



Vivoryon Therapeutics N.V. Reports Full Year 2022 Financial Results and Highlights Operational Progress

- *Significantly advanced varoglutamstat EU and U.S. clinical studies, VIVIAD and VIVA-MIND, providing promising initial safety data*
- *Both VIVIAD and VIVA-MIND studies on track; final data from VIVIAD expected in 1Q2024 and clinical update on VIVA-MIND expected in 2H2023*
- *Bolstered financial position with two successful private placements to support ongoing clinical development totaling EUR 36 million with option for up to additional EUR 15 million*
- *Management to host conference call today at 3:00 pm CEST (9:00 am EDT)*

Halle (Saale) / Munich, Germany, April 19, 2023 – Vivoryon Therapeutics N.V. (Euronext Amsterdam: VVY; NL00150002Q7) (**Vivoryon**), a clinical stage company focused on the discovery and development of small molecule medicines to modulate the activity and stability of pathologically altered proteins, today announced financial results for the twelve-month period ended December 31, 2022, and provided an update on its corporate progress. The report is available on the Company's website <https://www.vivoryon.com/investors-news/financial-information/>

“We continue to solidify our position as leaders in developing novel treatments for Alzheimer’s disease by following differentiating science to thoughtfully inform the design of our clinical trials. Our progress in 2022 underlines our dedication as we continued to advance both VIVIAD and VIVA-MIND, while optimizing their design based on meaningful findings both from varoglutamstat and the broader AD treatment landscape,” said Dr. Ulrich Dauer, CEO of Vivoryon. “In parallel, we’ve strengthened our financial position with two successful private placements, welcoming in new investors while also receiving continued support from existing investors. Our extended cash runway enables Vivoryon to continue executing against our pipeline goals and we are incredibly pleased with the progress we’ve already made in 2023. We are driven by our passion for developing small molecule-based medicines with a focus on alleviating disease burden in more ways than just addressing symptoms, such as ease of administration. We look forward to upcoming inflection points later this year for our VIVA-MIND trial in the U.S. and early next year for the final data from our VIVIAD study.”



2022 and Post-Period Portfolio Highlights

Varoglutamstat Clinical Program:

VIVIAD

VIVIAD (NCT04498650) is a state-of-the-art Phase 2b study being conducted in Europe and designed to evaluate the safety, tolerability, and efficacy of varoglutamstat in 250 subjects with mild cognitive impairment (MCI) and mild Alzheimer's disease (AD).

- In June 2022, Vivoryon announced that it had completed the parallel group, dose-finding part of its VIVIAD study and that the independent Data Safety Monitoring Board (DSMB) selected the highest dose investigated, 600 mg twice daily (BID), as the final dose to be administered in the second part of the study.
- At the Alzheimer's Association International Conference (AAIC) in San Diego (July 31 to August 4, 2022), Vivoryon presented detailed safety data from the VIVIAD study showing that varoglutamstat was well-tolerated at 600 mg BID.
- In November 2022, Vivoryon announced enrollment was completed and the study was adapted to enable longer average treatment duration of participants (anticipated average treatment duration ~82 weeks).
- In March 2023, Vivoryon announced an update on the clinical development of varoglutamstat, including the VIVIAD trial, at the International Conference on Alzheimer's and Parkinson's Diseases and related neurological disorders (AD/PD) in Gothenburg, Sweden. As of the data cut-off date of January 5, 2023, over 100 of the 259 participants randomized into the VIVIAD study had been treated for at least 48 weeks. Varoglutamstat showed no on-target toxicity and no clinical signs of brain swelling or hemorrhages (ARIA), which are a limiting class side effect of Abeta antibodies and has been well-tolerated in the study to date, with a low number of adverse events (AEs), serious adverse events (SAEs), and treatment emergent adverse events (TEAEs) observed. Both the total number of SAEs and the discontinuation rate were considerably lower than the respective numbers at the 800 mg BID varoglutamstat dose in Vivoryon's completed Phase 2a SAPHIR study, while retaining a similar level of target inhibition (around 90%) at the dosing in both studies.
- Vivoryon remains on track to report the final data readout from the VIVIAD study in the first quarter of 2024.

VIVA-MIND

VIVA-MIND (NCT03919162) is a complementary Phase 2 study for varoglutamstat conducted in the U.S. which seeks to enroll 180 patients with early AD into the Phase 2a adaptive dose finding portion and enroll a further 234 patients in the Phase 2b portion of the study.

- In November 2022, Vivoryon announced the study design had been adapted to enable all 180 patients to be treated for at least 72 weeks, allowing for the opportunity to



progress seamlessly to a potential Phase 3 study, possibly including further patients beyond the currently planned 414.

