

Buy EUR 41.00 Price EUR 11.40 Upside 259.6 %	Value Indicators: EUR SotP: 41.34	Warburg ESG Risk Score: 3.0 ESG Score (MSCI based): 2.0 Balance Sheet Score: 5.0 Market Liquidity Score: 2.0	Description: Biotech company that develops potential Alzheimer's disease treatment varoglutamstat
	Market Snapshot: EUR m Market cap: 251.37 No. of shares (m): 22.05 EV: 249.28 Freefloat MC: 93.01 Ø Trad. Vol. (30d): 383.62 th	Shareholders: Freefloat 37.00 % Den Danske Forskningsfond 8.00 % C. Christiansen 17.00 % T&W Holding 10.00 % KKR & Co 9.00 %	Key Figures (WRe): 2022e Beta: 1.5 Price / Book: 10.2 x Equity Ratio: 76 %

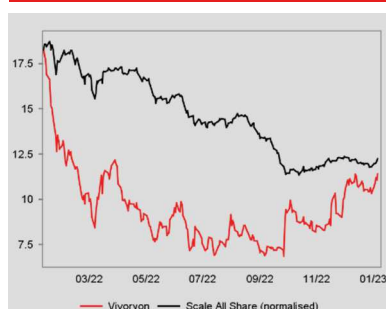
Alzheimer's: let's try something a little different - Initiation with Buy

We initiate coverage of Vivoryon Therapeutics N.V. (VYV). VYV is a clinical stage biotech company that is developing varoglutamstat, a Phase IIb small molecule asset as a potential disease-modifying treatment of Alzheimer's disease. Alzheimer's disease is an ultimately deadly, neurodegenerative disease of the central nervous system that leads to progressive deterioration of cognitive performance and memory and is, as yet, incurable (five established drugs on the market address symptoms only). Alzheimer's occurs mainly in older patients and represents a significant economic and social burden for the respective societies. It is estimated that currently some 6m patients in the US and around 9m in the EU27+UK are affected by Alzheimer's disease. Market analysts forecast the potential revenue of the global Alzheimer's market at USD 25bn in 2029. Varoglutamstat is a small molecule with a favourable safety profile that has already demonstrate positive very early stage efficacy data in slowing down the decline of cognitive performance of affected patients.

While many other drugs that set out to combat Alzheimer's have failed, VYV is going down a different road by attacking an earlier stage of the potential cause of the disease. Varoglutamstat inhibits the formation of highly neurotoxic and neuroinflammatory N3pE-Aβeta species that ultimately promote the formations of amyloid oligomers, fibrils and plaques which are thought to be one of the potential causes of the disease. Following many clinical developmental failures over the recent years (most recently Aduhelm from Biogen) the positive data release of **lecanemab**, which showed a 27% reduction in cognitive decline, followed by its approval, has reinvigorated the Alzheimer's space and investor interest.

In line with this sentiment, VYV was able to raise EUR 36m (plus an optional further 15m) in fresh capital last year to continue its ongoing Phase II trials VIVIAD in the EU and VIVA-MIND in the US. With anchor investor Claus Christiansen and the KKR Dawn fund, VYV has the necessary financial backing until the end of 2023 (not including the optional 15m). Phase IIb readout for the EU VIVIAD study on varoglutamstat is expected in first quarter of 2024 and would, if successful, generate enough attention to attract a commercial pharma company to ultimately finish the US Phase IIa study in 2024. Given the huge market opportunity and unmet medical need, we view VYV as an attractive investment for investors with the according risk/reward profile.

We initiate our coverage with a price target of **EUR 41.00 and a Buy recommendation**. In our opinion, VYV and by extension its clinically most advanced asset varoglutamstat is an overlooked, highly attractive investment to potentially participate in the exceedingly attractive market for Alzheimer's disease.

