VALBIOTIS RELEASES ITS 2020 ANNUAL RESULTS

2020 highlights and results

Global strategic partnership with Nestlé Health Science for the development and marketing of TOTUM-63, a plant-based active substance with clinically proven metabolic health benefits in prediabetic subjects.

Launch of REVERSE-IT, a global pivotal Phase II/III clinical trial of TOTUM-63 for reducing Type 2 Diabetes risk factors.

New milestones achieved with TOTUM-070, a plant-based active substance for lowering LDL-cholesterol, a risk factor for cardiovascular disease.

€14.6m in cash as at December 31, 2020.

Post-balance sheet events and outlook

Important milestones are expected to be reached in the development of TOTUM-070 (reduction in blood LDL-cholesterol levels).

Progress within sight in the development of TOTUM-854, a plant-based active substance for lowering blood pressure, a risk factor for cardiovascular disease.

La Rochelle, March 17, 2021 (5:40 pm CET) **VALBIOTIS** (FR0013254851 - ALVAL, eligible for the PEA/SME), a Research & Development company committed to scientific innovation for preventing and combating metabolic diseases, **releases its results for financial year 2020 and reports on recent progress.**

Main highlights in 2020

TOTUM-63

- **Global strategic partnership with Nestlé Health Science**

2020 saw the announcement of a strategic partnership between Nestlé Health Science and VALBIOTIS for the development and marketing of TOTUM-63 (Press release of February 5, 2020). Under the terms of this partnership, Nestlé Health Science will market TOTUM-63 on a worldwide scale, possibly before the health claim is approved in some parts of the world. The agreement also paves the way for additional sources of revenue, as it provides for the future supply of TOTUM-63 by VALBIOTIS to Nestlé Health Science, in addition to the milestone payments and progressive royalties on net sales agreed upon by the parties.

VALBIOTIS has already received almost CHF 8m, comprising an upfront payment of CHF 5m in April and a second payment of CHF 3m in July at the FPFV (First Patient First Visit) in the REVERSE-IT trial. Under the agreement signed, the milestone payments could amount to up to CHF 66m.

- **Launch of the REVERSE-IT trial, final clinical development phase, and inclusion of the first patient**

Following its partnership with Nestlé Health Science, and with the approval of the CPP (French Ethics Committee) and the ANSM (French National Agency for Medicines and Health Products Safety), VALBIOTIS announced the launch of REVERSE-IT, the final clinical development phase of TOTUM-63 (Press release of July 8, 2020).

REVERSE-IT, which is funded entirely by Nestlé Health Science, will include 600 subjects recruited in over 30 clinical centers worldwide. The main objective of the trial is to confirm the positive Phase II results obtained with TOTUM-63 on elevated fasting blood glucose, the main metabolic risk factor for Type 2 Diabetes.

The COVID-19 health and economic crisis did not affect VALBIOTIS' plans to produce clinical batches for REVERSE-IT. Thus, the first visit of the first patient in the REVERSE-IT clinical trial took place, as announced, in mid-2020 (Press release of July 15, 2020). Results from the trial are expected in the first half of 2022. If they confirm the efficacy of TOTUM-63, a health claim application will be filed with the American and European authorities.

In accordance with its research exploitation strategy, VALBIOTIS announced the results of the Phase II clinical trial of TOTUM-63 at the world's top two scientific conferences on diabetes: the annual scientific sessions of the American Diabetes Association (June 2020) and the annual meeting of the European Association for the Study of Diabetes (September 2020).

TOTUM-070

- **Acquisition of American and European patents**

In September 2020, VALBIOTIS was granted American and European patents for TOTUM-070 (Press release of September 14). TOTUM-070 is designed to reduce hypercholesterolemia, and the patents grant VALBIOTIS exclusive rights over the composition of the active substance for food and pharmaceutical applications. These patents are a key step in the ongoing development of TOTUM-070, the identification of commercial partners, and the approval of health claims in Europe and North America.

- **Start of the Phase II clinical trial HEART**

In October 2020, the Company initiated the launch of the Phase II clinical trial HEART. This multi-center, randomized, placebo-controlled, double-blind trial will include 120 subjects with untreated moderate hypercholesterolemia, with LDL-cholesterol levels ranging from 130 to 190 mg/dL. The participants will be divided into 2 equal arms of 60 subjects, who will receive TOTUM-070 or placebo for 6 months. The primary endpoint of the trial will be to reduce blood LDL-cholesterol levels. There are also several secondary endpoints of interest. The results are expected at the start of 2022.

