

## FIRST HALF OF 2017

**The initial public offering at the beginning of June successfully raised  
€11.7 M after exercising the overallotment option**

**Major progress in clinical studies and growth of the organization**

## OBJECTIVE CONFIRMED

**Valedia® to be marketed by 2020**



La Rochelle, September 29, 2017 (7:30 CEST) - VALBIOTIS (FR0013254851 - ALVAL / PEA/SME eligible), a company that specializes in developing innovative nutrition solutions designed to prevent cardiometabolic diseases and provide nutritional support for patients, today announced its consolidated results for the first half of 2017.

Sébastien PELTIER, CEO of VALBIOTIS spoke about business over the period:

*"2017 is a transitional year for the company during which we have made major progress with our roadmap. Five products are currently maturing along our pipeline and we have intensified our research efforts with the aim of marketing the products by 2020. From a financial perspective, the success of our initial public offering provided us with the means not only to accelerate our development but also to heighten our visibility with world leaders in nutrition and pharmacy. In addition, we have made the most of the past few months to expand our organization and thus increase our development potential. All this progress is perfectly in line with our strategy."*

### MAJOR EVENTS

#### Continuation of the clinical studies in humans

The Phase IIa clinical trial on Totum-63, active principle of Valedia®, flagship solution designed to reduce a risk factor for developing type 2 diabetes, was launched at the end of 2016 and the recruitment of volunteers continued in the first half of 2017. The clinical trial underway seeks to demonstrate the efficacy of the active ingredient, Totum-63, on 80 prediabetics with abdominal obesity and moderate untreated hypertriglyceridemia. This randomized, multicenter, double-blind, placebo-controlled study will objectify the effects of 6 months of Totum-63 supplementation on different parameters of carbohydrate and lipid metabolism. The results should be available in the second half of 2018.

The company has also completed the feasibility studies, thus making it possible to launch the two other international clinical trials (REVERSE-IT (Phase IIb1) and PREVENT-IT) required for submitting health claim applications in Europe and North America. The international trial REVERSE-IT, along with the Phase IIa trial, will enable the optimal daily dose to be determined. The authorization applications have been submitted to the French authorities. Authorization applications will then be initiated in the United States and Canada. The international clinical trial PREVENT-IT, similar to REVERSE-IT, will also enable the optimal dose to be confirmed.

These results will provide key data for the health claim applications to be submitted to the European and North American regulatory authorities. Obtaining these claims will be the ultimate step before marketing the product by 2020 through a license agreement with a food or pharmaceutical company.

As a reminder, Phase III trials are not required to obtain "health supplement" claims, contrary to drugs, and marketing this claim can, therefore, be rapidly envisaged.

Over the past few months, VALBIOTIS has also been working hard on its other product lines.

Following the launch of the Phase I/II clinical trial on Lipidrive® (health supplement for regulating weight gain to curb obesity and/or overweight) in September 2016, the recruitment of volunteers continued during the first half of the year. The recruitment of volunteers also began for VAL-070, a health supplement for decreasing LDL cholesterol, the rise of which is a risk factor for cardiovascular disease.

## **Greater visibility at major international events**

Our continuing research efforts have been combined with a greater presence at major international events dedicated to cardiometabolic diseases, including diabetes.

Since the initial public offering in June 2017, VALBIOTIS has participated in four major events:

- Scientific sessions of the *American Diabetes Association* (ADA, San Diego, June 2017);
- BIO International Convention (San Diego, June 2017);
- Nutriform' Business Days (Saint Raphaël, September 2017);
- Annual meeting of the European Association for the Study of Diabetes (EASD, Lisbon, September 2017).

These events provided VALBIOTIS with the opportunity to share its scientific and clinical progress with the main players in diabetes and nutrition: scientific experts, representatives of regulatory authorities, academics, etc. VALBIOTIS was notably chosen to present an overview of the results of its Phase I/II clinical study on Totum-63, the active ingredient of Valedia®, at the 77<sup>th</sup> scientific sessions of the *American Diabetes Association*.

These events also allowed us to pursue discussions and establish new contacts with potential customers in the food and pharmaceutical industry.

Finally, during the first half of the year, VALBIOTIS initiated the recruitments necessary for the execution of its ambitious roadmap. These recruitments are not included in the

workforce for the first half of the year (10 employees at the end of June 2017 compared to 6 at the end of June 2016) but will come into their own by the end of the year.

## FINANCIAL INFORMATION

### €12.5 M raised to accelerate research and prepare future commercial deployments

IFRS in K€ <sup>(1)</sup> , on 30 June	First half of 2017	First half of 2016
<b>Operating revenue</b>	448	341
of which		
Subsidies	104	172
Research tax credit	303	169
R&D expenses	(331)	(319)
G&A and commercial costs	(452)	(202)
<b>Recurring operating profit/loss</b>	<b>(335)</b>	<b>(181)</b>
<b>Operating profit/loss</b>	<b>(335)</b>	<b>(181)</b>
<b>Pre-tax profit/loss</b>	<b>(372)</b>	<b>(196)</b>
<b>Net result</b>	<b>(367)</b>	<b>(194)</b>
<b>IFRS in K€ <sup>(1)</sup></b>		
	<b>First half of 2017</b>	<b>2016</b>
Cash flow generated by the activity	(332)	(858)
Cash flow linked to investment operations	(158)	(117)
Cash flow linked to financial operations	12 463	910
<b>Net cash flow</b>	<b>11 973</b>	<b>(64)</b>
<b>Treasury</b>	<b>12 501</b>	<b>529</b>

<sup>(1)</sup> The accounts were closed by the Board of Directors on September 28, 2017. The auditors carried out a limited review of the accounts which are available on the VALBIOTIS website: [www.valbiotis.com](http://www.valbiotis.com)

For the first half of 2017, the operating revenue relates mainly to research tax credits (€303 K) and subsidies (€104 K). The increase in research and development expenditure remains moderate at €331 K compared to €319 K in the first half of 2016.

