

## ANNUAL RESULTS - 2017

2017: a decisive, foundational year

A solid cash position that ensures the continuity of operations

2018: major clinical milestones in product portfolio development, including results from the international and multicentric Phase IIA clinical trial with VALEDIA®

### Sébastien PELTIER

«We reached all of our objectives for 2017: we have taken decisive steps in the development of our product portfolio, and our financial resources have been strengthened following the Initial Public Offering. According to our strategic plan, these achievements enable us to confidently rise to the challenges heading into 2018. The new year has started on a very positive note, with promising announcements with regard to advancing our research and enhancing our organization, with the arrival of new expert employees.»



CEO of  
VALBIOTIS

### AN ENHANCED ORGANIZATION, FOR THE PROPER IMPLEMENTATION OF THE STRATEGIC PLAN

VALBIOTIS also focused on building up its teams. The Company went from having 8 employees at the end of 2016 to over 20 at the end of December 2017. This important move impacted the Research & Development teams especially, which account for 80% of the new hires.

La Rochelle, 3 April 2018 (7:00 pm CET) – VALBIOTIS (FR0013254851 - ALVAL / PEA/SME eligible), a French Research & Development company committed to scientific innovation for preventing and fighting against metabolic diseases, announces its consolidated results for 2017 and presents a progress report on its development program.

## 2017 STAND-OUT ACHIEVEMENTS

Thanks to an innovative, specific and rigorous development methodology, VALBIOTIS's portfolio already features five products with great potential proven in preclinical studies. These products are, or will soon be, in clinical phase.

VALEDIA® is designed to reduce the risk factors for type 2 diabetes and is the most advanced product in the VALBIOTIS portfolio. In June 2017, its main active ingredient, TOTUM-63 confirmed its potential through a Phase I/II trial in healthy volunteers, with positive results in terms of safety and efficacy. The international Phase IIA trial currently ongoing aims to verify these results on a larger scale, in prediabetic patients. The feasibility studies on the two complementary Phase II clinical trials, REVERSE-IT (Phase IIB 1) and PREVENT-IT (Phase IIB 2), were wrapped up in the first semester of 2017. The REVERSE-IT trial will be conducted in the company's top three target markets: the United States, Canada and Europe. Authorization from French health authorities was obtained in November 2017.

Regarding LpD64 and its potential in the fight against obesity, the Company released the preclinical results in October 2017. They revealed the active ingredient's potential for limiting fat mass gain and reducing insulin resistance. In the same publication, the Company also announced the recruitment completion for the ongoing Phase I/II clinical study in obese subjects.

Finally, VAL-63-NAFLD showed promising preclinical results in terms of reducing a risk factor for developing NASH (non-alcoholic steatohepatitis). The December 2017 publication indicates a very significant reduction in non-alcoholic hepatic steatosis (NAFL), a risk factor for developing NASH. The product is ready to move directly into Phase IIA clinical trials on its target population.

## 2018 NEXT CLINICAL STEPS

> VALEDIA®: Results of the international and multicentric Phase IIA clinical trial in prediabetics, a randomized, placebo-controlled and double-blind study, expected in the fourth quarter of 2018

> LpD64: Results of the monocentric and open-label Phase I/II clinical trial in obese subjects, expected in the third quarter of 2018

> VAL-070: Results of the monocentric Phase I/II clinical trial in subjects with moderate hypercholesterolemia and moderate hypertriglyceridemia, a randomized placebo-controlled and double-blind study, expected in the second quarter of 2018

## INCREASED INTERNATIONAL VISIBILITY

Finally, the year 2017 also provided opportunities for VALBIOTIS to expand its international reach by actively participating in key international scientific events, where the Company was able to promote its innovative approach and achievements. In the last few months of the year, the Company presented at three particularly major events:

- Cell Symposium: Metabolic Disease Therapies (San Diego, October 2017)
- Journées Francophones de Nutrition 2017 (JFN, Nantes, December 2017)
- International Diabetes Federation Annual Congress (UAE, Abu Dhabi, December 2017)

## FINANCIAL INFORMATION

Solid financial standing in order to fund Research & Development programs.

