



Vivoryon Therapeutics N.V. Reports H1 2021 Financial Results and Operational Progress

- Strategic regional licensing partnership with Simcere Pharmaceutical Group to treat AD in Greater China
- US Phase 2 VIVA-MIND study for varoglutamstat in AD initiated as planned
- Conference call and webcast scheduled for September 21, 2021 at 3:00 pm CEST / 9:00 am EDT

Halle (Saale) / Munich, Germany, September 21, 2021 – Vivoryon Therapeutics N.V. (Euronext Amsterdam: VVY; NL00150002Q7) (**Vivoryon**), a clinical stage company focused on 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 2021 and provided an update on clinical and corporate progress.

"In the first half of 2021, we made significant progress towards bringing our lead candidate varoglutamstat to patients suffering from Alzheimer's disease. Despite the ongoing pandemic, recruiting into our European Phase 2b study VIVIAD is on track and we're particularly excited about the initiation of our complementary Phase 2 study VIVA-MIND in the US. Furthermore, by entering into a strategic regional partnership with Simcere, we have made substantial headway towards making varoglutamstat available to AD patients in China in the future," said Dr. Ulrich Dauer, CEO of Vivoryon. "Beyond AD, we are pleased to see our diverse preclinical pipeline of oral small molecule inhibitors maturing in a number of indications with exceptionally high medical need."

Corporate Highlights and R&D Updates

Varoglutamstat

- Vivoryon's US Phase 2a/b VIVA-MIND study for varoglutamstat in patients with early AD is being initiated as planned. VIVA-MIND is a combined Phase 2a/b study expecting to enroll 180 patients into the Phase 2a adaptive dose finding part, with an interim futility analysis planned for H1/2023. If predefined criteria are fulfilled, the trial is stage-gated into the Phase 2b part, enrolling an additional 234 patients treated at the selected dose for ≥ 72 weeks. 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 VIVA-MIND study is sponsored by Vivoryon and the study director is Dr. Howard Feldman, Professor of Neurosciences and Director of the Alzheimer's Disease Cooperative Study (ADCS) at the University of California San Diego School of Medicine. The study is coordinated by the ADCS, and supported by the National Institute on Aging (NIA), part of the National Institutes of Health (NIH) (NIA award number R01AG061146). The study's first site is now approved to initiate screening of its first participant.
- On June 29, 2021, Vivoryon and Simcere Pharmaceutical Group Ltd announced that they have entered into a strategic regional licensing partnership to develop and commercialize medicines targeting the neurotoxic amyloid species N3pE (pGlu-Abeta)



to treat AD in Greater China. The agreement grants Simcere a regional license to develop and commercialize varoglutamstat (PQ912), Vivoryon's Phase 2b-stage N3pE amyloid-targeting oral small molecule glutaminy cyclase (QPCT) inhibitor with disease-modifying potential for AD, as well as the Company's preclinical monoclonal N3pE-antibody PBD-C06 in the Greater China region.

- Enrollment into the ongoing European Phase 2b VIVIAD study in patients with mild cognitive impairment (MCI) and mild AD is on track, with an interim safety readout anticipated in mid-2022. A number of additional study centers were opened to balance the effects of COVID-19 related patient and staff protection policies implemented at German study sites. Details on the study led by Prof. Dr. Philip Scheltens, University Medical Center, Amsterdam, were recently published in a peer-reviewed journal as *Vijverberg et al., Alzheimer's Research & Therapy (2021) 13:142* (<https://doi.org/10.1186/s13195-021-00882-9>).

Patent Portfolio

- Throughout the first half of 2021, Vivoryon has significantly expanded its patent portfolio with eight additional patents granted for the Company's small molecule inhibitors and antibody-based medicines in development to treat AD and other diseases with exceptionally high medical need. Year to date (as of September 21, 2021) a total of 14 additional patents have been granted.

