

VALBIOTIS Provides 2018 Financial Results and Corporate Update

- All VALBIOTIS products have progressed to the clinical development stage
- €7.4M in liquid assets, as of December, 31 2018
- Results of Phase IIA VALEDIA study are expected in summer 2019
- Confirmation of marketing in 2021

La Rochelle, 8 March 2019 (5:40 CET) – **VALBIOTIS** (FR0013254851 - ALVAL / PEA/SME eligible), a French Research & Development company committed to scientific innovation for preventing and combating metabolic diseases, **today announced the results of the 2018 fiscal year and provided an update on its development program.**



“Sébastien Peltier, CEO of VALBIOTIS, commented, *“2018 was a very busy year. We made important progress with our pipeline products, strengthened our intellectual property rights, and launched our proprietary R&D platform. Our priority for 2019 is the continued development of our lead program, VALEDIA®. Clinical results from the Phase IIA program in prediabetes are expected in summer 2019, which will allow us to launch the product in 2021. 2019 will therefore be a critical year for VALBIOTIS.”*

Sébastien PELTIER
CEO of VALBIOTIS

2018 HIGHLIGHTS

Prediabetes - reduction in the risk of type 2 diabetes (TOTUM-63, the active ingredient of VALEDIA®).

Recruitment was completed in November 2018 for the European Phase IIA clinical study, evaluating the efficacy of VALEDIA® on three risk factors, recognized by the US FDA: fasting glycemia, post-prandial glycemia (glucose intolerance) and insulin resistance. The results of this randomized, multi-center, double-blind, placebo-controlled clinical study are expected in summer 2019.

- Preclinical proof of a significant effect on intestinal microbiota: VALEDIA® acts on microbiota imbalances associated with metabolic diseases.
- Acquisition of a strategic patent in the United States: direct coverage for TOTUM-63, the active ingredient of VALEDIA®, with the highest level of protection (composition, use, method).

NAFL (fatty liver) - reduction in the risk of NASH (TOTUM-63, the active ingredient of VALEDIA®).

- There is a new use for VALEDIA®, supported by preclinical results obtained as part of a scientific partnership with Leiden University (Netherlands).
- Results have demonstrated the complete reversion of fatty liver by the active ingredient, TOTUM-63, in an NAFLD *in vivo* model. *In vivo* studies have highlighted a mechanism of action of TOTUM-63 on 3 key cellular targets of the physiopathology of non-alcoholic fatty liver: Ppar β/δ and FXR transcription factors, and Fsp27 (a protein). The study detailed this mechanism of action for treating metabolic liver diseases, and was presented at the American Association for the Study of Liver Diseases (AASLD) Conference, held between November 9-13, 2018 in San Francisco. VALBIOTIS has also reported additional results of the Phase I/II clinical study conducted on healthy volunteers, demonstrating a potential effect of VALEDIA® on the level of triglycerides in the blood. Based on these results, VALBIOTIS will launch a Phase IIA clinical study in patients with NAFL (i.e. fatty liver), which is a risk condition for developing NASH. Ultimately, the aim is to obtain the first health claim in Europe and North America for reducing the risk of NASH.

Regulation of body fat mass - Overweight / Obesity (LpD64).

- Preclinical results have demonstrated a major effect of LpD64 on the intestinal microbiota and the regulation of body fat mass, confirming the benefits of LpD64 for overweight and/or obese patients.
- Clinical proof of its effect on energy metabolism and validation of its tolerance and safety in a Phase I/II study, conducted by the Clinical Investigation Center, CIC Inserm 1405, University Hospital Center in Clermont-Ferrand (France), under the direction of Prof. Gisèle Pickering, Doctor and Professor in Clinical Pharmacology.

Reduction in LDL-cholesterol - reduction in the risk of cardiovascular disease (TOTUM-07, the active ingredient of VAL-070).