Commercial costs and general & administrative costs have increased by €250 K, in particular as a result of the new recruitments and expenditure linked to the initial public offering. In total, recurring operating losses amount to €335 K. The net loss is €367 K.

The cash flow needs generated by the activity amount to €332 K for the first half of the year. The flows linked to investments, associated primarily with the market maker agreement implemented with the shares, are negative at €158 K. The revenue generated by the

financial operations amount to nearly €12.5 M, including the net product of the capital increase in June 2017 within the framework of the initial public offering on Euronext Growth (reaching €11.7 M net after exercising the overallotment option).

Thanks to the success of this operation, VALBIOTIS is in a strong financial position and can thus pursue its strategy with serenity. For the period ending June 30, 2017, the equity amounts to nearly €12.1 M compared to €369 K at the end of December 2016, and the cash flow stands at €12.5 M compared to €529 K at the end of December 2016.

## PROSPECTS

**Several clinical milestones in sight.**

**New stages to be conquered regarding recruitments and the internalization of the technical platform.**

During the second half of the year, VALBIOTIS will pursue its clinical and preclinical programs concentrating its human and financial efforts on the development of Valedia<sup>®</sup>, the recruitment of new employees and the internalization of its technical platform.

In the field of research, VALBIOTIS plans to reach several clinical milestones:

- The acceleration of recruitments for the Phase IIa clinical trial conducted on the active ingredient of Valedia<sup>®</sup>. In this respect, a second clinical investigation center was opened in September at the Pasteur Institute in Lille. This new center also marks the association of the company with a new Center of Excellence that brings together multidisciplinary and transversal expertise, particularly in relation to metabolic diseases, diabetes and obesity;
- The authorizations issued by the competent authorities in France to start the Phase IIb1 clinical trial (REVERSE-IT) on the active ingredient of Valedia<sup>®</sup>;
- The finalization of the recruitments for the Phase I/II clinical trials conducted on Lipidrive<sup>®</sup> and VAL-070.

Over the next few months, we will also continue to expand our teams. By the end of the 2017 financial year, VALBIOTIS will employ nearly 30 people.

Pascal SIRVENT joined VALBIOTIS in September 2017 as Director of Discovery and Preclinical and Translational Research. As a member of the Scientific Committee and manager of collaborative projects between Clermont Auvergne University and VALBIOTIS, Pascal SIRVENT has been participating in the development of the company for several years. He has solid expertise in preclinical research and has nearly 30 papers in international scientific journals and numerous presentations at international conferences to his credit. He will ensure the continuity of the company's Research & Development and reinforce the expertise of VALBIOTIS in discussions with the food and pharmaceutical industry.

VALBIOTIS has also decided to expand its Supervisory Board with the appointment of Dr. Jean ZETLAOUI <sup>(1)</sup>. Jean ZETLAOUI has over 25 years' experience in various managerial posts abroad (NOVARTIS, Nestlé Health Science, SANOFI...). He is also Vice-President of the

Alliance for Research and Innovation in Health Industries (ARIIS) and chairman of the working group on the attractiveness of France for clinical research headed by Leem, an association of French pharmaceutical companies. Dr. ZETLAOUI brings his advanced knowledge of the pharmaceutical and nutrition sectors, of their environments and their challenges. VALBIOTIS works with major pharmaceutical and nutrition corporations and the arrival of Dr. ZETLAOUI further reinforces this unique high-added-value positioning.

With work starting on the development project, the next few months will be dedicated to internalizing the technical platform (animal house/cell culture/biochemistry). The facility should be operational by the beginning of 2018.

In the light of these elements, VALBIOTIS is confident about the execution of its strategy and roadmap presented within the framework of its initial public offering.

The VALBIOTIS half-year financial report ending June 30, 2017, has been filed with the AMF and is available to the public on the Valbiotis website: [valbiotis.com](http://valbiotis.com) (investors section).

- (1) The appointment of Dr. Jean ZETLAOUI will be proposed at the Shareholders' Meeting: 26 October 2017, Cabinet Granrut, law firm, sis 91 rue du Faubourg Saint-Honoré - 75008 Paris, sixth floor.

## ABOUT VALBIOTIS

VALBIOTIS specializes in developing innovative nutrition solutions designed to prevent cardiometabolic diseases and provide nutritional support for patients. Its products are made for manufacturers in the agro-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 partnerships have enabled Valbiotis to benefit from strong financial leverage, particularly thanks to experts and technical partners who support its 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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