



Press release - regulated information

Biotalys Reports Full-Year 2022 Financial Results and Business Highlights

- *Established strategic partnerships in preparation of U.S. market calibration of Evoca™**
- *Improved manufacturing efficiencies for the next generation of Evoca, tapping the proprietary AGROBODY Foundry™ platform*
- *Updated regulatory approval timelines in view of ongoing review by government agencies*
- *Year-end cash and cash equivalents amounted to €34 million*
- *Management to host a conference call and live webcast at 16:00 CET / 15:00 GMT / 10:00 AM EST today, details below*

Ghent, BELGIUM – 28 February 2023, 07:00 CET – [Biotalys \(Euronext - BTLS\)](#), an Agricultural Technology (AgTech) company developing protein-based biocontrol solutions for sustainable protection of crops and food, today announces key business achievements and consolidated financial results for 2022, prepared in accordance with IFRS as adopted by the European Union, and an outlook for 2023. The annual report, including the full financial report, will be published on [the Company's website](#) on 24 March 2023.

Patrice Sellès, Chief Executive Officer of Biotalys, stated: “Despite 2022 being a tumultuous year globally and across the agricultural industry, Biotalys achieved important milestones demonstrating the ability of its AGROBODY™ technology platform to develop innovative biocontrols at scale. We believe Biotalys’ strategy and focus are fully aligned with the dawn of a new crop and food protection era, addressing both European Green Deal targets for chemical pesticide reduction and the global need to safely and sustainably feed our world.”

“The regulatory procedure for our first biofungicide Evoca is still ongoing. During our dialogue with the U.S. Environmental Protection Agency, we have learned that additional time is required to review all submitted data. We will continue to work closely with the Agency as it completes its review, now expected for Q3 2023, to bring this innovative technology into the hands of the growers.”

2022 Operational Highlights (including post-period regulatory update for Evoca)

Throughout the year, Biotalys made significant headway in key areas to further develop its platform and pipeline.

Biotalys solidified strategic partnerships with global leaders to prepare for the market calibration of Evoca, the Company’s first biofungicide:

- At the start of 2022, Biotalys [partnered with Olon](#), a world-leading bioactive manufacturing organization, to significantly scale-up the production of the active ingredient of Evoca.
- Biotalys [appointed Kwizda Agro](#), an established crop protection manufacturer, as formulator of its protein-based biocontrols – critical in the supply chain for high quality products, starting with Evoca.



- After entering into [a partnership with Novozymes](#), a world leader in biotech solutions, to explore additional routes to scale efficient production of the bioactive protein of Evoca, Biotalys announced the results of its [successful feasibility study](#) in H2. The study identified new, cost-effective ways to further scale the Evoca active ingredient.

Evoca continued to demonstrate its efficacy in our field trial program as future valuable tool for growers seeking more sustainable solutions to control devastating fungal diseases:

- The [field trial results](#) based on data from grapes across vineyards in diverse climates throughout California and New York demonstrated excellent preventative control of Botrytis bunch rot in grapevines.
- Evoca significantly outperformed a leading chemical product when positioned at the flowering stage of grapes in a fungicide rotation program.
- Wine grape juice quality, vinification and wine characteristics exhibited no differences for Evoca-treated vineyards compared to non-Evoca treated vineyards.

Biotalys also achieved additional **technology milestones** for Evoca in 2022, including:

- Earning an [entirely new mode of action class by the Fungicide Resistance Action Committee \(FRAC\)](#) for the active ingredient in Evoca. The new class granted by an international panel of renowned technical experts confirms Evoca offers a novel way to manage known resistance to fungicides.
- Realizing a significant [breakthrough in protein expression](#) for the bioactive ingredient of Evoca, whereby the Biotalys' R&D teams confirmed they could deliver substantially lower production costs for both Evoca and future product candidates.
- Winning a [World BioProtection Award 2022 for Best Biofungicide Product](#) based on the innovative character, scientific value and market potential of the product.

Regulatory update for Evoca

- Biotalys submitted its regulatory dossier to the relevant authorities in both the U.S. (in December 2020) and the E.U. (in March 2021). In view of the progress made by these authorities as communicated to the Company, Biotalys is providing the following update:
 - The U.S. Environmental Protection Agency (EPA) is actively reviewing the regulatory dossier, and Biotalys has addressed all requests received by the EPA to date. The Company acknowledges the breakthrough nature of the protein-based biocontrol product requires more time than originally anticipated. The Company now expects to obtain the registration for Evoca in Q3 2023. As soon as obtained, the registration will allow the use of the product in selected fruit and vegetable crops. As a reminder, the first generation of Evoca represents a market calibration product that will not generate positive cashflow margins, but will enable the Company to create market demand and introduce growers to the new product in anticipation of a commercial, profit-generating version in 2026.
 - In the E.U., the Board for Authorisation of Plant Protection Products (College voor Toelating van Gewasbeschermingsmiddelen or Ctgb) in The Netherlands as Rapporteur Member State is currently reviewing the regulatory dossier that Biotalys submitted for the active ingredient of Evoca. Biotalys expects to obtain the first registration in the E.U. in 2025, opening a path to launching the commercial version of Evoca in Europe in 2026.



