

## **VALBIOTIS publishes its 2020 half-year results and provides an update on its global strategic partnership with Nestlé Health Science, its strong financial visibility and the promising advances in its pipeline**

### **TOTUM-63, prediabetes:**

- Signature of a global strategic partnership with Nestlé Health Science;
  - Launch of REVERSE-IT, the last phase of clinical development, and inclusion of the first patient;
  - Cumulative payments since the signature of the partnership: CHF 8M.
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### **TOTUM-070, reduction of LDL hypercholesterolemia ("*bad cholesterol*"):**

- Launch of the Phase II clinical study in the second half of 2020;
  - American and European patent obtained.
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### **TOTUM-854, blood pressure reduction, and TOTUM-448, liver steatosis reduction:**

- Clinical development program currently being designed.
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### **A solid financial position:**

- A cash position of €10.9M at June 30, 2020, not including the financing obtained since this date, i.e. nearly €8M (CHF 3M milestone payment from Nestlé Health Science, €3M from the French State-guaranteed loan (PGE) and the proceeds of the capital increase carried out with AMIRAL GESTION for an amount of €2M) providing financial visibility until S1 2022, not including potential additional revenue.
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**La Rochelle, September 30, 2020** (5:40 pm CEST) **VALBIOTIS** (FR0013254851 - ALVAL, eligible for the PEA/SME), a Research & Development company committed to scientific innovation for preventing and combating metabolic diseases, **announces its results for the first half of 2020 and provides an update on developments since the beginning of the year.**



**Sébastien PELTIER**  
CEO of VALBIOTIS

*"Events in the first half of 2020 have transformed our outlook and helped further boost our international recognition. With the signature of the development and marketing partnership for TOTUM-63 and the launch of the final clinical phase for this Nutrition Healthcare product, entirely financed by Nestlé Health Science, we have demonstrated the soundness of our development model. We are now moving confidently towards marketing and claim submission for TOTUM-63 and, thanks to a solid financial position, we are also working to apply this same model to the rest of our Nutrition Healthcare portfolio. At the head of the pipeline is TOTUM-070, which has just obtained U.S. and European patents, required to establish a commercial partnership in the future. We still have work to do with this product and our other ongoing developments, but the road ahead is now clear!"*

Key achievements since the beginning of 2020

### **TOTUM-63, prediabetes**

- **Signature of a global strategic partnership with Nestlé Health Science**

At the beginning of fiscal year 2020, VALBIOTIS announced the signature of a global strategic partnership with Nestlé Health Science for the development and marketing of TOTUM-63, a plant-based active substance clinically proven to have metabolic benefits in prediabetics just six months earlier ([press release of February 5, 2020](#)).

This strategic partnership guarantees the financing of TOTUM-63's late-stage clinical development until the health claims are obtained from the American and European authorities. In addition to milestone payments and royalties expected from marketing, this agreement also includes an additional source of revenue: the supply of TOTUM-63 by VALBIOTIS to Nestlé Health Science.

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

Following the conclusion of this agreement and with the favorable opinion of the CPP (French Committee for the Protection of Persons) and the authorization of the ANSM (French National Agency for the Safety of Medicines and Health Products), VALBIOTIS announced the launch of REVERSE-IT, the last phase of clinical development for TOTUM-63 ([press release of July 8, 2020](#)).

REVERSE-IT, fully funded by Nestlé Health Science, will include 600 people recruited in more than 30 international clinical centers. The main objective of the study is to confirm the positive Phase II results already obtained with TOTUM-63 on fasting blood glucose, a risk factor for type 2 diabetes.

The COVID-19 public health and economic crisis has not impacted VALBIOTIS' business plan, which had anticipated the production of clinical batches for REVERSE-IT.

As a result, the first visit of the first patient in the REVERSE-IT clinical study was carried out as announced in mid-2020 ([press release of July 15, 2020](#)). The results of this study are expected in the first half of 2022 and will allow, in the event of positive results, the filing of a health claim application with the American and European authorities.

