

In line with the strategy developed with Nestlé Health Science, data on TOTUM•63 has been published in three international peer-reviewed journals, highlighting the focus on scientific promotion, which is decisive in preparing for future commercialization. These articles ([press release of June 3, 2021](#)) were published in the *American Journal of Physiology-Endocrinology and Metabolism*, the *International Journal of Obesity* and *Nutrients*. They constitute a validation by the scientific community of the work performed and allow the latter to better understand the mechanism of action of this active substance.

- **Announcement of the implementation of a clinical mode of action study by INAF at Laval University in Quebec City ([press release of June 28, 2021](#))**

On the scientific front, a new study co-designed by Valbiotis teams, INAF experts and Nestlé Health Science experts was also announced. It should provide additional data to support scientific communication and the marketing of this active substance. The launch of the study is planned for the fourth quarter of 2021.

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

- **Launch of the HEART Phase II clinical study and First Patient First Visit**

In February 2021 ([press release of February 15, 2021](#)), the company was authorized to launch the HEART Phase II clinical study and subsequently completed the First Patient First Visit ([press release of February 22, 2021](#)). The recruitment of the last volunteer in this study was announced at the beginning of September 2021 ([press release of September 6, 2021](#)), fully in line with the study's roadmap. Results are expected in the second quarter of 2022.

This study will evaluate the effect of TOTUM•070 on the reduction of LDL-cholesterol, a risk factor for cardiovascular disease, in people with mild to moderate hypercholesterolemia.

With the simultaneous launch of a clinical study to characterize all the metabolites and identify their effects in human cell models, as well as extensive preclinical work to be submitted to the American Heart Association (AHA) annual meeting in November 2021, this program will provide comprehensive data to position TOTUM•070 as a breakthrough innovation in the cardiovascular risk prevention market.

TOTUM•854, reduction of blood pressure

This program is seeing a strong acceleration in its development following the publication of positive preclinical results at the annual congress of the European Society of Hypertension (ESH) and the International Society of Hypertension (ISH) in April 2021 ([press release of April 12, 2021](#)).

¹Limin Wang et al. JAMA. 2017 ; 317(24) :2515-2523

²Chinese national nutrition and chronic disease report 2020, National Health Commission www.scienceetavenir.fr/sante/plus-d-un-chinois-sur-deux-desormais-en-surpoids_150360 (published on April 21, 2021)

The Company announced the launch of a Phase II/III international, multicenter, randomized, placebo-controlled study in a population with mild to moderate blood pressure elevation. A second international, multicenter, randomized, placebo-controlled clinical study will be conducted in parallel. This strategy will allow Valbiotis to put together a complete health claim file. Finally, Valbiotis will conduct a third clinical study at the same time to measure the bioavailability of TOTUM•854, characterize its metabolites and explore their mode of action.

As the protocols are expected to be filed in the fourth quarter for results scheduled for the second half of 2023, acceleration of the program should allow commercialization as soon as Phase II/III results are available, up to 3 years ahead of the initial plan.

TOTUM•448, reduction of hepatic steatosis

The development strategy is being finalized. It will address the reduction of non-alcoholic fatty liver disease, a condition that puts individuals at risk of developing NASH ("fatty liver disease"). A Phase II study should be initiated in the second half of the year.

Structuring of Marketing and Commercial Operations

During the first part of the year, strengthening the organization was also a priority. This was demonstrated in particular by the appointment of Sébastien BESSY as Chief Operating Marketing and Business Officer, responsible for the global deployment and coordination of the international strategy related to Valbiotis' marketing and commercial development ([press release of June 7, 2021](#)). Former Vice President Global Strategic Operations Consumer Healthcare at Ipsen, Sébastien BESSY brings his international expertise in Consumer Healthcare at a key time for the Company. He has more than 20 years of experience in international marketing strategy, commercial strategy, portfolio strategy and business development. Upon his appointment, Sébastien BESSY became a member of the Company's Board of Directors.

Obtaining of ISO-9001:2015 certification

The strengthening of the organization was also highlighted by the awarding of ISO-9001:2015 certification, issued by AFNOR, for all activities relating to "Design, development and production control of solutions for preventing and combating metabolic and cardiovascular diseases" ([press release of March 22, 2021](#)). This certification guarantees expertise in all Discovery, Preclinical Research, Clinical Research, Production and Product Quality Management activities. Once again, this recognition constitutes a decisive asset in the pursuit of the strategy and the prospect of future market launches.