The status of Biotalys' current pipeline of product candidates, which includes novel biofungicides, biobactericides and bio-insecticides, is as follows:

- **The next generation of Evoca** (containing the same bioactive protein, with optimized manufacturing and formulation) has progressed into the development stage and is currently expected to enter both the U.S. and the E.U. markets by 2026, subject to regulatory approval. The Company expects this next generation of Evoca to generate positive cashflow margins as production efficiency improves and market potential further develops.
- **BioFun-6** continues to progress according to plan and moved into in-depth in vitro characterization in 2022, with the goal of obtaining a novel mode of action differentiating it from Evoca, opening up the new product to a wider range of crops and regions. The Company expects to move this product candidate into development stage by the end of 2023, on track to bring an additional and complementary solution to fruit and vegetables growers by 2028.
- **BioFun-7**, in partnership with the Bill & Melinda Gates Foundation, was initiated at the beginning of 2022 and is progressing as per plan with the identification of candidate molecules now ongoing.
- **BioFun-4** was initiated by Biotalys in the beginning of 2023 with the development of the project plan and target product profile, in collaboration with key opinion leaders, including members of the newly established Scientific Advisory Committee (SAC).
- **Biolns-1** made progress with the discovery of potential binders to insect targets, creating prospects for potential development of a product candidate by the Company or in collaboration with partners.
- **BioBac-1 and BioFun-2** are expected to continue to provide valuable IP and know-how, strengthening the Company's AGROBODY Foundry platform, and could form the basis of further R&D collaborations.

Actively strengthening its team, Biotalys made important appointments throughout the year:

- Biotalys expanded its executive team with the [hiring of Dr. Carlo Boutton as Chief Scientific Officer](#). A proven leader in antibody innovation with a track record building world-class research platforms, Dr. Boutton is supporting the acceleration of technical innovation and development of Biotalys' AGROBODY Foundry platform.
- Biotalys further strengthened its Board of Directors with [the appointment of Dr. Michiel van Lookeren Campagne](#), a prominent industry leader in plant science and biotechnology who has spent decades driving scientific advances for the agricultural industry.
- The Company also [established a Scientific Advisory Committee](#) (SAC) to deepen its network of scientific experts. Dr. Adrian Percy, an accomplished agricultural industry leader and Executive Director of NC Plant Sciences Initiative, was named Chairman of the SAC. Dr. Claude Bensoussan, an industrial biotechnology specialist; Dr. Hans-Jürgen Rosslenbroich, an agronomy disease management pioneer; and Dr. Ioannis Stergiopoulos, an authority in genetics and plant pathogens, joined the SAC at its creation to provide continued scientific direction and support as Biotalys matures its product pipeline for global commercialization.

** 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.*

Detailed financial review for 2022

In € thousand	2022	2021
Other operating income	2,949	1,995
Research and development expenses	(18,813)	(13,880)
General and administration expenses	(5,081)	(4,905)
Marketing expenses	(1,586)	(1,289)
Operating loss	(22,531)	(18,079)
Financial income	320	1,510
Financial expenses	(557)	(343)
Loss before taxes	(22,769)	(16,913)
Income taxes	38	(16)
Loss for the period	(22,731)	(16,929)
Remeasurement gains (losses) on defined benefit plans	(43)	5
Exchange differences on translating foreign operations	4	5
Total comprehensive loss for the period	(22,770)	(16,919)
Basic and diluted loss per share (in EUR)	(0.74)	(1.10)
Profit/(loss) for the period attributable to the owners of the company	(22,731)	(16,929)
Total comprehensive income for the period attributable to the owners of the company	(22,770)	(16,919)
Cash and cash equivalents	34,096	56,107
Net increase (decrease) in cash and cash equivalents	(22,017)	33,005