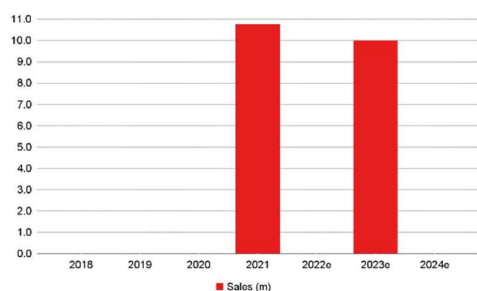


Rel. Performance vs Scale All	
1 month:	4.4 %
6 months:	58.6 %
Year to date:	6.7 %
Trailing 12 months:	-5.5 %

Company events:

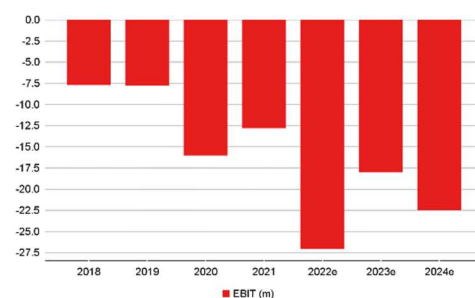
FY End: 31.12. in EUR m	CAGR (21-24e)	2018	2019	2020	2021	2022e	2023e	2024e
Sales	-	0.00	0.00	0.00	10.76	0.00	10.00	0.00
Change Sales yoy	-	n.a.	n.a.	n.a.	n.a.	-100.0 %	n.a.	-100.0 %
Gross profit margin	-	n.a.	n.a.	n.a.	85.4 %	n.a.	90.0 %	n.a.
EBITDA	-	-7.71	-7.78	-16.03	-12.81	-27.07	-18.00	-22.51
Margin	-	n.a.	n.a.	n.a.	-119.0 %	n.a.	-180.0 %	n.a.
EBIT	-	-7.71	-7.78	-16.03	-12.81	-27.07	-18.00	-22.51
Margin	-	n.a.	n.a.	n.a.	-119.0 %	n.a.	-180.0 %	n.a.
Net income	-	-7.75	-7.94	-16.62	-12.58	-27.57	-18.50	-23.01
EPS	-	-0.94	-0.63	-0.83	-0.63	-1.25	-0.77	-0.91
EPS adj.	-	-0.94	-0.63	-0.83	-0.63	-1.25	-0.77	-0.91
DPS	-	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Dividend Yield	-	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
FCFPS	-	-0.85	-0.92	-0.73	-0.57	-1.25	-0.89	-0.80
FCF / Market cap	-	-13.4 %	-20.5 %	-14.3 %	-3.3 %	-11.0 %	-7.8 %	-6.7 %
EV / Sales	-	n.a.	n.a.	n.a.	30.0 x	n.a.	27.3 x	n.a.
EV / EBITDA	-	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
EV / EBIT	-	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
P / E	-	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
P / E adj.	-	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
FCF Potential Yield	-	-15.4 %	-46.3 %	-20.7 %	-4.1 %	-11.9 %	-6.6 %	-7.5 %
Net Debt	-	-1.93	-39.26	-24.03	-15.61	-23.59	-2.09	2.92
ROCE (NOPAT)	-	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Guidance:	Sufficient cash to fund R&D and operations at least until December 2023							

Sales development in EUR m



Source: Warburg Research

EBIT development in EUR m



Source: Warburg Research

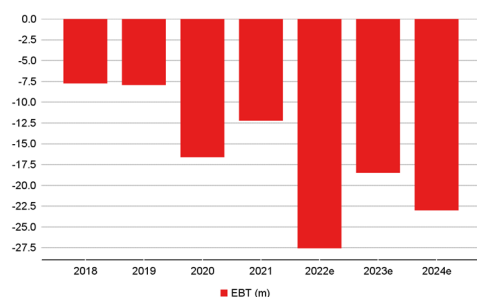
Company Background

- Vivoryon Therapeutics is a biotech company based in Halle and Munich (Germany) focusing on the development of drugs for the treatment of age-related diseases such as Alzheimer's disease (AD) and cancer.
- Vivoryon developed varoglutamstat a QPCT/L-inhibitor that is currently under Phase II evaluation for the treatment of early-stage Alzheimer's disease
- Vivoryon has an extensive portfolio (60+ APIs) of patented inhibitors of glutaminy-peptide-cyclotransferase (QPCT) and glutaminy-peptidecyclotransferase-like enzymes (QPCTL).
- Vivoryon is backed by two major strategic investors: Claus Christiansen (founder of Nordic Bioscience) and KKR

