

Press release - Regulated information - Inside information (*)

Biotalys Provides Company Update

Review by new CEO Kevin Helash leads to focus on core capabilities and organizational changes

- Progress to next-generation AGROBODY™ technology platform
- Update on product pipeline and regulatory review for EVOCA™(**)
- CSO Dr. Carlo Boutton to drive all research and early development while Dr. Eva Van Hende to head regulatory and field development; COO Luc Maertens and CBO Patrick McDonnell leaving the company
- Management to host a conference call and live webcast today at 15:00 CET / 14:00 GMT / 09:00 AM EST, details below

Ghent, BELGIUM – 29 November 2023, 07:00 CET – Biotalys (Euronext – BTLS), today provided a company update following a strategic review of the company by CEO Kevin Helash and the board of directors. The review leads to a shift to the second-generation AGROBODY™ technology to develop protein-based biocontrols for crop and food protection. This move to AGROBODY 2.0 entails organizational changes to concentrate resources on core R&D capabilities while focusing on obtaining registration for Biotalys' first product candidate EVOCA.

Kevin Helash, Chief Executive Officer of Biotalys, commented: "Since my appointment as CEO of Biotalys in early October, I have conducted a thorough review and am even more convinced of the power and potential of our AGROBODY Foundry™ platform and the company's strategy. As an organization focused on creating sustainable crop protection products, we need to deliver on two fronts: one, to roll out the next-generation AGROBODY technology, which we believe will increase potency and efficacy of our bioactive agents with multiple modes of action while lowering cost of goods per hectare, allowing for a broader market penetration of our biocontrol products. And two, to ensure that the organization is set up to operate with a laser-like focus on execution while prudently managing costs."

The AGROBODY 2.0 technology platform

Biotalys' AGROBODY platform is based on VHH-technology already successfully applied in the pharmaceutical industry and Biotalys is pioneering this technology for agriculture. By applying a discovery method based on defined molecular targets, Biotalys is now pursuing novel opportunities to identify potent bioactive ingredients for use in crop protection. This AGROBODY 2.0 approach will therefore become the main focus of the R&D organization. It has the potential to clearly differentiate the company's protein-based biocontrols from other biological solutions thanks to a larger range of modes of action to fight agricultural pests and diseases.

With this new approach, Biotalys builds on EVOCA, the company's first protein-based product candidate, which again showed convincing results in extension trials by academic institutes in the U.S. and trials by its business partners.



Updated pipeline of protein-based biocontrols

In view of the new approach, Biotalys has evaluated its pipeline and decided to focus on biofungicides and bioinsecticides. The company will proceed with the following programs:

- EVOCA, a biofungicide candidate aimed at targeting botrytis bunch rot and powdery mildew in fruits and vegetables; see below for a regulatory update;
- EVOCA NG (next generation), a biofungicide program currently in development, with the same molecule as EVOCA but an optimized production process and formulation;
- BioFun-4, a biofungicide program aimed at targeting Oomycetes in fruits and vegetables;
- BioFun-6, a biofungicide program aimed at targeting botrytis, powdery mildew and anthracnose in fruits and vegetables;
- BioFun-7, a biofungicide program in collaboration with the Bill & Melinda Gates Foundation, aimed at targeting leafspot disease in cowpeas and other legumes;
- Biolns-2, a bioinsecticide program in collaboration with Syngenta Crop Protection, aimed at targeting key pests.

A leadership and organization fit for purpose

Under the leadership of CEO Kevin Helash, the new executive committee comprises CSO Dr. Carlo Boutton, who takes responsibility for all early R&D activities, and CFO Douglas Minder. COO Luc Maertens and CBO Patrick McDonnell will leave the company and their roles will be consolidated into the new leadership. The senior management team is completed by Dr. Eva Van Hende, who will lead regulatory and field development; Sophie Snijders, Head of HR; and Toon Musschoot, Head of IR & Communications.

The organizational changes will result in a reduction in headcount of 8 positions and annualized cost savings, leading to an approximate 10% reduction in operating expenses going forward. Together with savings realized during the current year and planned reductions in future spend, the company has revised its expected cash burn for FY 2023 from approximately €22 million to less than €20 million.

Simon Moroney, Chairman of Biotalys, said: "I would like to thank Luc Maertens for his pivotal role in demonstrating that our AGROBODY biocontrols have outstanding promise as novel crop protection agents. I also thank Patrick McDonnell and our other departing colleagues for their contribution to Biotalys over the past years and wish them well in their future careers. Our new leadership is committed to driving implementation of the second-generation AGROBODY platform with the goal of maximising value for the company's stakeholders and, ultimately, for growers."

Update on EVOCA's regulatory review

The regulatory review of EVOCA is ongoing in both the United States and the European Union.

In the U.S., the Environmental Protection Agency (EPA) is evaluating the regulatory dossier, and we are working with industry experts to support our submission. As part of the ongoing dialogue and exchange of information with the authority, from time to time the EPA requests additional information, which is not uncommon considering the novelty of the product candidate. The company remains committed to responding to all requests for information in a timely and appropriate manner.



In the E.U., Biotalys received confirmation from the competent authority – the Dutch Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) – that it had concluded the first review of all sections of the full data package. As a result, the Ctgb has requested additional information, which the company plans to provide in due course. If accepted, the authority will be able to finalise this first phase of the E.U. review and pass its assessment report to both EFSA and the European Member States for the next phase of the review at E.U. level.

(*) This press release contains inside information to the extent that it relates to the changes at the level of the Executive Committee.

(**) EVOCA™: Pending Registration. This product is not currently registered for sale or use in the United States, the European Union, or elsewhere and is not being offered for sale.

Live webcast and conference call

Company management will host a live webcast today, 29 November 2023 at 15:00 CET / 14:00 GMT / 09:00 AM EST.

Webcast link: https://edge.media-server.com/mmc/p/avz2wgbp

Dial-in details: To ask questions live to the management, please also register for the conference call via https://register.vevent.com/register/BI1f6fce3935ef4e1e8243c13beccecc9a

About Biotalys

Biotalys is an Agricultural Technology (AgTech) company developing protein-based biocontrol solutions for the protection of crops and food and aiming to provide alternatives to conventional chemical pesticides for a more sustainable and safer food supply. Based on its novel AGROBODY™ technology platform, Biotalys is developing a strong and diverse pipeline of effective product candidates with a favorable safety profile that aim to address key crop pests and diseases across the whole value chain, from soil to plate. Biotalys was founded in 2013 as a spin-off from the VIB (Flanders Institute for Biotechnology) and has been listed on Euronext Brussels since July 2021. The company is based in the biotech cluster in Ghent, Belgium. More information can be found on www.biotalys.com.



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Important Notice

Biotalys, its business, prospects and financial position remain exposed and subject to risks and uncertainties. A description of and reference to these risks and uncertainties can be found in the 2022 annual report on the consolidated annual accounts and the half-year report for 2023.

This announcement contains statements which are "forward-looking statements" or could be considered as such. These forward-looking statements can be identified by the use of forward-looking terminology, including the words 'aim', 'believe', 'estimate', 'anticipate', 'expect', 'intend', 'may', 'will', 'plan', 'continue', 'ongoing', 'possible', 'predict', 'plans', 'target', 'seek', 'would' or 'should', and contain statements made by the company regarding the intended results of its strategy. By their nature, forward-looking statements involve risks and uncertainties and readers are warned that none of these forward-looking statements offers any guarantee of future performance. Biotalys' actual results may differ materially from those predicted by the forward-looking statements. Biotalys makes no undertaking whatsoever to publish updates or adjustments to these forward-looking statements, unless required to do so by law.