Financial information for the first half of 2021: a secure long-term financial position

The Company's half-yearly financial statements, prepared in accordance with IFRS, were approved by the Board of Directors on September 27, 2021. 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, at June 30 (1)	First half of 2021	First half of 2020
Operating income	748	714
Including:		
- Turnover	148	121
- Grants	28	156
- Research Tax Credit	572	437
R&D expenditure	(2 355)	(1 939)
Sales and Marketing expenditure	(542)	(545)
Overhead expenditure	(549)	(638)
Share-based payment expenditure	(632)	(226)
Operating profit for the period	(3 386)	(2 557)
Operating profit	(3 386)	(2 557)
Earnings before tax	(3 469)	(2 830)
Net profit	(3 469)	(2 931)
IFRS in €K (1)	First half of 2021	First half of 2020
Cash flow from operating activities	(3 706)	3 323
Cash flow from investing activities	76	(101)
Cash flow from financing activities	14 865	(341)
Net cash flow	11 235	2 881
Cash flow	25 820	10 914

For the first half of 2021, Valbiotis generated €748K of operating income, consisting mainly of the Research Tax Credit and revenue from the recognition of the share for the first half of 2021 of the upfront payment of CHF 5 million received under the partnership signed with Nestlé Health Science in February 2020.

Research and Development expenses increased by €416K, mainly due to the continuation of the Phase II/III REVERSE-IT clinical study on TOTUM•63 and the launch of the Phase II clinical study on TOTUM•070. The company also continued its preclinical research work at its technical platform in Riom.

Commercial and marketing expenditure remained stable at €542K and overhead expenditure decreased by €89K to €549K. This decrease is explained in particular by the finalization of the implementation of a new ERP system at the end of 2020.

During the first half of the year, cash flow from operating activities amounted to €3 706K reflecting the continuation and intensification of R&D activities. Cash flow from investing activities was positive at €76K, mainly due to the refinancing by the banking partner (lease back) of technical equipment for the Riom platform acquired during the second half of 2020 and the first half of 2021. Cash flow from financing activities was positive at €14 865K, mainly related to the capital increase by private placement in April 2021, for a gross amount of €15 million ([press release of April 15, 2021](#)), as well as to two loans obtained from Bpifrance for an amount of €1.3 million ([press release of May 26, 2021](#)).

At June 30, 2021, Valbiotis had a cash position of €25 820K, up nearly 77% compared to December 31, 2020.

To date, and taking into account in particular:

- Its available cash on June 30, 2021 amounting to €25 820K;
- Its operating expenses related to its current development plan;
- The maturity of its current financial debt;
- The upcoming receipt of the Research Tax Credit for the 2020 fiscal year in the amount of €1 257K (amount received in August 2021).

The Company has conducted a specific review of its liquidity risk and considers that it does not face any short-term risk. The cash flow horizon is therefore estimated at the first half of 2024 and does not take into account additional milestone payments that may be made by Nestlé Health Science or additional revenues that could come from new strategic partners.

Update on post-closing events

The month of September opened with the recruitment of the last volunteer in the Phase II HEART study conducted with TOTUM-070 for hypercholesterolemia ([press release of September 6, 2021](#)). The completion of this recruitment confirms the announced schedule of the HEART clinical study, the results of which will be available in the second quarter of 2022. The HEART study is a key step in the development of TOTUM-070 and in the commercialization strategy for the non-drug hypercholesterolemia market, which is estimated at €1.2 billion in Europe and the United States³.

In addition, Valbiotis announced the consolidation of its development of innovative natural health solutions, by integrating the exploration of microalgae produced in New Caledonia, through an exclusive agreement with ADECAL-Technopole and IFREMER ([press release of September 29, 2021](#)). This program should allow to develop a bank of high-potential strains selected by ADECAL-Technopole and IFREMER since 2013 in New Caledonia as part of the "AMICAL" joint research project.

— About Valbiotis

Valbiotis is a Research & Development company committed to scientific innovation for preventing and combating metabolic 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, based on a multi-target approach 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 a PEA-SME eligible company.

For more information about Valbiotis please visit: www.valbiotis.com

↳ Contacts

Corporate communication / Valbiotis

Carole ROCHER / Marc DELAUNAY

+33 5 46 28 62 58

media@valbiotis.com

Financial communication / Actifin

Stéphane RUIZ

+33 1 56 88 11 14

sruiz@actifin.fr

³AEC Partners data, for Valbiotis



Name: Valbiotis
ISIN code: FR0013254851
Mnemonic code: ALVAL
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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 approved by the French Financial Markets Regulator (AMF) on July 27, 2021 (application number R 21-039). This document is available on the Company's website (www.valbiotis.com).

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