Competitive Quality

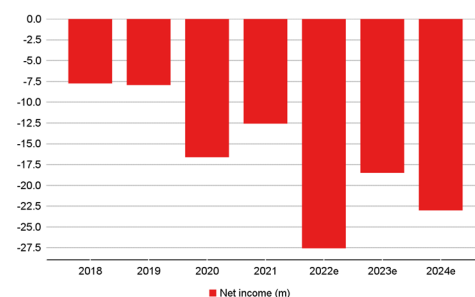
- Varoglutamstat inhibits the formation of this highly reactive amyloid beta protein species and thus differs significantly from previous attempts to combat AD causally
- Varoglutamstat showed a very encouraging safety profile during the first safety interim analysis of the ongoing EU trial which outperforms current best-in-class treatments

EBT development in EUR m



Source: Warburg Research

Net income development in EUR m



Source: Warburg Research

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Summary of Investment Case

Investment triggers

- Donanemab's data readout, which is expected in H1 2023
- Final trial data of varoglutamstat EU study VIVIAD in Q1 2024 for efficacy and safety
- Final commercial price-setting of lecanemab (brand name Leqembi) following its approval (priced initially at USD 27k pa by Eisai)

Valuation

- Valuation based on varoglutamstat's EU27+UK and USA market potential
- Base-case scenario: market entry in 2028/2029: rNPV EUR 1,060m
- Bull-case scenario: market entry in 2026/2027: rNPV EUR 1,190m
- rNPV valuation of VVY: EUR 1,083m or EUR 41.34 per share
- Value Simcere option: EUR 201m (Base Case) or EUR 251m (Bull Case)

Growth

- Between the EU27+UK, USA and China, the global patient population of Alzheimer's disease amounts to 29.3m patients who continue to suffer from progressive cognitive decline, ultimately leading to death.
- With lecanemab's approval by the FDA, the first potentially disease-modifying treatment for Alzheimer's disease has been given the green light but there is still sufficient opportunity for efficacy and safety improvements by other drug makers such as VVY

Competitive quality

- Varoglutamstat showed encouraging very early efficacy data to slow the progression of cognitive decline and also displays a superior safety profile compared to Alzheimer's drugs based on the principle of β -amyloid clearing (such as Aduhelm or lecanemab)
- The VIVIAD and VIVA-MIND studies are set up in a complementary manner to generate a comprehensive dataset and display a potentially convincing efficacy and safety profile

Warburg versus consensus

- Similar to consensus, we issue a Buy recommendation. Average consensus price target is EUR 50.00 vs WRe EUR 41.00

Company Overview

Mission

- **Vivoryon Therapeutics** focuses on the development of drugs for the treatment of age-related diseases such as **Alzheimer's disease (AD)** and **cancer**.
- The company's lead product candidate is **varoglutamstat**, a QPCTL-inhibitor currently under Phase IIb evaluation for the treatment of early-stage AD.
- AD affects over 40 million people worldwide and is thus the most common form of dementia. At this point in time, AD is considered non-curable.