- **Cumulative payments since the signature of the partnership: CHF 8M**

With this major agreement, in April VALBIOTIS received a first payment (upfront) from Nestlé Health Science for an amount of CHF 5M. The partnership also includes milestone payments (up to CHF 66M), such as the CHF 3M payment validated by Nestlé Health Science for the inclusion of the first patient in July, received in September 2020.

As a reminder, TOTUM-63 may be marketed before health claims are obtained. The negotiated agreement also includes progressive royalties on net sales.

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

- **Launch of the Phase II clinical study in the second half of 2020**

On the strength of this major success, VALBIOTIS confirmed the continuation of its well-established development strategy. As a consequence, the Company announced the development of three innovative Nutrition Healthcare active substances from its proprietary R&D platform, also targeting the early stages of chronic metabolic and cardiovascular diseases with unmet medical needs.

The first active substance being developed is TOTUM-070 for the reduction of blood LDL cholesterol levels, a risk factor for cardiovascular disease ([press release of April 16, 2020](#)). A Phase II clinical study is planned to start in the second half of 2020 and will evaluate the effect of TOTUM-070 on the reduction of LDL-cholesterol in individuals with mild to moderate hypercholesterolemia. The results of this study are expected by the end of fiscal year 2021/early 2022. This research program is supported by a €500K grant awarded by the European Regional Development Fund (ERDF) of the Nouvelle Aquitaine region.

VALBIOTIS plans to obtain, notably in Europe and North America, the first proprietary health claim relating to the reduction of LDL cholesterol, a risk factor for cardiovascular disease, for a product containing neither phytosterols nor red rice yeast.

- **Obtaining an American and European patent**

VALBIOTIS has taken a key step in the development of its active substance TOTUM-070 with the granting of its US and European patent ([press release of September 14, 2020](#)). This protects the composition of TOTUM-070 for food and pharmaceutical applications in strategic international markets.

It is estimated that in 2020, more than 174 million adults in the United States and Europe will be living with hypercholesterolemia, and the market for non-prescription products is estimated at €1.2 billion in these regions<sup>1</sup>.

<sup>1</sup>AEC Partners data for the United States and VALBIOTIS' 5 priority European countries (Germany, Spain, France, Italy and the United Kingdom), 2020.

## **TOTUM-854, blood pressure reduction, and TOTUM-448, liver steatosis reduction: clinical development programs in progress**

In line with its roadmap, VALBIOTIS has also made progress on two other Nutrition Healthcare development programs ([press release of April 16, 2020](#)). These two active substances are now ready to enter Phase II of clinical development with:

- The initiation of a Phase II clinical study in the first quarter of 2021 evaluating the effect of TOTUM-854 on the reduction of blood pressure, a risk factor for cardiovascular disease, in patients with mild to moderate hypertension, and;
- The launch of a Phase II clinical study in the second half of 2021 evaluating the effect of TOTUM-448 on the reduction of liver steatosis, a condition that increases the risk of developing NASH, in patients with non-alcoholic fatty liver (NAFL).

## **Major scientific recognition**

During fiscal year 2020, VALBIOTIS has intensified its scientific promotion strategy for its clinical results.

VALBIOTIS was selected by the American Diabetes Association (ADA) to present Phase II clinical results for TOTUM-63 demonstrating the metabolic benefits of its Nutrition Healthcare active substance in prediabetic subjects ([press release of June 12, 2020](#)). This fourth publication at the world's largest diabetes congress is a sign of strong recognition by the scientific community.

A few months later, VALBIOTIS was selected for the third consecutive year by the European Association for the Study of Diabetes (EASD) to present its results on TOTUM-63 ([press release of September 21, 2020](#)). This new selection by the leading European diabetes congress is further testimony to the value of these clinical results.

These publications at the two largest world diabetes congresses highlights the quality of VALBIOTIS' research programs and its innovative approach, to the main scientific and industrial players in the field of Nutrition Healthcare.