<b>IFRS <sup>(1)</sup> in €K, as at 31 December</b>	<b>2017</b>	<b>2016</b>
<b>Operational outputs, including</b>	<b>782</b>	<b>646</b>
<i>Grants</i>	291	303
<i>Research tax credit</i>	474	338
<b>R&amp;D expenses</b>	<b>-1653</b>	<b>-788</b>
<b>Sales and marketing expenses</b>	<b>-533</b>	<b>-183</b>
<b>General expenses</b>	<b>-995</b>	<b>-252</b>
<b>Current operating income</b>	<b>-2379</b>	<b>-572</b>
<b>Operating income</b>	<b>-2379</b>	<b>-572</b>
<b>Current gross income</b>	<b>-2443</b>	<b>-593</b>
<b>Net income</b>	<b>-2443</b>	<b>-593</b>

<b>IFRS <sup>(1)</sup> in €K</b>	<b>2017</b>	<b>2016</b>
<b>Cash flow generated by activity</b>	<b>-2172</b>	<b>-858</b>
<b>Cash flow linked to investment operations</b>	<b>-844</b>	<b>-117</b>
<b>Cash flow linked to financing operations</b>	<b>13087</b>	<b>910</b>
<b>Net cash flow</b>	<b>10071</b>	<b>-64</b>
<b>Cash flow</b>	<b>10599</b>	<b>528</b>

(1) The 2017 IFRS financial statements were approved by the Board of Directors on 28 March 2018 as per the going concern principle. They were examined by registered auditors and are available on the VALBIOTIS website [www. VALBIOTIS.com](http://www.VALBIOTIS.com)

Over the fiscal year 2017, the operational outputs are mainly comprised of the research tax credit (€474 k) and grants (€291 k). Today, VALBIOTIS's activity centers around product development: no significant turnover was generated in 2017, in line with its strategic plan.

R&D expenses, representing nearly 52% of the Company's operational expenses, increased by €865 k. This raise reflects the ramping up of development for the various product lines and the recruitment of 10 additional employees assigned to preclinical research, clinical development and intellectual property management.

General and marketing expenses increased to €1,528 k by 31 December 2017 (compared to €435 k on 31 December 2016). These expenses mostly entail the expansion of staff dedicated

to support functions, assisting the Research & Development teams (€818 k of personnel costs in 2017, including the corporate officers' fees, versus €201 k in 2016,) to meet the Company's development demands and its new listed status. They also include the calculation of the different types of share purchase warrants for a global amount of €164 k and the forecasted retirement benefits up to €21 k. The total net loss comes to €2,443 k.

The amount of cash flow used for operational activities reached €2,172 k over the year, and investment cash flow closed at a negative figure, -€844 k. This investment flow included the costs of patent filings and extensions as well as the set-up of the new headquarters and the Riom technical platform, which will be up and running in the first half of 2018.

Resources generated by financial activities equal nearly €13 M, taking into account mainly:

Net output of the June 2017 capital increase in the context of the initial public offering on Euronext Growth (which reached €11.7 M following the implementation of an over-allotment option).

The conversion of convertible bonds during the initial public offering in the amount of €1.5 M.

By 31 December 2017, cash flow had increased to nearly €10.6 M compared to €528 k at year end 2016.

In November 2017, VALBIOTIS also announced funding support of up to €1 M from public institutional partners, specifically:

A €350 k grant from the Nouvelle-Aquitaine region to be claimed in 2018

An interest-free loan from BPIFrance of €250 k, in addition to a first interest-free loan of € 350 k granted in May 2017

An EIF investment start-up loan from BPIFrance of €350 k

A reimbursable €100 k advance from the Puy-de-Dôme Renewal Mutual Fund

Since closing the year end 2017, the Company collected the first €175 k installment of the €350 k grant provided by the Nouvelle-Aquitaine Regional Council.

VALBIOTIS is supported by a solid financial foundation which provides the necessary peace of mind to pursue its development plan.

## 2018 AN EXCELLENT START TO THE NEW YEAR

The year 2018 has already kicked off with some major progress in the product portfolio.