Other highlights

- **A capital increase to strengthen VALBIOTIS' financial resources**

In addition to the CHF 8m received through the partnership with Nestlé Health Science to develop and market TOTUM-63, the Company has successfully increased its capital by securing a €2m private placement from AMIRAL GESTION (Press release of July 17, 2020). This placement was based on a share price of €4.50, representing a premium of 5.4% over the closing price on July 16, 2020. With the €2 million raised, the Company will have additional financial resources to support the development of the other active substances in its pipeline.

- **Inclusion in the EnterNext© PEA-SME 150 index**

With effect from the trading session of October 1, 2020, VALBIOTIS has joined the EnterNext© PEA-SME 150 index, a stock market index composed of French companies eligible for the PEA-SME equity savings plan. Broader than the CAC SME, the EnterNext© PEA-SME 150 is made up of 150 of the most liquid small and medium-sized shares.

A well-controlled financial situation, and financial resources allocated to implementing the R&D roadmap as a priority

The Company's 2020 financial statements, drawn up in accordance with IFRS, were approved by the Management Board on March 15, 2021. They were examined by the Statutory Auditor and are available on the VALBIOTIS website: www.valbiotis.com/en/investors.

Income statement - IFRS, in €K, as at 31 December	**2020**	**2019**
Operating income *including*	5,099	1,913
Turnover	*3,092*	*91*
Grants	*750*	*602*
Research Tax Credit	*1,257*	*1,219*
R&D expenditure	(5,411)	(3,974)
Sales and Marketing expenditure	(1,031)	(1,473)
Overhead expenditure	(1,387)	(1,343)
Operating profit for the period	**(3,407)**	**(5,157)**
Operating profit	(3,407)	(5,157)
Earnings before tax	(3,829)	(5,504)
Net profit	**(3,829)**	**(5,504)**

IFRS in €K	**2020**	**2019**
Cash flow from operating activities	2,693	(4,946)
Cash flow from investing activities	(332)	(290)
Cash flow from financing activities	4,191	5,850
Variation in cash	6,552	614
Cash at end of period	14,585	8,033

In 2020, VALBIOTIS generated a turnover of €3,092K, consisting mainly of the first milestone payment of CHF 3m (i.e. €2,821K) from Nestlé following the launch of the Phase II/III international clinical trial REVERSE-IT. This turnover also includes part of the initial payment of CHF 5m received by the Company in April 2020 and spread over the term of the licensing agreement (i.e. until October 2035). Of the CHF 5m paid upfront (i.e. €4,679K), only €271K have been recorded as turnover for the period.

In addition to turnover, operating income (€5,099K, up 166% compared to 2019) consists mainly of the Research Tax Credit received over the period (€1,257K) and grants (€750K), which were stable year on year.

Research and Development expenditure rose by 36% to €5,411K (compared to €3,974K in 2019). This fully expected increase reflects the continuation of preclinical research and the launch of two clinical trials during the year (final clinical development phase for TOTUM-63 in the REVERSE-IT trial, and the start of Phase II for TOTUM-070). Sales and marketing expenditure fell 30% to €1,031K (compared to €1,473K in 2019). This decline in business development expenditure is explained by the agreement of the strategic partnership with Nestlé Health Science. Lastly, overhead expenditure remained constant at €1,387K compared to €1,343K in 2019. In all, net loss over the period amounted to €3,829K.

Over the year, the cash flow from operating activities was positive at €2,693K (compared to (€ 4,946K) in 2019), due to the payments received under the agreement with Nestlé Health Science. The cash flow from investing activities was negative at €332K, due to the purchase of new state-of-the-art equipment for the R&D platform in Riom and the extension of international patents. The cash flow from financing activities was positive at €4,191K, due mainly to the €2 million capital increase from AMIRAL GESTION and a state-guaranteed loan totalling €3 million from Bpifrance, Société Générale and BNP Paribas.
As at December 31, 2020, VALBIOTIS had a cash position of €14,585K, up 81% versus the end of December 2019 (€8,033K).

At present, given:
- its available cash flow at December 31, 2020 (i.e. €14,585K),
- its operating expenditure related to its ongoing development plan,
- its current debt repayment schedule,

the Company is in a strong financial position, enabling it to meet its operational requirements until the end of the first half of 2022. This cash outlook does not take account of any further milestone payments from Nestlé Health Science, or any additional revenue from new strategic partners. It also excludes any unplanned expenditure arising from changes of direction in development programs.