- In March 2023, Vivoryon provided an update on the VIVA-MIND study, which is ongoing and continuing to recruit patients at 18 sites across the U.S. The study's independent DSMB recently provided a unanimous recommendation to continue the study without modification. The Company anticipates a decision on final trial size following the data readout of the VIVIAD study.
- Vivoryon expects the first cohort to be fully randomized into the study within the second quarter of this year and plans to provide the next update on the VIVA-MIND study in the second half of 2023.

Preclinical Programs:

- At the AAIC (July 31 to August 4, 2022), Vivoryon presented preclinical data on the Company's N3pE amyloid-targeting molecules. The results underscore the unique potential of Vivoryon's N3pE amyloid-targeting therapeutic strategy in both mono- and combination therapy settings in AD. The data showed that a combination treatment of aducanumab and varoglutamstat achieves additive effect on Abeta pathology, indicating feasibility of dose reduction to improve safety of Abeta antibody-based AD treatments. This demonstrates the potential benefit of a combination therapy designed to simultaneously make use of two different and independent molecular N3pE-related mode of actions, small molecule based QPCT/L inhibition and anti-N3pE-immunotherapy. Additional data from murine analog of PBD-C06 highlight the differentiated safety profile vs. other anti-Abeta antibodies at N3pE amyloid-lowering concentrations.
- In October 2022, Nature Communications issued a joint publication of Vivoryon and Fraunhofer IZI and Monash University, Melbourne, Australia, titled, "Helical ultrastructure of the metalloprotease meprin α in complex with a small molecule inhibitor." The article outlined the protein's involvement in tissue homeostasis by influencing inflammation, immunity and extracellular matrix remodeling. Dysregulation of this protein family leads to many severe diseases, many of which are addressed by Vivoryon's pipeline, including acute kidney injury, inflammatory disease, in addition to some cancers. Deepening Vivoryon's understanding of meprin α 's structure will strongly support the Company's research and development program for selective and highly potent small molecule meprin inhibitors.

Corporate Development Highlights

- In February 2022, Vivoryon and its partner, Sincere Pharmaceutical Group Ltd ("Sincere"), announced that China's Center for Drug Evaluation (CDE) of National Medical Products Administration (NMPA) approved the Clinical Trial Application (CTA)

for varoglutamstat for the development in Greater China by Simcere. Simcere is fully responsible for the further development and marketing within Greater China region.

- In April 2022, Vivoryon announced that it had successfully completed a private placement by way of accelerated book building, raising gross proceeds of EUR 21 million. The Company placed 2,000,000 registered shares at an offering price of EUR 10.50 per share. The new shares were admitted to trading on Euronext Amsterdam on April 5, 2022.
- In June 2022, the Company expanded and diversified its Non-Executive Board with the appointments of Claudia Riedl, PhD and Samir Shah, MD.
- In September 2022, the Company entered into a private placement of 2,054,796 registered shares at an offering price of EUR 7.30 per share, resulting in gross proceeds of EUR 15 million. In addition, the investors have the option to purchase further shares which, if exercised in full, could raise up to an additional EUR 15 million. The private placement was supported by Vivoryon's longstanding investor Claus Christiansen and Kohlberg Kravis Roberts & Co. L.P. ("KKR") Dawn Aggregator L.P. ("Dawn Biopharma"), a platform controlled by affiliates of KKR, a leading global investment firm, as new investor to the Company. The private placement was closed in the fourth quarter of 2022 and the funds will support the ongoing clinical development of Vivoryon's lead candidate varoglutamstat.

Financial Results for the Full Year 2022

No **revenues** were generated in 2022. The Company generated license revenues of EUR 10.8 million in 2021 from a regional licensing partnership with Simcere for Greater China (Mainland China, Hong Kong, Macao and Taiwan).

Research and development expenses increased by EUR 2.8 million to EUR 20.2 million in the year ended December 31, 2022, compared to EUR 17.5 million in the year ended December 31, 2021. Third-party research and development services increased by EUR 2.5 million mainly because of EUR 1.5 million higher manufacturing costs following the Company's risk mitigation strategy in establishing a second source for study drug supply and higher clinical costs of EUR 1.0 million mainly due to the progress of the Phase 2b clinical trial VIVIAD. Other expenses increased by EUR 0.1 million as a result of higher traveling costs.

General and administrative expenses were EUR 8.9 million in 2022, compared to EUR 4.5 million in 2021. The increase of EUR 4.4 million was largely attributable to EUR 2.6 million in expensed capital raising costs, including legal and consulting fees associated with strategic and operational efforts. An additional EUR 1.7 million in costs was due to higher expenses for share based payments.

Net loss for the twelve months ended December 31, 2022, was EUR 28.2 million, compared to EUR 12.7 million for the twelve months ended December 31, 2021. The Company held



EUR 26.6 million in **cash and cash equivalents** as of December 31, 2022, compared to EUR 14.7 million as of December 31, 2021.