Consolidated statements of profit and loss

- **Other operating income** amounted to €2.9 million and relates to R&D tax incentives received and grants awarded to support R&D activities. The primary increase relates to the grant from the Bill & Melinda Gates Foundation, for which the activities started in 2022. R&D tax incentives increased by €0.4 million, while income from government grants decreased slightly by €0.2 million compared to 2021.
- **Research and development expenses** amounted to €18.8 million for 2022, an increase of €4.9 million compared to 2021. This increase is mainly driven by external spending for the production of Evoca in preparation of the market calibration planned for later this year and field trials for further product testing. Other increases in the R&D expenses include the indexation of salary costs and non-cash expenses for the stock options.
- **General and administrative expenses** amounted to €5.1 million for 2022, compared to €4.9 million in 2021, mainly driven by a limited increase in expenses for employee benefits and technical systems. There was a decrease in professional services as there was a one-time charge of €0.5 million in 2021 related to the preparation for the initial public offering in July 2021.



- **Marketing expenses** rose from €1.3 million in 2021 to €1.6 million in 2022 as a result of further developing the sales and marketing team in support of the expanded market calibration of Evoca planned for 2023 and beyond.
- **Financial income** amounted to €0.3 million in 2022, compared to €1.5 million in 2021, and related primarily to foreign exchange gains in 2022, while the figure for 2021 was impacted by the full release of the remaining derivative liability of the Anti-Dilution warrants as they were cancelled upon the IPO.
- **Financial expenses** amounted to €0.6 million and related primarily to interest expenses for the leases and bank loans and foreign exchange losses.
- **Income taxes expense** show the impact of the creation of a deferred tax asset related to the R&D expenses in our U.S. subsidiary.
- **Loss of the period** was €22.8 million, compared to €16.9 million in 2021.
- **Basic and diluted loss per share** for 2022 amounted to €0.74 compared to €1.10 in 2021. There was a lower average number of shares outstanding in 2021 versus 2022 as the shares issued at the time of the initial public offering were only outstanding for approximately half of 2021.
- **Cash and cash equivalents** at year-end amounted to €34.1 million in 2022 (compared to €56.1 million in 2021), slightly higher than expected as a result of a combination of savings and timing differences for certain cash payments for manufacturing.

Outlook for 2023

- Biotalys expects to initiate the market calibration of Evoca with Biobest in select U.S. states, subject to regulatory approval. As the field trial program for the first generation of Evoca has been completed, the Company will now focus on testing improved product formulations and the next generation product, both in the U.S. and the E.U. In addition, Biotalys plans to test Evoca with a broader number of potential commercial partners for Europe and other regions.
- In addition to the ongoing internal work on the next generation of Evoca, Biotalys is also exploring strategic supply and commercialization agreements with Novozymes for a next generation of Evoca.
- The Company expects to advance the product pipeline in 2023 with the planned promotion of the BioFun-6 program into development stage while progressing current pipeline programs further in the discovery stage. Biotalys also aims to continue selectively leveraging its AGROBODY Foundry platform and pipeline to further expand into new markets and crops, with an increased focus on strategic collaborations that could drive additional value.
- The Company expects cash burn in 2023 to be slightly higher than last year (2022: €22 million), in line with the planned investments in our pipeline, platform and manufacturing. Together with the cash and cash equivalents balance of €34 million at the end of 2022, the Company expects the financial runway to extend to mid 2024.

Auditor Statement

The consolidated financial statements have been prepared in accordance with IFRS, as adopted by the EU. The financial information included in this press release is an extract from the full IFRS consolidated financial statements, which will be published on 24 March 2023. The statutory auditor, Deloitte Bedrijfsrevisoren /Réviseurs d'Entreprises, represented by Pieter-Jan Van Durme, has confirmed that its audit procedures, which have been substantially completed, have not revealed any material adjustment that should be made in the accounting information included in this press release.



Financial calendar and upcoming IR events

- 14-15 March 2023: Biotalys' management will meet with institutional investors and industry players at the World AgriTech Conference in San Francisco
- 24 March 2023: Online publication of annual report 2022
- 25 March 2023: Biotalys' management will meet with retail investors at the Flemish Retail Investor Association (VFB) Annual Happening in Ghent
- 3-5 April 2023: Biotalys' management will meet with institutional investors at the Global Ag Investing Conference in New York
- 25 April 2023: Annual General Shareholders Meeting at the Company's headquarters
- 11 May 2023: Biotalys Shareholders Club at Biotalys' HQ in Ghent

Live webcast and conference call

Company management will host a live webcast in English to discuss its full year 2022 financial results and business highlights today, 28 February 2023, at 16:00 CET / 15:00 GMT / 10:00 AM EST. Please register via the following webcast link: <https://edge.media-server.com/mmc/p/hv39hzvy>.