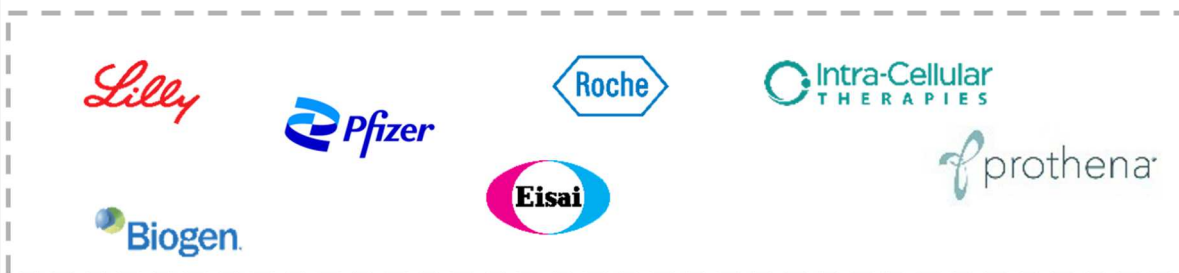
Product Pipeline

Disease	Program	Approach	Discovery	Preclinical	Phase 1	Phase 2a	Phase 2b	Phase 3
AD	Varoglutamstat (PQ912)	SMI QPCTL	VIVIAD – Ph2b in EU					
	Varoglutamstat (PQ912)	SMI QPCTL	VIVA-MIND – Ph2a/b in US					
	Varoglutamstat (SIM0408, PQ912)	SMI QPCTL	CTA approval in China					
	PBD-C06	mAb N3pE amyloid						
Cancer	Multiple	SMI QPCTL						
Liver inflammation	Multiple	SMI QPCTL						
Fibrosis & Kidney	Multiple	SMI Meprin						

USP

- With varoglutamstat, Vivoryon is developing small molecule inhibitors to **prevent N3pE amyloid formation, rather than aiming to clear existing Abeta plaques**.
- Besides blocking the formation of this toxic Abeta species, these inhibitors also act through a **second mechanism that targets QPCTL**, which inhibits neuroinflammation by modulating CCL2 activity.
- Current treatments with varoglutamstat **show preliminary but significant effects on working memory, synaptic function, and CSF biomarkers** after 12 weeks.

Selected Competitors



Source: Vivoryon Therapeutics, Warburg Research

Alzheimer's disease: state of play

- VVY's varoglutamstat is a novel treatment approach for a potential USD 25bn global Alzheimer's disease market
- Recent advances of lecanemab (brand name Leqembi) from Biogen and Eisai have opened up an additional treatment avenue and have reinvigorated investor interest

Vivoryon Therapeutics N.V. focuses on the development of drugs for the treatment of age-related diseases such as Alzheimer's disease and cancer. Alzheimer's disease is a neurodegenerative, as yet incurable disease of the central nervous system that leads to progressive deterioration of cognitive performance and memory.

Alzheimer's mainly affects older patients and represents a significant economic and social burden for the respective societies. It is estimated that currently some 6m people in the US and around 9m in the EU27+UK are affected by Alzheimer's disease. These patients face continuous cognitive decline to the point where they are no longer able to care for themselves and become dependent on carers. Untreated, the disease continues to progress and leads to complete neurological deterioration and ultimately, death.

Until last week's approval of lecanemab (brand name Leqembi) from Eisai/Biogen, no cure or even a disease-modifying drug for Alzheimer's disease has been found. Based on the high demand and earnings potential a successful drug would offer, pharma companies have sunk USD 42.5bn since 1995 into the development of an effective tool to fight the disease (Cummings et al., 2021, Alzheimer's and Dementia, 18, 3).

Market analysts from iHealthcareAnalyst estimate, that the global Alzheimer's disease market could amount to USD 25bn by 2029, reflecting the vast clinical demand. Alzheimer's disease is the sixth-leading cause of death in the United States, and the fifth-leading cause of death among those aged 65 and older. It also is a leading cause of disability and poor health. There are a large number of patients with the earliest stages of disease, before the onset of dementia, currently undiagnosed and untreated (prodromal disease).

In contrast to currently available or clinically more advanced drugs such as lecanemab and donanemab, Vivoryon's proprietary small molecule varoglutamstat attacks an earlier stage of the amyloid cascade by inhibiting the modification of amyloid- β -1-40/42 proteins into the highly neurotoxic pyroglutamate (N3pE) form.

