

# Letter to Shareholders No.5



— Sébastien PELTIER, Chairman of the Board of Directors

Dear Shareholders.

ids\_150360 (viewed on 27 April 2021).

Over the past months, we have made significant progress with the implementation of our strategic roadmap. In 2020, we signed a major, promising global strategic agreement with Nestlé Health Science regarding TOTUM•63, our flagship product dedicated to reducing type 2 diabetes risk factors.

Thanks to this partnership, we have now entered the final phase of development of this active substance, whose efficacy has already been scientifically demonstrated. It will then be rolled out in high-growth markets, in particular the United States, Canada and the top five European countries, with their 134 million prediabetics, and an overweight and obese population of about 70%, growing continuously.

Further progress has been achieved with regard to the protection of our intellectual property following the signing of this agreement, with the patent granted in China for TOTUM•63, its composition and its use to prevent type 2 diabetes and metabolic diseases. The prevalence of prediabetes in China's adult population is estimated at 35%, i.e. 390 million people<sup>1</sup>, and the prevalence of excess weight and obesity at 50%<sup>2</sup>.

In line with the strategy agreed with Nestlé Health Science, we have published data on TOTUM•63 in three international scientific peer-reviewed journals, thereby kicking off our scientific promotion strategy, a key factor for the successful commercialization of this promising product. We also recently announced the launch of a new study on the mode of action of TOTUM•63 at the Institute of Nutrition and Functional Foods (INAF) at Laval University in Quebec City in partnership with Nestlé Health Science. Also, the last Phase II/III REVERSE-IT clinical study is under way and results are expected in mid-2022.

In addition to TOTUM•63, our portfolio includes three other active substances targeting major indications that are currently under clinical development: reduction of LDL-cholesterol (TOTUM•070), arterial hypertension (TOTUM•854) and hepatic steatosis (TOTUM•448).

Today, we are ready to accelerate development of these products in our pipeline, which are also strategic. It is with this in mind that, in the first half of 2021, we completed a highly successful capital increase of €15 million. Thanks to the funds raised, we will be able to reach new milestones in the development of TOTUM•854 (arterial hypertension) with the launch of three clinical studies at the end of the year, with a marketing horizon of 2023.

With regard to TOTUM•070 (LDL-cholesterol), the recruitment of the Phase II clinical study HEART was completed in September. The results will be communicated in the second quarter of 2022. TOTUM•070 has high potential in the market for non-drug LDL-cholesterol products as, according to the WHO, this disease concerns close to 40% of the world's adult population.

As you can see, thanks to our sound financial position, today, we are fully focused on our roadmap alongside our committed, enthusiastic team. We are proud of the work accomplished together, and are grateful for the trust of you, our shareholders, whose numbers are growing.

The entire Valbiotis team joins me in thanking you most sincerely for this support.

Letter to Shareholders September 2021

## Latest news

## Sustainable and secure financial position

The Company's financial structure received a considerable boost over recent months thanks to a successful capital increase completed on April 15, 2021 in the amount of €15 million and two innovation support loans from Bpifrance in May in a total amount of €1.25 million.

As of today, financing requirements are met until the first half of 2024, without taking into account milestone payments and potential royalties paid under the partnership with Nestlé Health Science.

### ISO-9001:2015 certification granted

Valbiotis has been granted ISO-9001:2015 certification by AFNOR for all of its activities in the "Design, development and production control of solutions for preventing and combating metabolic and cardiovascular diseases". This certification process guarantees the control of all discovery, preclinical research, clinical research and production activities, as well as product quality management.

## Coverage of the Company by four analysts, of which two initiated in 2021

#### Midcap Partners

Analyst: Corentin MARTY

Analyst's opinion: "With a first global partnership with Nestlé Health Science on TOTUM•63 (which we estimate will be marketed in the second half of 2022) highlighting all of Valbiotis' work, we are very confident about the growth potential of the Company."

Target price: €14.30 (April 2021)

#### Oddo BHF

Analyst: Martial DESCOUTURES Target price: €13.30 (May 2021)

#### **Invest Securities**

Analyst: Thibaut VOGLIMACCI-STEPHANOPOLI

Analyst's opinion: "By capitalizing on a founding partnership with Nestlé Health Science on TOTUM•63 as well as on solid financial visibility, Valbiotis has all the assets to effectively pursue its innovative strategy aimed at marketing food supplements with specific health claims. In our view, the current valuation, put into perspective with the agreement signed with Nestlé Health Science on TOTUM•63, does not fully reflect the potential."

Target price: €14.10 (April 2021)

#### Portzamparc

Analyst: Christophe DOMBU / Mohamed KAABOUNI

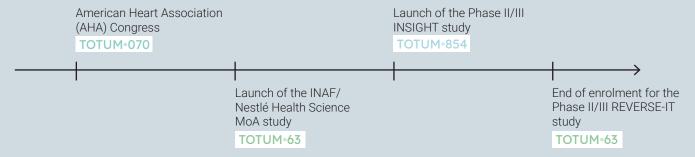
Analyst's opinion: "The signing of the Nestlé Health Science deal on TOTUM•63 was the turning point in the stock market's remarkable history since February 2020. Moreover, this deal was structuring for Valbiotis which has 1/ built a rich and realistic clinical calendar; 2/ was able to take advantage of it to strengthen its financial visibility (S1 2024), testify the two capital increases in the last twelve months. In 2022, the newsflow will be even richer with the results of REVERSE-IT and HEART and the launch of Phase II/III on TOTUM•854. The positive momentum of the title should therefore continue over the coming months."