Financial Guidance

Following the capital raise settled in October 2022, according to current planning and estimates, Vivoryon expects that its existing cash and cash equivalents will be sufficient to fund its research and development expenses as well as the general and administrative expenses and cash flows from investing and financing activities at least through end of December 2023. This guidance does not include exercise of share options issued in October 2022, potential milestone payments from development partnerships, potential payments from licensing agreements and/or additional financing measures, as far as such payments have not yet been recognized in revenues. The financial guidance takes into account all costs to ensure sustainable study drug supply with varoglutamstat for the VIVA-MIND U.S. study.

Conference Call and Webcast

Vivoryon will host a conference call and webcast today, April 19, 2023, at 3:00 pm CEST (9:00 am EDT). A Q&A session will follow the presentation of the full year results.

A live webcast and slides will be made available at: www.vivoryon.com/investors-news/news-and-events/presentations-webcasts/

To join the conference call via phone, participants may pre-register and will receive dedicated dial-in details to easily and quickly access the call via the following website: <https://register.vevent.com/register/BI4258c63704394e8283359d44ef59a7ea>

It is suggested participants dial into the conference call 15 minutes prior to the scheduled start time to avoid any delays in attendance.

Approximately one day after the call, a slide-synchronized audio replay of the conference will be available on: www.vivoryon.com/investors-news/news-and-events/presentations-webcasts/

Vivoryon Therapeutics N.V. Financial Statements

Statement of Operations and Comprehensive Loss for the Years Ended December 31, 2022 and 2021

<i>in kEUR, except for share data</i>	<u>2022</u>	<u>2021</u>
Revenue	–	10,764
Cost of Sales	–	(1,569)
Gross profit	–	9,196
Research and development expenses	(20,224)	(17,452)
General and administrative expenses	(8,908)	(4,549)
Other operating income	19	7
Operating loss	(29,113)	(12,798)
Finance income	1,710	967
Finance expense	(952)	(392)
Finance result	758	575
Result before income taxes	(28,355)	(12,223)
Income taxes	199	(432)
Net loss for the period	(28,156)	(12,655)
Items not to be reclassified subsequently to profit or loss		
Remeasurement of the net defined benefit pension liability	392	83
Total other comprehensive income / (loss)	392	83
Comprehensive loss	(27,764)	(12,572)
Loss per share in EUR (basic and diluted)	(1.28)	(0.63)

The accompanying notes are an integral part of these financial statements.

Vivoryon Therapeutics N.V.

Statements of Financial Position as of December 31, 2022 and 2021

in kEUR	<u>2022</u>	<u>2021</u>
ASSETS		
Non-current assets		
Property, plant and equipment	49	66
Intangible assets	494	533
Right-of-use assets	127	219
Financial assets	14	3,473
Total non-current assets	<u>684</u>	<u>4,291</u>
Current assets		
Financial assets	3,716	3,074
Other current assets and prepayments	423	2,494
Cash and cash equivalents	26,555	14,661
Total current assets	<u>30,694</u>	<u>20,229</u>
TOTAL ASSETS	<u>31,378</u>	<u>24,520</u>
Equity		
Share capital	24,105	20,050
Share premium	113,382	83,211
Other capital reserves	9,656	6,168
Accumulated other comprehensive loss	(180)	(572)
Accumulated deficit	(120,457)	(92,300)
Total equity	<u>26,506</u>	<u>16,557</u>
Non-current liabilities		
Pension liability	1,323	1,823
Provisions long-term	12	12
Lease liabilities	38	132
Other liabilities	–	513
Deferred tax liabilities	234	432
Total non-current liabilities	<u>1,607</u>	<u>2,912</u>
Current liabilities		
Provisions	–	35
Trade payables	2,543	4,360
Lease liabilities	94	92
Other liabilities	628	564
Total current liabilities	<u>3,265</u>	<u>5,051</u>
Total liabilities	<u>4,872</u>	<u>7,963</u>
TOTAL EQUITY AND LIABILITIES	<u>31,378</u>	<u>24,520</u>

Vivoryon Therapeutics N.V. Statements of Changes in Shareholders' Equity for the Years Ended December 31, 2022 and 2021

<i>in kEUR</i>	Share capital	Share premium	Other capital reserves	Accumulated other comprehensive loss	Accumulated deficit	Total equity
January 1, 2021	19,975	82,143	4,404	(655)	(79,646)	26,221
Net loss for the period	—	—	—	—	(12,655)	(12,655)
Remeasurement of the net defined benefit pension liability	—	—	—	83	—	83
Comprehensive income / (loss)	—	—	—	83	(12,655)	(12,572)
Share-based payments	—	—	1,763	—	—	1,763
Proceeds from exercise of share options	75	1,069	—	—	—	1,144
December 31, 2021	20,050	83,211	6,168	(572)	(92,300)	16,557
Net loss for the period	—	—	—	—	(28,156)	(28,156)
Remeasurement of the net defined benefit pension liability	—	—	—	392	—	392
Comprehensive income / (loss)	—	—	—	392	(28,156)	(27,764)
Proceeds from the issuance of common shares	4,055	31,945	—	—	—	36,000
Transaction costs of equity transactions	—	(1,774)	—	—	—	(1,774)
Share-based payments	—	—	3,488	—	—	3,488
December 31, 2022	24,105	113,382	9,656	(180)	(120,457)	26,506