The use of varoglutamstat in the causal treatment of Alzheimer's disease is the most clinically advanced compound in Vivoryon's portfolio and also the current focus of VVY's capital allocation. The value of the company will therefore be largely determined by the success of varoglutamstat as an Alzheimer's drug. In addition to varoglutamstat, VVY also has the N3pE specific antibody PBD-C06 in its portfolio. Plus, QPCT/L inhibitors have been shown to have potential applications in immunoncology (SIRPalpha/CD47 pathway). Furthermore, VVY has patented novel potential inhibitors of meprin proteases that have been identified as potential drug targets to combat fibrosis. We view all assets other than varoglutamstat as optional upside that could materialize once varoglutamstat has achieved approval.

Unlike previous pharmaceutical industry efforts such as Eli Lilly (solanezumab; amyloid- β monoclonal antibody), Novartis (umibecestat; beta secretase 1 (BACE1) inhibitor), or Biogen (Aduhelm), VVY does not seek to prevent the formation of amyloid- β proteins in general by inhibiting BACE1 or to force the degradation and removal of existing amyloid plaques with appropriate antibodies. Rather, VVY's approach aims to prevent the formation of highly neurotoxic pyroglutamate (N3pE) form and amyloid- β oligomers (A β O), which have only ever attracted attention as secondary intermediates in previous research.

Alzheimer's pathology

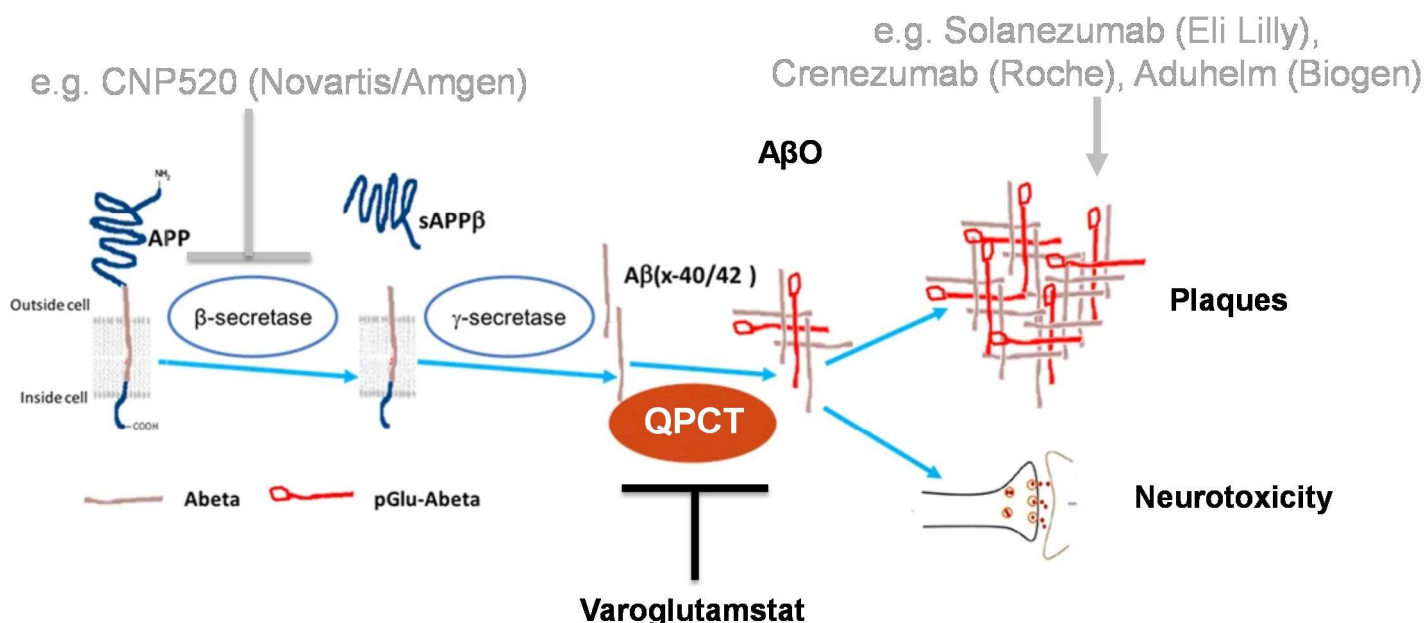
Alzheimer's disease is a degenerative disease of the brain that affects more than 40m people worldwide, making it the most common form of dementia. As mentioned above, the progression of the disease is accompanied by an increasing deterioration in cognitive performance.