## Financial information for the first half of 2020: a solid financial situation

The Company's interim financial statements, prepared in accordance with IFRS, were approved by the Executive Board on September 24, 2020. They have been subject to a limited review by the Statutory Auditors and are available on the VALBIOTIS website: [www.valbiotis.com](http://www.valbiotis.com)

IFRS in €K <sup>(1)</sup> , at June 30	S1 2020	S1 2019
Operating revenue, of which	714	1,023
<i>Turnover</i>	121*	46
<i>Grants</i>	156	372
<i>Research tax credit</i>	437	605
R&D expenses	(1,939)	(2,105)
Sales and Marketing expenses	(545)	(823)
Overheads	(638)	(641)
Current operating result	(2,557)	(2,639)
Operating result	(2,557)	(2,639)
Pre-tax profit or loss	(2,830)	(2,724)
Net result	(2,931)	(2,724)

IFRS in €K <sup>(1)</sup>	S1 2020	S1 2019
Cash flow generated by activity	3,323	(3,139)
Cash flow linked to investments	(101)	(54)
Cash flow linked to financing activities	(341)	(330)
Net cash flow	2,881	(3,523)
Balance	10,914	3,897

\*For the first half of 2020, VALBIOTIS generated turnover of €121K, resulting from recognition of the initial payment of CHF 5M received by the Company in April 2020. This initial payment, acquired from the date of signature, is considered to be part of the service price and is therefore spread over the duration of the contract, i.e. until October 2035.

Operating income therefore amounted to €714K, mainly consisting of research tax credits, turnover and state subsidies.

In the first half of the year, Research and Development expenses decreased by 8% compared to the same period last year, to €1,939K. This evolution is mainly due to the absence of clinical studies carried out during the period, which was focused on the preparation of the launch of REVERSE-IT and the continuation of preclinical research work on the technical platform in Riom. Sales and Marketing expenses were also down 34% compared to the first half of 2019, at €545K. This decrease in business development efforts follows the effective signature of the contract with Nestlé Health Science. Finally, overheads expenses remained stable at €638K in S1 2020 compared to €642K in S1 2019. Overall, VALBIOTIS recorded a net loss of €2,931K.

For the first half of the year, cash flow generated by activity was positive at €3,323K, driven by the CHF 5M upfront payment from Nestlé Health Science. Cash flow linked to investments was negative by €101K, mainly related to activities aimed at extending VALBIOTIS' intellectual property rights with the registration of trademarks and patents internationally. Finally, cash flow linked to financing activities was negative by €341K, largely due to the restatement of lease contracts in the context of the implementation of IFRS 16.

At June 30, 2020, VALBIOTIS had a cash position of €10,914K, up 36% compared to December 31, 2019.

To date, and taking into account in particular:

- €10,914K of available cash as at June 30, 2020;
- Operating expenses related to the current development plan;
- The maturity schedule of the current financial debt;
- Receipt in the second half of 2020 of the CHF 3M milestone payment resulting from the partnership signed with Nestlé Health Science;
- The capital increase of €2M carried out in July 2020;
- Receipt in the summer of 2020 of €3M from the French State-guaranteed loan (PGE) obtained from the banking consortium made up of Bpifrance, Société Générale and BNP Paribas;

The Company has carried out a specific review of its liquidity and considers that it does not face any short-term risk. As of today, the end of cash flow is estimated to be in the first half of 2022.

On the basis of the current development plan, this timeframe could be extended if additional revenues are generated to complement the milestone payments already scheduled with Nestlé Health Science. This scenario may arise in particular in the event that TOTUM-63 is marketed before the health claim is obtained, which would result in the early payment of progressive royalties on net sales. The communicated cash horizon also does not include revenues from new strategic partnerships that may be entered into for other products in the current portfolio.

VALBIOTIS' half-year financial report at June 30, 2020 has been made available to the public and filed with the French financial markets regulator (AMF). This document can be consulted on the website: [valbiotis.com](http://valbiotis.com) («Investors» section).

## 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](http://www.valbiotis.com)

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This press release contains forward-looking statements about VALBIOTIS' objectives, based on rational hypotheses and the information available to the company at the present time. However, in no way does this constitute a guarantee of future performance, and these projections can be reconsidered based on changes in economic conditions and financial markets, as well as a certain number of risks and doubts, including those described in the VALBIOTIS core document, filed with the French Financial Markets Regulator (AMF) on 31 July 2020 (application number R20-018), these documents being available on the Company's website ([www.valbiotis.com](http://www.valbiotis.com)).



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