Vivoryon Therapeutics N.V. Reports H1 2022 Financial Results and Highlights Operational Progress

HALLE (SAALE) / MUNICH, GERMANY, September 30, 2022 – 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 reported financial results for the first six months of 2022 and provided an update on clinical and corporate progress. The report is available on the Company's website at https://www.vivoryon.com/investors-news/financial-information/.

"The first half of 2022 was marked by decisive progress in the development of our lead candidate varoglutamstat in AD, which cumulated in several data presentations at the prestigious AAIC 2022 in San Diego in July and August," said Dr. Ulrich Dauer, CEO of Vivoryon. "Firstly, we have been able to further de-risk clinical development of varoglutamstat with extremely encouraging safety results from our VIVIAD Phase 2b study. At the same time, adding to the preclinical data package by characterizing the additive effect of varoglutamstat in combination with anti-Abeta antibodies, we continue to explore the full potential for its application in a variety of therapeutic settings. These data, which have sparked excitement within the medical community and beyond, substantiate our commitment to making a difference to all those affected by Alzheimer's disease. Having secured a significant private placement will enable us to continue to follow our carefully crafted development strategy. We warmly welcome our new investor KKR Dawn Aggregator L.P. and are very grateful to them and to our longstanding investor Claus Christiansen for their support through the upcoming clinical milestones."

Portfolio Highlights (H1 2022 and post-period)

VIVIAD

- VIVIAD (NCT04498650) is a state-of-the-art Phase 2b study 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).
- On June 23, 2022, Vivoryon announced that it has completed the parallel group, dose-finding part of its VIVIAD study and that the independent Data Safety Monitoring Board (DSMB) has selected the highest dose investigated, 600 mg twice daily (BID), as the final dose to be administered in the second part of the study. The DSMB decision is based on safety data from 181 patients, 90 of which had completed the week 24 treatment visit at the May 17 cut-off date. All subjects randomized to the treatment arm will be treated at the selected dose of 600 mg BID moving forward and will continue treatment for up to 48-96 weeks dependent on study entry date.
- Vivoryon presented detailed safety data from the VIVIAD study at the Alzheimer's Association International Conference (AAIC) in San Diego (July 31 to August 4, 2022). The safety data showed that varoglutamstat was well tolerated with only 14% of overall reported adverse events (AEs) considered to be potentially related to study treatment. All of the AEs were gastrointestinal, general, or related to the nervous system or skin.

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Only four patients (2.2%) experienced serious AEs (SAEs) and only two patients (1.1%) discontinued the study. 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 (NCT02389413; 15% SAEs, 33% discontinuation), while retaining a similar level of target inhibition.
- VIVIAD is actively enrolling patients at 22 study centers in five European countries and will continue to evaluate its primary and secondary outcome measures, which include multiple cognitive, safety and biomarker endpoints. Vivoryon remains on track for final data readout for the study in the second half of 2023.

VIVA-MIND

- VIVA-MIND (NCT03919162) is a combined Phase 2a/b study for varoglutamstat conducted in the U.S. which seeks to enroll 180 patients with early AD into the Phase 2a adaptive dose finding part. If predefined criteria are fulfilled, the trial will pass a stage-gate into the Phase 2b part, enrolling an additional 234 patients treated at the selected dose for at least 72 weeks. Thus, taken together a total of 414 patients will be treated on stable doses of varoglutamstat for 18 months in the course of the study. The primary endpoint for this study is CDR-SB (clinical dementia rating scale – sum of boxes), an established approvable endpoint measuring a combination of cognitive abilities and activities of daily living. The study is coordinated by the Alzheimer's Disease Cooperative Study (ADCS), and supported by a USD15 million grant from the National Institute on Aging (NIA award number R01AG061146).
- VIVA-MIND is actively enrolling patients, with currently 14 sites open and on track for an interim futility analysis planned for the first half of 2023.

Preclinical Programs

- Also at AAIC 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 show, 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.

Partnered Programs

- On February 28, 2022, Vivoryon and its partner Simcere announced that China's Center for Drug Evaluation (CDE) of National Medical Products Administration (NMPA) has approved the Clinical Trial Application for varoglutamstat for the development in Greater China by Simcere. Simcere has communicated that the company is currently preparing for initiation of clinical studies in China.

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Corporate Development Highlights (H1 2022 and post-period)