The resulting economic costs amounted to USD 290bn in 2019 in the U.S. alone. In many cases, Alzheimer's disease begins 20 years before the affected person notices the first symptoms. In addition to the familiar dementia-related problems such as memory loss, these include complaints such as speech problems and loss of the ability to think rationally. These problems are a result of the progressive destruction of nerve cells in the brain and can lead to irreparable damage to the areas of the brain responsible for respiration and heartbeat in the final stages of the disease.

The Amyloid Hypothesis

Since the early 1990s, intensive research into Alzheimer's disease led to the hypothesis that the deposition of amyloid- β proteins in amyloid plaques is the central element of Alzheimer's pathology. These conclusions were based on data suggesting that patients with Down syndrome showed a dose-dependent progression of AD because these patients have an additional gene for the amyloid- β precursor protein (APP). Subsequently, duplication of the corresponding locus was shown to trigger the familial form of Alzheimer's disease. Cell and animal studies have shown that A β -aggregates (A β A) are toxic and that this toxicity is reversible with anti-A β A antibodies that degrade A β A. The formation of A β A also precedes the development of intra-neuronal tau fibrils and global inflammatory responses in the brain, which were responsible for most of the neuronal damage in the later stages of the disease.

Vivoryon's different A β O therapy approach with varoglutamstat



Source: Scheltens et al., 2018, Alzheimer's Research and Therapy, 10, 107-121, modified, Warburg Research

The first approaches to causal therapy of Alzheimer's disease were therefore based on the so-called amyloid cascade hypothesis. The β -secretase 1 (BACE1) was identified as one of the first drug targets. APP, an integral membrane protein found on the surface of all cells, serves as a substrate for BACE1, and its cleavage is the first step in the formation of amyloid- β -1-40/42 proteins. After cleavage of soluble APP- β s (sAPP), the actual amyloid- β -1-40/42 proteins are removed from the membrane by the activity of γ -secretase.