The positive clinical results of the Phase I/II study confirm the benefits of VAL-070 for reducing LDL-cholesterol, and validate tolerability and safety. Following these results, VALBIOTIS will begin a Phase IIA clinical study in patients with mild to moderate hypercholesterolemia, with the ultimate aim of obtaining a health claim in Europe and North America for reducing LDL-cholesterol, a risk factor of cardiovascular disease.

CORPORATE DEVELOPMENTS

Completion of the R&D center, in Riom (63), a 1200 m² state-of-the-art infrastructure conforming to GLP standards (Good Laboratory Practices). On a site complying with pharmaceutical standards and previously operated by MSD, VALBIOTIS now has an innovative center which significantly increases its ability to complete the development of the current portfolio, including VALEDIA®, accelerate the pace of innovations, as well as identify new products.

Ongoing recruitment activities to support the implementation of its marketing plan. The Company increased its workforce from 20 employees in December 2017 to 38 employees as of December 31, 2018, of which 75% work in R&D.

Escalation of VALBIOTIS' participation in major international conferences for cardio-metabolic diseases and investors. Over the course of 2018, there are almost 10 key events, during which VALBIOTIS has had the opportunity to present clinical progress.

VALBIOTIS US Strategy:

- Opened corporate office in FrenchTech in Boston, Massachusetts to strengthen clinical and corporate relationships in the US.
- Developing relationships with American investors, through the signing of a contract with the firm Solebury Trout, a biotechnology company specialist in the United States.

2018 FINANCIAL INFORMATION

Financial resources were predominantly affected by work done by Research and Development.

The 2018 IFRS financial statements were prepared on a going-concern basis by the Board of Directors on 7 March 2019. They were examined by Auditors and are available on the VALBIOTIS website: www.valbiotis.com.

Financial results, as of 31 December 2018

IFRS in €K, as of 31 December	2018	2017
Operating income, <i>including</i>	1 509	782
<i>Grants</i>	46	291
<i>Research Tax Credit</i>	1 183	474
R&D expenses	-3 826	-1 653
Sales and marketing expenses	-1 059	-533
Overhead costs	-1 284	-995
Operating profit for the period	-4 876	-2 379
Operating profit	-4 876	-2 379
Earnings before tax and interest	-4 967	-2 443
Net profit	-4 967	-2 443

IFRS in €K	2018	2017
Cash flow generated by activities	- 4 546	-2 172
Cash flow from investment activities	-723	-844
Cash flow from financing activities	2 090	13 087
Variation in cash	-3 179	10 071
Cash at end of period	7 419	10 599

During the 2018 fiscal year, the operating income increased to €1,509, a growth of 93% in comparison with 2017. It is largely constituted of Research Tax Credit (€1,183K), demonstrating the escalation of R&D efforts. VALBIOTIS is now focused on developing its products: there was no significant turnover during the 2018 fiscal year, as set out in our strategic plan.

As expected, Research and Development expenses increased significantly, rising from €1,653K in 2017 to €3,826K in 2018, as a result of preclinical and clinical research ramping up and new employees being recruited. Commercial and overhead costs increased to €980K, which includes, in particular, the strengthening of the Research and Development "support" teams, marketing and communication expenses related to the development of VALEDIA®, and the expenses associated with the company's public status. Overall, the net loss was €4,967K.

The net cash flow generated by operating activities came to €4,546K for the fiscal year, and the cash flow from investments amounted to a negative total of €723K (linked mainly to the construction of the technical platform in Riom, and the purchase of state-of-the-art technical equipment for this platform). The cash flow from financing activities was positive, totaling €2,090K. This is mainly linked to the private placement carried out by the Company in October 2018, resulting in a net income of €2,074K.

As of 31 December 2018, liquid assets are valued at €7.4M, compared to €10.6M on 31 December 2017.

To date, in view of:

- Its available liquid assets as of 31 December 2018, valued at €7,419K;
- Its operating expenses associated with its ongoing development plan;
- The repayment schedule for its current financial debt;
- The receipt of more than €330K in the form of grants during the 1st half of 2019;
- The receipt of the 2018 RTC, totaling €1,183;

The Company believes that it can meet its operational requirements for 2019, whilst remaining attentive to market conditions and potential opportunities.