- On September 30, 2022, the Company entered into a private placement of 2,054,796 registered shares at an offering price of EUR 7.30 per share. The new shares from the capital increase represent 9.3% of Vivoryon's existing share capital and will be issued from the Company's authorized capital under exclusion of the existing shareholders' pre-emptive rights. Consequently, the Company's issued share capital will increase to EUR 24,105,278.00 on completion of the private placement. In addition, the investors will have the option to purchase, in aggregate, up to another 2,054,796 registered shares at a price of EUR 7.30 during a period ending twelve months after the date of the approval of a EU Recovery prospectus (in accordance with Section 14a Prospectus Regulation) or three months after the achievement date of a defined clinical milestone, whichever is later. The gross proceeds of the private placement amount to EUR 15.0 million, and up to an additional EUR 15.0 million will be raised if the option to purchase the additional shares is exercised in full. Vivoryon intends to use the net proceeds from the offering to support the ongoing clinical development of its lead candidate varoglutamstat, currently in Phase 2 in Europe and the United States for the treatment of patients with Alzheimer's disease, as well as for general corporate purposes. The private placement was supported by Vivoryon's longstanding investor Claus Christiansen and KKR Dawn Aggregator L.P. ("Dawn Biopharma"), a platform controlled by affiliates of Kohlberg Kravis Roberts & Co. L.P. ("KKR"), a leading global investment firm, as new investor to the Company. Completion of the private placement is expected to occur on October 6, 2022.
- In an in-person and webcasted breakfast and networking event at AAIC 2022, held on August 2, 2022, Vivoryon met with researchers, clinicians and the investment community to discuss the future of AD treatments and provided updates on its VIVA-MIND and VIVIAD studies for varoglutamstat. The event also featured spotlight presentations by Prof. Howard Feldman, MD, Professor of Neurosciences and Director of the ADCS at UC San Diego and VIVA-MIND study director, Cynthia Lemere, PhD, Associate Professor of Neurology, Ann Romney Center for Neurologic Diseases, Brigham and Women's Hospital, Harvard Medical School, Boston and Dr. Frank Weber, CMO of Vivoryon.
- On June 22, 2022, Vivoryon held its Annual General Meeting where all voting items were approved with a large majority. Voting items included the re-appointment of Charlotte Lohmann, Dr. Erich Platzer, Dr. Dinnies von der Osten and Dr. Jörg Neermann as members of the Company's Non-Executive Board, as well as the appointment of Dr. Claudia Riedl and Samir Shah, MD, to its Non-Executive Board of Directors.
- On April 1, 2022 Vivoryon announced the successful completion of a private placement, raising gross proceeds of EUR 21 million, with net proceeds from the offering intended to be used to support the ongoing clinical development of varoglutamstat, as well as for general corporate purposes. The capital raise was supported by a number of high-quality institutional investors from Europe and the U.S. as well as members of Vivoryon's Executive and Non-Executive Boards.

Financial Results for the First Half Year 2022

The Company generated no license revenues or smaller revenue in half year 2022 or 2021.

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Research and development expenses increased in 2022 by EUR 1.6 million compared to the six months ended June 30, 2021. This increase is primarily attributable to EUR 1.7 million higher expenses related to our clinical trial VIVIAD, which has advanced significantly compared to the six months ended June 30, 2021.

General and administrative expenses for the six months ended June 30, 2022 are about the same level as for the six months ended June 30, 2021. Higher expenses for share based payments with EUR 0.3 million were compensated by EUR 0.3 million lower expenses for legal and consulting services.

Net loss for the six months ended June 30, 2022 was EUR 12.6 million, compared to EUR 11.7 million for the six months ended June 30, 2021. The Company held EUR 24.4 million in cash and cash equivalents as of June 30, 2022, compared to EUR 14.7 million as of December 31, 2021.

Cash flows provided from financing activities were EUR 19.6 million for the six months ended June 30, 2022 compared to cash used in financing activities of EUR 0.5 million in the six months ended June 30, 2021. The change mainly relates to a private placement on April 1, 2022 by way of accelerated book building, placing 2,000,000 registered shares at an offering price of EUR 10.50 per share. The Company's issued share capital has increased to EUR 22,050,482. The gross proceeds of the offering amounted to EUR 21.0 million.

Financial Guidance

Including the proceeds from the private placement entered into on September 30, 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 the general and administrative expenses and cash flows from investing and financing activities at least through December 2023. This does not include the exercise of the option to acquire up to an additional 2.054.796 shares for a period ending the later of twelve months after the date of the approval of a EU Recovery prospectus (in accordance with Section 14a Prospectus Regulation) or the achievement date of a defined clinical milestone.

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Vivoryon Therapeutics N.V. Financial Statements
Condensed Statements of Profit or Loss and Other Comprehensive Income for the six months ended June 30, 2022 and 2021

in kEUR, except for share data	For the six months ended June 30, 2022	2021
Research and development expenses	(11,067)	(9,456)
General and administrative expenses	(2,311)	(2,337)
Other operating income	—	5
Operating loss	**(13,378)**	**(11,788)**
Finance income	**989**	219
Finance expenses	**(105)**	(102)
Finance result	**884**	**117**
Result before income taxes	**(12,494)**	**(11,671)**
Income taxes	(89)	—
Net loss for the period	**(12,583)**	**(11,671)**
Items not to be reclassified subsequently to profit or loss		
Remeasurement of the net defined benefit pension liability	261	—
Total other comprehensive income / (loss)	261	—
Comprehensive loss	**(12,322)**	**(11,671)**
Loss per share in EUR (basic and diluted)	(0.60)	(0.58)