### PROVEN SIGNIFICANT EFFECTS ON THE INTESTINAL MICROBIOTA: A NEW ADVANTAGE ON THE PREVENTION MARKET

**JANUARY 2018** VALBIOTIS announced significant preclinical results for VALEDIA®, demonstrating its effects on the intestinal microbiota. In addition to the evidence for the product's efficacy already obtained in humans, these new data reinforce the value of VALEDIA® regarding the reduction of the risk factors for the development of type 2 diabetes.

**FEBRUARY 2018** The Company also announced positive preclinical results for LpD64 on the intestinal microbiota, showing a positive specific effect on populations of microorganisms involved in the development of obesity.

These results add value to VALBIOTIS's portfolio, from a scientific as well as a marketing perspective.

### TOTUM-63 U.S. PATENT OBTAINED: RECOGNITION OF VALBIOTIS'S INNOVATIVE APPROACH AND PROMISING PRODUCTS

**MARCH 2018** The Company also announced it had obtained a strategic patent to protect the main active ingredient TOTUM-63. This patent covers three products in the VALBIOTIS portfolio in the U.S., at the highest level of protection (composition, use, method): VALEDIA®, VAL-63-NAFLD and VAL-630.

Having obtained a French patent in 2016, this U.S. patent serves to reaffirm VALBIOTIS's innovative potential and strengthens its industrial property.

### CONTINUED ACTIVE DEVELOPMENT ON OTHER PRODUCT LINES

**FEBRUARY 2018** VALBIOTIS announced that the recruitment of volunteers was completed for the Phase I/II clinical study on VAL-070, which aims to reduce lipid abnormalities, also known as dyslipidemia. The efficacy and safety results of this randomized, placebo-controlled and double-blind clinical trial led in subjects with moderate hypercholesterolemia and hypertriglyceridemia are expected for mid 2018.

## INTERNALIZATION OF THE TECHNICAL PLATFORM CONFIRMED FOR THE FIRST HALF OF THE YEAR

To accompany the upswing in its R&D programs, VALBIOTIS has confirmed the internalization of its technical platform, dedicated to Discovery and preclinical research activities, for the first half of 2018. The Company will build a high-tech facility of nearly 900 m<sup>2</sup> in Riom (Puy-de-Dôme). A 300 m<sup>2</sup> area will be connected to this platform, allowing data analysis, follow-up of the experiments and quality management processes according to Good Laboratory Practice (GLP).

## CLINICAL RESULTS: IMPORTANT MILESTONES AHEAD

Three key clinical results are anticipated by the end of the year, perfectly in line with the strategic plan:

- VALEDIA®: clinical results of the international Phase IIA trial in the fourth quarter of 2018,
- LpD64: clinical results of the Phase I/II trial in the third quarter of 2018,
- VAL-070: clinical results of the Phase I/II trial in the second quarter of 2018.

In light of these favorable prospects, VALBIOTIS confirms its clinical development schedule for its most advanced product, VALEDIA®, as well as for its entire product portfolio.

VALBIOTIS's annual financial report was made public and was submitted to the AMF on 31 December 2017. The document is available on the VALBIOTIS website: [VALBIOTIS.com](http://VALBIOTIS.com) (investors page).

VALBIOTIS has confirmed that it meets the PEA-SME eligibility criteria set out by section D.221-113-5 of implementing decree No. 2014-283 of 4 March 2014, namely:

- A total staff of less than 5,000 employees;
- A turnover of less than 1.5 billion euros, or a total balance of under 2 billion euros.

As a result, the activities of VALBIOTIS continue to be incorporated into the PEA-SME accounts which benefit from the same financial benefits as the traditional share savings plan (PEA).

## ABOUT VALBIOTIS

VALBIOTIS is a French Research & Development company committed to scientific innovation for preventing and fighting against metabolic diseases. Its products are made for manufacturers in the agri-food and pharmaceutical industries. 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, where the company opened a second office. These agreements enable it to benefit from a considerable leverage effect since it was set up thanks, in particular, to the experts and technical partners mobilized for these projects. 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).

Find out more about VALBIOTIS:

<http://valbiotis.com>



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