Target price: €13.40 (April 2021)

### New appointment to the Board of Directors

Valbiotis has appointed Sébastien BESSY, an international expert in consumer healthcare, as Chief Operating Marketing and Business Officer. Previously the Vice-President Global Strategic Operations Consumer Healthcare at Ipsen, he has over 20 years of experience in international marketing strategy, commercial strategy, portfolio strategy and business development, he is responsible for the global deployment and coordination of the international strategy related to Valbiotis' marketing and commercial development.

# Upcoming key milestones



# — Focus on innovation

Since the initial clinical success of TOTUM•63 and the signing of the partnership with Nestlé Health Science in 2020, the pipeline has been consolidated with a market launch in view for four high-potential indications: prediabetes, LDL-hypercholesterolemia, arterial hypertension and non-alcoholic steatohepatitis. Our R&D teams have made significant progress in these different indications over recent months.

# TOTUM•63

## Commercialization planned in partnership with Nestlé Health Science

The last Phase II/III REVERSE-IT clinical study is under way and results are expected in mid-2022. This international multicentric study should confirm the positive results obtained in the Phase II clinical study on the main risk factors for developing type 2 diabetes. In addition, a mode of action exploratory study in humans will be conducted by the INAF at Laval University in Quebec City in partnership with Nestlé Health Science. The launch of this study is planned for the end of 2021. This data will support scientific communication and the commercialization of TOTUM•63.

# TOTUM•070

## Recruitment completed for the Phase II clinical study on hypercholesterolemia



This image is for information only - product not marketed

The international, multicentric, randomized, placebo-controlled HEART study was launched in February 2021. Recruitment is finalized and results will be communicated in the second quarter of 2022. It should demonstrate the efficacy of TOTUM•070 against excess blood LDL-cholesterol in 120 volunteers with hypercholesterolemia. In parallel, a clinical study to characterize all the metabolites and identify their effects on human cell models is in progress.

# TOTUM•854

## An ambitious plan to fight arterial hypertension with results expected in 2023



This image is for information only - product not marketed

The positive preclinical results selected by the Annual ESH-ISH Joint Meeting in April 2021 led to a rigorous clinical development plan being drawn up to meet this healthcare challenge: two concomitant international clinical studies, including a pivotal Phase II/III study will be launched at the end of 2021. Finally, the Company will conduct a third clinical study at the same time to measure the bioavailability of TOTUM•854, characterize its metabolites and explore their modes of action.

# TOTUM•448

# A development strategy currently being finalized to fight non-alcoholic steatohepatitis

The development strategy is nearing completion. It will address the reduction of non-alcoholic hepatic steatosis, a risk condition for developing NASH ("fatty liver disease").

# Achievements validated by the scientific community and protected by new patents

As has been the case since the Company was founded, our preclinical and clinical results have been selected by international congresses, the European Association for the Study of Diabetes (EASD) for TOTUM•63 in 2020 and the European Society of Hypertension - International Society of Hypertension (ESH-ISH) for TOTUM•854 in 2021. Moreover, an initial set of data from the TOTUM•63 program was the subject of three scientific publications in three international peer-reviewed journals (*American Journal of Physiology - Endocrinology and Metabolism, International Journal of Obesity* and *Nutrients*) in May 2021. Patents for TOTUM•63 in China and for TOTUM•70 in the US and Europe have been granted, thereby extending the protection of our intellectual property.

# — Stock market information

## Share price evolution

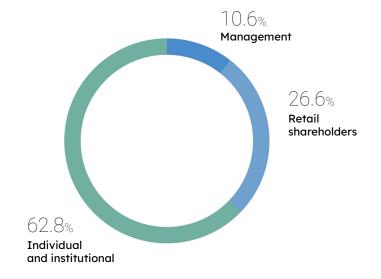
ALVAL Euronext Paris, from January 1, 2020 to September 2, 2021.



Valbiotis' market capitalization totals approximately €67 million, at September 2, 2021. Number of shares: 9,729,942, with a free float of 89.4%.

## Breakdown of share capital

Euronext PoLA based on Euroclear TPI (identifiable bearer shares) as of 06/11/2021 and registered shareholdings.



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### Financial calendar

## September 30

Publication of the Half-Year Financial Report

## Corporate information

#### **Euronext Paris, ALVAL**

- ISIN code: FR0013254851
- · Mnemonic code: ALVAL
- EnterNext® PEA-PME 150





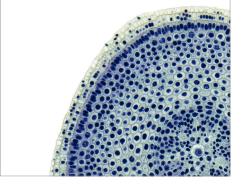
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