Review of post-balance sheet events and outlook

Intensification of TOTUM-070 development efforts

Initiated in October 2020, the Phase II clinical trial HEART was officially launched in February 2021 with the first visit of the first patient (Press release of February 22, 2021).

At the same time, to improve and broaden its knowledge of TOTUM-070 and its effects on human lipid metabolism, VALBIOTIS decided to perform a complementary clinical trial with a small number of volunteers. The results are expected by the end of 2021.

Finally, a series of preclinical experiments will also be launched and completed in 2021. These studies should provide further details on the impact of TOTUM-070 on lipid metabolism in a predictive model of human pathophysiology. The results will be submitted to the American Heart Association (AHA) annual conference in November 2021.

Given the potential of TOTUM-070, several clinical and preclinical studies will be conducted concurrently alongside the HEART Phase II trial and should provide a large amount of data by early next year, thus confirming TOTUM-070 as a major breakthrough in cardiovascular disease prevention.

International recognition of TOTUM-854

In March 2021, VALBIOTIS announced that the preclinical results obtained with TOTUM-854 for arterial hypertension have been selected for presentation at the joint annual meeting of the European Society of Hypertension (ESH) and the International Society of Hypertension (ISH) (Press release of March 8, 2021). This meeting will take place in April 2021. TOTUM-854 will be the third active substance in VALBIOTIS' pipeline to enter the clinical development phase, in 2021.

Sébastien PELTIER
CEO, Chairman of the Board of Directors at VALBIOTIS

"In 2020 a global strategic partnership was agreed with Nestlé Health Science, illustrating the strength of our business model and the efficiency of our R&D platform, both of which have been set up in less than five years. This achievement is also a fitting reward for all the hard work done by our teams. The partnership guarantees that the final phases of development of our active substance TOTUM-63 will be completed, and the prospects for marketing it on a large scale are growing. But the adventure is far from over. Because we are in a stronger financial position, we are now ready to unlock the potential of the other active substances in our portfolio and bring them swiftly to market. This will be a key step towards fulfilling the mission that has driven our company from day one: to deliver solutions for the widespread prevention of cardiometabolic disease, which today affects the health and quality of life of millions of people worldwide."

VALBIOTIS' annual financial report as at December 31, 2020 has been published and filed with the AMF. This document is available on the website: www.valbiotis.com/en/investors

VALBIOTIS confirms that it meets the PEA-SME eligibility criteria set out in Article D.221-113-5 of implementing decree no. 2014-283 of March 4, 2014, namely:

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

Accordingly, VALBIOTIS' shares are still eligible for inclusion in PEA-SME accounts, which enjoy the same tax benefits as conventional equity savings plans (PEAs).

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 nutritional health solutions designed to reduce the risk of major metabolic diseases, based on a multi-target approach and made possible by the use of plant-based ingredients.

Its products are intended to be licensed to players in the health world.
VALBIOTIS was founded in La Rochelle in early 2014 and has formed numerous partnerships with top academic centers. The Company has established three sites in France – Périgny, La Rochelle (17) and Riom (63).

VALBIOTIS is a member of the "BPI Excellence" network and received the «Innovative Company» status accorded by BPI France. VALBIOTIS has also been awarded "Young Innovative Company" status and has received major financial support from the European Union for its research programs by obtaining support from the European Regional Development Fund (ERDF). VALBIOTIS is a PEA-SME eligible company.

Find out more about VALBIOTIS: www.valbiotis.com

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Le présent communiqué contient des déclarations prospectives sur les objectifs de VALBIOTIS. VALBIOTIS considère que ces projections reposent sur des informations actuellement disponibles par VALBIOTIS et sur des hypothèses raisonnables. Toutefois, celles-ci ne constituent en aucun cas des garanties d'une performance future et peuvent être remises en cause par l'évolution de la conjoncture économique, des marchés financiers et par un certain nombre de risques et d'incertitudes, dont ceux décrits dans le Document d'Enregistrement Universel de VALBIOTIS déposé auprès de l'Autorité des marchés financiers (AMF) le 31 juillet 2020 (numéro de dépôt R 20-018), ce document étant disponible sur le site internet de la Société (www.valbiotis.com).

Ce communiqué et les informations qu'il contient ne constituent ni une offre de vente ou de souscription, ni la sollicitation d'un ordre d'achat ou de souscription des actions ou de titres financiers de VALBIOTIS dans un quelconque pays.

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