Corporate Developments

- On June 28, 2021, Vivoryon held its 2021 Annual General Meeting as a virtual event. All items presented for resolution by the Board of Directors were approved with a large majority and can be found on the Company's website.
- On April 15, 2021, Vivoryon hosted a virtual event covering next steps in AD treatment options with leaders and experts in the field. The interactive session covered discussions surrounding current hurdles and exciting, novel approaches to the challenging AD space, including varoglutamstat, the Company's small molecule inhibitor of QPCT designed to target all three hallmarks of AD: amyloid-beta, tau, and neuroinflammation.
- On April 1, 2021, Florian Schmid joined Vivoryon as Chief Financial Officer. He joined the Company from InflaRx, where he served as Director Finance & Controlling. Prior to Vivoryon Mr. Schmid led the Global Deal & Business Support department at T-Systems International GmbH. He began his career as certified Tax Advisor and Public Accountant at Arthur Andersen and Ernst & Young. Mr. Schmid holds a business degree from the Ludwig-Maximilian-University, Munich.

Financial Results for the First Six Months of 2021

In the first two quarters of 2021, **research and development expenses** amounted to EUR 9,456 k (H1 2020: EUR 6,380 k). This increase was mainly driven by higher expenses for production (H1 2021: EUR 4,194 k, H1 2020: EUR 1,876 k), expenses for share-based payments (H1 2021: EUR 464 k, H1 2020: EUR 3 k) and higher costs associated with basic



research projects in connection with Meprin (H1 2021: EUR 220 k, H1 2020: nil) and cancer (H1 2021: EUR 162 k, H1 2020: nil).

General and administrative expenses increased to EUR 2,337 k (H1 2020: EUR 1,138 k). This increase is largely attributable to costs for consulting (H1 2021: EUR 1,030 k, H1 2020: EUR 481 k) and expenses for share based payments (2021: EUR 464 k, 2020: nil). The increase in consulting costs resulted from the transformation of the Company's legal form, subsequent adaptation of administrative structures and preparations for potential future capital measures.

The Company did not generate any **licensing revenues** in the reporting period. Revenues deriving from the strategic regional licensing partnership with Simcere will be recognized starting in the third quarter of 2021.

Net loss of the period was EUR 11,671 k compared to EUR 7,572 k in the first half of 2020. The Company held EUR 19,832 k in cash and cash equivalents as of June 30, 2021, compared to EUR 26,306 k as of December 31, 2020.

Conference Call and Webcast

Vivoryon will host a conference call and webcast today, September 21, 2021, at 3:00 pm CEST / 9:00 am EDT. A Q&A session will follow the presentation of the half year results.

Please dial one of the following access numbers:

From Germany: +49 69 201 744 220

From The Netherlands: +31 207 168 020

From UK: +44 20 30 092 470

From the US: +18 774 230 830

PIN Code: 53651371#

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/.

The statement for the first six months of 2021 is available on the Company's website www.vivoryon.com/investors-news/financial-information.

Vivoryon Therapeutics N.V.
Condensed Statements of Profit or Loss and Other Comprehensive Income

(in EUR thousand, except for share data)	For the six months ended June 30,	
	2021	2020
Operating Expenses		
Research and development expenses	9,456	6,380
General and administrative expenses	2,337	1,138
Total Operating Expenses	11,793	7,518
Other income	(5)	(38)
Operating loss	11,788	7,480
Finance income	(219)	—
Finance expenses	102	92
Finance result	(117)	92
Loss for the Period	11,671	7,572
Share Information		
Weighted average number of shares outstanding	19,975,482	19,975,482
Loss per share (basic/diluted)	(0.58)	(0.38)
Loss for the Period	11,671	7,572
Items not to be reclassified subsequently to profit or loss:		
Remeasurement of the net defined benefit pension liability	—	20
Total Comprehensive Loss	11,671	7,592