Dial-in details: To ask questions live to management, please also register for the conference call via <https://register.vevent.com/register/BI31434e7ab1764b25a7eadb82a0ff4e9e>.

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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

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.

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

ASSETS

(in thousands of euros)	Note	31 December 2022	31 December 2021
Non-current assets		11.755	11.336
Intangible assets	7	596	665
Property, plant and equipment	8	5.335	5.407
Right-of-use assets	9	3.667	3.885
Deferred tax assets		125	-
Other non-current assets	10	2.031	1.380
Current assets		37.762	58.938
Receivables	11	820	451
Other financial assets	12	2.100	2.100
Other current assets		746	279
Cash and cash equivalents	12	34.096	56.107
TOTAL ASSETS		49.517	70.274

EQUITY AND LIABILITIES

(in thousands of euros)	Note	31 December 2022	31 December 2021
Equity attributable to owners of the parent		38.114	58.915
Share capital	13	44.548	81.969
Share premium	13	10.164	31.303
Accumulated losses		(19.661)	(55.855)
Other reserves		3.064	1.498
Total equity		38.114	58.915
Non-current liabilities		5.443	6.150
Borrowings	14	5.338	6.037
Employee benefits obligations	15	16	26
Provisions	8	89	87
Current liabilities		5.960	5.209
Borrowings	14	1.163	1.186
Trade and other liabilities	16	4.204	3.119
Other current liabilities	17	592	904
Total liabilities		11.402	11.359
TOTAL EQUITY AND LIABILITIES		49.517	70.274

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME FOR THE YEARS ENDED 31 DECEMBER

in € thousands	Note	2022	2021
Other operating income	19	2.949	1.995
Research and development expenses	20	(18.813)	(13.880)
General and administrative expenses	20	(5.081)	(4.905)
Sales and marketing expenses	20	(1.586)	(1.289)
Operating loss		(22.531)	(18.079)
Financial income	22	320	1.510
Financial expenses	22	(557)	(343)
Loss before taxes		(22.769)	(16.913)
Income taxes	23	38	(16)
LOSS FOR THE PERIOD		(22.731)	(16.929)
Other comprehensive income (OCI)			
<i>Items of OCI that will not be reclassified subsequently to profit or loss</i>			
Remeasurement gains (losses) on defined benefit plans		(43)	5
<i>Items of OCI that will be reclassified subsequently to profit or loss</i>			
Exchange differences on translating foreign operations		4	5
TOTAL COMPREHENSIVE LOSS OF THE PERIOD		(22.770)	(16.919)
Basic and diluted loss per share (in €)	24	(0,74)	(1,10)
Profit/(loss) for the period attributable to the owners of the Company		(22.731)	(16.929)
Total comprehensive income for the period attributable to the owners of the Company		(22.770)	(16.919)

CONSOLIDATED STATEMENT OF CASH FLOWS FOR THE YEARS ENDED 31 DECEMBER

in € thousands	Note	2022	2021
CASH FLOW FROM OPERATING ACTIVITIES			
Operating result		(22.531)	(18.079)
Adjustments for:			
Depreciation, amortization and impairments		1.575	1.470
Equity-settled share-based payment expense		1.733	511
Provisions		(55)	(20)
R&D tax credit		(768)	(405)
Other		0	7
Operating cash flows before movements in working capital		(20.045)	(16.516)
Changes in working capital:			
Receivables		(247)	(225)
Other current assets		(467)	(175)
Trade and other payables		997	(70)
Other current liabilities		(304)	256
Cash used in operations		(20.067)	(16.731)
Taxes paid		(24)	(23)
Net cash used in operating activities		(20.091)	(16.754)
CASH FLOW FROM INVESTING ACTIVITIES			
Interests received		23	1
Purchases of property, plant and equipment		(707)	(1.324)
Purchases of Intangible assets		-	(8)
Proceeds from disposal of PPE		0	7
Investments in other financial assets		(0)	(0)
Net cash used in investing activities		(684)	(1.324)
CASH FLOW FROM FINANCING ACTIVITIES			
Repayment of borrowings and other financial liabilities	14	(1.233)	(1.127)
Proceeds from borrowings	14	-	2.780
Interests paid		(245)	(244)
Proceeds from issue of equity instruments of the Company (net of issue costs)	13	236	49.675
Net cash provided by financing activities		(1.242)	51.083
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS		(22.017)	33.005
CASH AND CASH EQUIVALENTS at beginning of year		56.107	23.103
Effect of foreign exchange rate changes		6	-
CASH AND CASH EQUIVALENTS at end of year		34.096	56.107

The accompanying notes are an integral part of these consolidated financial statements. Please see the full report available on www.biotallys.com.