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

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Vivoryon Therapeutics N.V.
Condensed Statements of Financial Position

in kEUR	June 30, 2022	December 31, 2021
ASSETS		
Non-current assets		
Intangible assets	512	533
Property, plant and equipment	54	66
Right-of-use assets	173	219
Financial assets	14	3,473
Total non-current assets	**753**	**4,291**
Current assets		
Financial assets	3,812	3,074
Other current assets and prepayments	2,795	2,494
Cash and cash equivalents	24,383	14,661
Total current assets	**30,990**	**20,229**
TOTAL ASSETS	**31,743**	**24,520**
Equity		
Share capital	22,050	20,050
Share premium	101,181	83,211
Other capital reserves	7,200	6,168
Accumulated other comprehensive loss	(311)	(572)
Accumulated deficit	(104,883)	(92,300)
Total equity	**25,237**	**16,557**
Non-current liabilities		
Pension liability	1,505	1,823
Provisions long-term	12	12
Lease liabilities	86	132
Other liabilities	—	513
Deferred tax liabilities	521	432
Total non-current liabilities	**2,124**	**2,912**
Current liabilities		
Provisions	35	35
Trade payables	3,681	4,360
Lease liabilities	93	92
Other liabilities	573	564
Total current liabilities	**4,382**	**5,051**
Total Liabilities	**6,506**	**7,963**
TOTAL EQUITY AND LIABILITIES	**31,743**	**24,520**

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Vivoryon Therapeutics N.V.
Statements of Changes in Shareholders' Equity for the six months ended June 30, 2022 and 2021

(in kEUR)	Share capital	Share premium	Other capital reserves	Accumulated other Compre-hensive loss	Accumulated deficit	Total equity
January 1, 2022	**20,050**	**83,211**	**6,168**	**(572)**	**(92,300)**	**16,557**
Net loss for the period	–	–	–	–	(12,583)	(12,583)
Remeasurement of the net defined benefit pension liability	–	–	–	261	–	261
Comprehensive income / (loss)	**–**	**–**	**–**	261	**(12,583)**	**(12,322)**
Proceeds from the issuance of common shares	2,000	19,000	–	–	–	21,000
Transaction costs of equity transactions	–	(1,030)	–	–	–	(1,030)
Share-based payments	–	–	1,032	–	–	1,032
June 30, 2022	**22,050**	**101,181**	**7,200**	**(311)**	**(104,883)**	**25,237**
January 1, 2021	**19,975**	**82,143**	**4,404**	**(655)**	**(79,646)**	**26,221**
Net loss for the period	–	–	–	–	(11,671)	(11,671)
Comprehensive loss	**–**	**–**	**–**	**–**	**(11,671)**	**(11,671)**
Share-based payments	–	–	920	–	–	920
June 30, 2021	**19,975**	**82,143**	**5,325**	**(655)**	**(91,317)**	**15,471**

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Vivoryon Therapeutics N.V.
Condensed Statements of Cash Flows

(in kEUR)	For the six months ended June 30, 2022	2021
Operating activities		
Result before income taxes	(12,494)	(11,671)
Adjustments for:		
Finance result	(884)	(117)
Depreciation and amortization	81	82
Share based payments	1,032	921
Other non-cash adjustments	764	(10)
Changing in:		
Financial assets	2,721	(660)
Other current assets and prepayments	44	1,302
Pension liabilities	(318)	(40)
Provisions	—	—
Trade payables	(679)	4,076
Other liabilities	(504)	49
Interest received	3	4
Interest paid	(3)	(9)
Cash flows used in operating activities	**(10,237)**	**(6,072)**
Investing activities		
Purchase of plant and equipment	(2)	(16)
Purchase of intangible assets	—	(8)
Cash flows used in investing activities	**(2)**	**(24)**
Financing activities		
Proceeds from the issuance of common shares	21,000	—
Capital raising costs	(1,374)	(468)
Payment of lease liabilities	(46)	(45)
Cash flows provided by / (used in) financing activities	**19,581**	**(513)**
Net decrease in cash and cash equivalents	**9,342**	**(6,609)**
Cash and cash equivalents at the beginning of period	14,661	26,306
Effect of exchange rate fluctuation on cash held	380	135
Cash and cash equivalents at end of period	**24,383**	**19,832**

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Half Year Financial Report 2022
The condensed interim financial statements of Vivoryon have been prepared in accordance with IAS 34 Interim Financial Reporting and International Financial Reporting Standards (IFRS) of the International Accounting Standards Board, as adopted by the European Union (EU-IFRS). The half-year financial statements were not audited or reviewed. The reports are available on the Company's website www.vivoryon.com.

Conference Call and Webcast
Vivoryon will host a conference call and webcast today, September 30, 2022, at 3:00 pm CEST (9:00 am EDT). A Q&A session will follow the presentation of the full year results.

Please dial one of the following access numbers:
From Germany: +49 (0)69 22222 5197
From The Netherlands: +31 (0)20 703 8218
From Switzerland: +41 (0)44 580 7279
From UK: +44 (0)330 165 4012
From the U.S.: +1 646 828 8143

Access Code: *8323708*

Please dial in ten minutes prior to commencement.
A live webcast and slides will be made available at: www.vivoryon.com/investors-news/news-and-events/presentations-webcasts/

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/

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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

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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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