Vivoryon Therapeutics N.V.
Condensed Statements of Financial Position

(in EUR thousand)	June 30, 2021	December 31, 2020
ASSETS		
Non-current assets		
Property, plant and equipment	343	390
Intangible assets	553	565
Financial assets	14	3
Total non-current assets	910	958
Current assets		
Other assets	1,631	2,466
Financial assets	667	21
Cash and cash equivalents	19,832	26,306
Total current assets	22,130	28,793
TOTAL ASSETS	23,041	29,751
EQUITY AND LIABILITIES		
Equity		
Share capital	19,975	19,975
Share premium	82,143	82,143
Other capital reserves	5,324	4,404
Accumulated other comprehensive loss	(655)	(655)
Accumulated deficit	(91,316)	(79,646)
Total equity	15,471	26,221
Non-current liabilities		
Post-employment benefits	1,940	1,981
Provisions long-term	12	–
Lease liabilities long-term	179	224
Trade payables	168	–
Total non-current liabilities	2,299	2,205
Current liabilities		
Provisions	35	47
Trade payables	4,988	911
Lease liabilities	91	90
Other liabilities	157	276
Total current liabilities	5,271	1,325
Total Liabilities	7,570	3,530
TOTAL EQUITY AND LIABILITIES	23,041	29,751

Vivoryon Therapeutics N.V.
Statements of Changes in Shareholders' Equity
for the six months ended June 30, 2021 and 2020

(in EUR thousand, except for share data)	<u>Shares out- standing</u>	<u>Share capital</u>	<u>Share pre- mium</u>	<u>Other capital reserve s</u>	<u>Accu- mulated deficit</u>	<u>Accumu- lated other compre- hensive loss</u>	<u>Total equity</u>
Balance as of January 1, 2021	19,975,482	19,975	82,143	4,404	(79,646)	(655)	26,221
Loss for the period	–	–	–	–	(11,671)	–	(11,671)
Remeasurement of the net defined benefit pension liability	–	–	–	–	–	–	–
Total comprehensive loss	–	–	–	–	(11,671)	–	(11,671)
Contributions							
Equity-settled share-based payments	–	–	–	920	–	–	920
Total Contributions	–	–	–	920	–	–	920
Balance as of June 30, 2021	19,975,482	19,975	82,143	5,325	(91,317)	(655)	15,471
Balance as of January 1, 2020	19,975,482	19,975	82,143	4,245	(63,136)	(562)	42,665
Loss for the period	–	–	–	–	(7,572)	–	(7,572)
Remeasurement of the net defined benefit pension liability	–	–	–	–	–	(20)	(20)
Total comprehensive loss	–	–	–	–	(7,572)	(20)	(7,592)
Contributions							
Equity-settled share-based payments	–	–	–	3	–	–	3
Total Contributions	–	–	–	3	–	–	3
Balance as of June 30, 2020	19,975,482	19,975	82,143	4,247	(70,708)	(582)	35,075

Vivoryon Therapeutics N.V.
Condensed Statements of Cash Flows for the six months
ended June 30, 2021 and 2020

(in EUR thousand)	For the six months ended June 30, 2021 (unaudited)	For the six months ended June 30, 2020 (unaudited)
Operating activities		
Loss for the period	(11,671)	(7,572)
Adjustments for:		
Finance result	(117)	92
Depreciation and amortization of property, plant, equipment, right-of-use assets and intangible assets	83	67
Share-based payment expense	920	3
Other non-cash adjustments	(9)	0
Changes in:		
Other assets	834	1,105
Other financial assets	(660)	309
Pension liabilities	(40)	(40)
Trade and other payables	4,125	(313)
Interest paid	(9)	(4)
Interest received	4	—
Net cash used in operating activities	(6,540)	(6,353)
Investing activities		
Purchase of intangible assets, laboratory and office equipment	(24)	(574)
Net cash from/ (used in) investing activities	(24)	(574)
Financing activities		
Repayment of lease liabilities	(45)	(45)
Net cash from/ (used in) financing activities	(45)	(45)
Net decrease in cash and cash equivalents	(6,609)	(6,972)
Effect of exchange rate changes on cash and cash equivalents	135	(81)
Cash and cash equivalents at beginning of period	26,306	41,524
Cash and cash equivalents at end of period	19,832	34,471



For more information, please contact:

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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

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. This press release does not constitute an offer to sell or a solicitation of an offer to buy any securities of the Company in any jurisdiction.