Vivoryon Therapeutics N.V. Statements of Cash Flows for the Years ended December 31, 2022 and 2021

<i>in kEUR</i>	<u>2022</u>	<u>2021</u>
Operating activities		
Net loss for the period	(28,156)	(12,655)
Adjustments for:		
Finance result	(758)	(575)
Depreciation and amortization	161	165
Share based payments	3,488	1,763
Capitalized capital raising costs that were expensed	2,633	–
Actuarial gains / (losses) from pension liabilities	392	83
Foreign currency gain (loss) from other items than cash	373	287
Deferred income tax	(199)	432
Other non-cash adjustments	61	(192)
Changing in		
Financial assets	2,817	(6,522)
Other current assets and prepayments	191	1,852
Pension liabilities	(500)	(158)
Provisions	(35)	–
Trade payables	(1,817)	3,449
Other liabilities	(449)	800
Interest received	9	21
Interest paid	(5)	(7)
Taxes paid	–	–
Cash flows used in operating activities	<u>(21,794)</u>	<u>(11,257)</u>
Investing activities		
Purchase of plant and equipment	(11)	(20)
Purchase of intangible assets	(2)	(8)
Cash flows used in investing activities	<u>(13)</u>	<u>(28)</u>
Financing activities		
Proceeds from the issuance of common shares	36,000	–
Transaction costs of equity transactions	(1,774)	–
Capital raising costs	(753)	(1,881)
Payment of lease liabilities	(92)	(90)
Proceeds from exercise of share options	–	1,144
Cash flows provided by /(used in) financing activities	<u>33,381</u>	<u>(827)</u>
Net decrease in cash and cash equivalents	<u>11,574</u>	<u>(12,112)</u>
Cash and cash equivalents at the beginning of period	14,661	26,306
Effect of exchange rate fluctuation on cash held	320	467
Cash and cash equivalents at the end of period	<u>26,555</u>	<u>14,661</u>



Annual Financial Report 2022

The financial statements of Vivoryon have been prepared in accordance with International Financial Reporting Standards (IFRS) of the International Accounting Standards Board, as adopted by the European Union (EU-IFRS) and with Section 2:362(9) of the Netherlands Civil Code. The auditor KPMG has issued an unqualified auditor's report for both statements. The reports are available on the Company's website www.vivoryon.com.

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About Vivoryon Therapeutics N.V.

Vivoryon is a clinical stage biotechnology company focused on developing innovative small molecule-based medicines. Driven by our passion for ground-breaking science and innovation, we strive to change the lives of patients in need suffering from severe diseases. We leverage our in-depth expertise in understanding post-translational modifications to develop medicines that modulate the activity and stability of proteins which are altered in disease settings. Beyond our lead program, varoglutamstat, which is in Phase 2 clinical development to treat Alzheimer's disease, we have established a solid pipeline of orally available small molecule inhibitors for various indications including cancer, inflammatory diseases and fibrosis. www.vivoryon.com

Vivoryon Forward Looking Statements

This press release includes forward-looking statements, including, without limitation, those regarding the business strategy, management plans and objectives for future operations of the Vivoryon Therapeutics N.V. (the "Company"), estimates and projections with respect to the market for the Company's products and forecasts and statements as to when the Company's products may be available. Words such as "anticipate," "believe," "estimate," "expect," "forecast," "intend," "may," "plan," "project," "predict," "should" and "will" and similar expressions as they relate to the Company are intended to identify such forward-looking statements. These forward-looking statements are not guarantees of future performance; rather they are based on the Management's current expectations and assumptions about future events and trends, the economy and other future conditions. The forward-looking statements involve a number of known and unknown risks and uncertainties. These risks and uncertainties and other factors could materially adversely affect the outcome and financial effects of the plans and events described herein. Actual results, performance or events may differ materially from those expressed or implied in such forward-looking statements and from expectations. As a result, no undue reliance should be placed on such forward-looking statements. This press release does not contain risk factors. Certain risk factors that may affect the Company's future financial results are discussed in the published annual financial statements of the Company. This press release, including any forward-looking statements, speaks only as of the date of this press release. The Company does not assume any obligation to update any information or forward-looking statements contained herein, save for any information required to be disclosed by law.



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