2019 UPDATES

Since the start of the 2019 fiscal year, VALBIOTIS has already made some important announcements:

- The appointment of Josep INFESTA as Head of Global Business Development*. Doctor and former vice president at Sanofi, Johnson & Johnson and Pfizer, with 25 years of experience in international Marketing, Strategy and Business Development; Josep INFESTA's main priority is seeking partnerships for the launch of VALEDIA® in Europe and North America.
- The partnership established with AEC Partners, a firm specializing in life sciences, licensing and strategic consulting for access to the market.
- The consolidation of the Board of Directors with the appointment of Murielle CAZAUBIEL, Director of Development and Medical Affairs for VALBIOTIS. After managing a team responsible for creating and developing clinical study management at Nantes University Hospital, in 2002, Murielle CAZAUBIEL created BIOFORTIS, a CRO (Contract Research Organization) which is now a leader in contract clinical research. Murielle CAZAUBIEL's contribution will be essential in ensuring VALBIOTIS's future growth trajectory on an international scale.

*External consultant IZ3 Consulting

- The acquisition of a European patent for TOTUM-63, which covers the use of the active ingredient of VALEDIA® in 38 European countries on the prediabetes and metabolic diseases market.
- Financing agreement, in the form of a grant totaling €350K, from Bpifrance and the Auvergne-Rhône-Alpes region.

VALBIOTIS' annual financial report (31 December 2018) was made available to the public and filed with the AMF. This document is available on our website: valbiotis.com (within the "investors" section).

VALBIOTIS confirms that it complies with the PEA/SME eligibility criteria, as specified in article D.221-113-5 of Enforcement Decree n°2014-283 of 4 March 2014, namely:

- A total workforce of less than 5,000 employees;
- A turnover of less than 1.5 billion euros, or total assets of less than 2 billion euros.

As such, VALBIOTIS' shares continue to be included in PEA/SME accounts, which benefit from the same tax advantages as the traditional French share savings plan (PEA).

ABOUT VALBIOTIS

VALBIOTIS is a French Research & Development company committed to scientific innovation for preventing and combating metabolic diseases. Its products are made for major players in the healthcare sector. VALBIOTIS particularly focuses on solutions to prevent type 2 diabetes, NASH (nonalcoholic steatohepatitis), obesity and cardiovascular diseases. VALBIOTIS was founded in La Rochelle in early 2014 and has formed numerous partnerships with top academic centers in France and abroad, including the La Rochelle University, the CNRS and the Clermont Auvergne University located in Clermont-Ferrand. These partnerships have enabled VALBIOTIS to benefit from strong financial leverage, particularly thanks to experts and technical partners who support its projects. The company is located at 3 sites in France - Périgny, La Rochelle (17) and Riom (63) - in addition to an american office in Boston (MA).

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 PEA/SME eligible.

Find out more about VALBIOTIS:

www.valbiotis.com



Name: VALBIOTIS - ISIN Code: FR0013254851 - Mnemonic code: ALVAL



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Disclaimer

This press release contains forward-looking statements concerning the objectives of VALBIOTIS. VALBIOTIS considers that these projections are based on information currently available by VALBIOTIS and on reasonable assumptions.

However, there can be no assurance that the estimates contained in such forward-looking statements will be verified, which estimates are subject to numerous risks including the risks set forth in the reference document of VALBIOTIS filed with the French Financial Markets Authority (Autorité des Marchés Financiers) under number I.17-012 on April 5, 2017 as well as in its 2018 annual financial report filed with the French Financial Markets Authority on March 8, 2019. These documents are available on the Company's website (www.valbiotis.com).

VALBIOTIS declines all responsibility for updating or revising these forward-looking statements. This press release and the information that it contains do not constitute an offer to sell or subscribe for, or a solicitation of an offer to purchase or subscribe for, VALBIOTIS shares in any country.