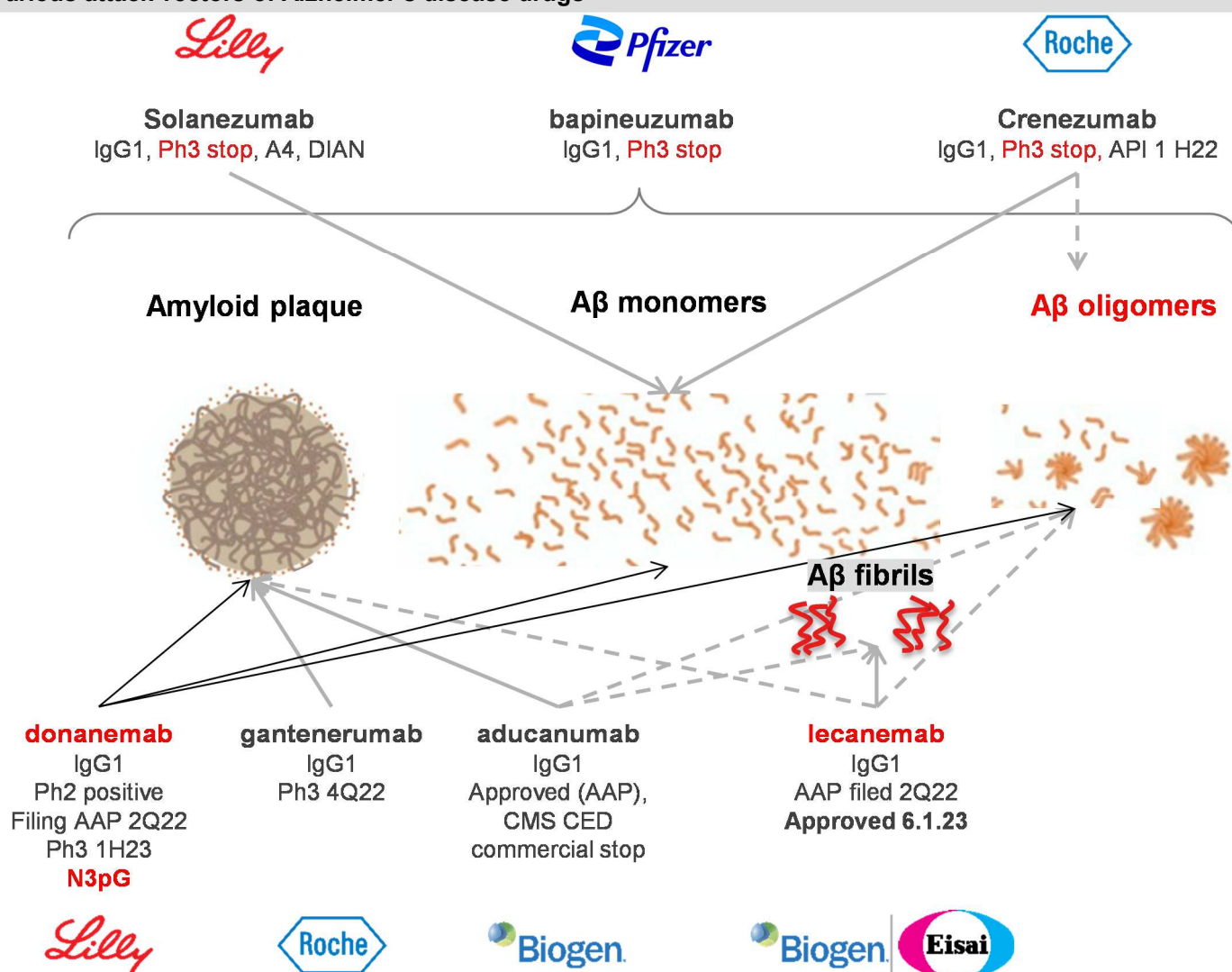
As a result, the amyloid- β proteins increasingly aggregate via oligomers and fibrils to form the familiar amyloid plaques.

Previous attempts have focused therapeutically on complete inhibition of BACE1 or immune system-mediated degradation or immunization against the already condensed amyloid plaques:

BACE1 inhibitors to completely prevent the formation of amyloid- β proteins (including CNP520, Novartis/Amgen; lanabecestat, Eli Lilly/AstraZeneca) were frequently discontinued in phase III clinical trials because of excessive side effects or lack of efficacy or an unfavourable benefit-risk ratio. Patients treated with verubecestat (Merck) showed worse results in key cognitive tests, while other compounds showed severe liver damage (atabecestat, Janssen/Shionogi Pharma) or no significant neurological improvement in Phase III (LY3202626, Eli Lilly).

Unlike the agents described here, which simultaneously inhibit both secretases BACE1 and BACE2, the Phase III inhibitor elenbecestat was specific for BACE1. Although the drug was shown in a Phase II study (n=70) to reduce cognitive decline in the group receiving the drug, Biogen/Eisai announced on Sept. 13, 2019, that elenbecestat will not be developed further due to a poor risk-benefit ratio.

Various attack vectors of Alzheimer's disease drugs



Source: based on data from Acumen Pharmaceuticals, modified, Warburg Research

The second treatment approach is to try to stimulate the immune system to break down soluble or condensed amyloid- β proteins. In general, a distinction is made between active and passive immunization. Active immunotherapy approaches aim to provide the body's immune system with antigens that enable immune cells to recognize amyloid- β proteins on their own and produce the corresponding antibodies.

In the passive variant, monoclonal antibodies (mAb) are administered to the patient. These monoclonal antibodies allow direct recognition of amyloid- β proteins by immune cells.

The latest entry in this list of failure was Aduhelm (aducanumab) from Biogen. The drug failed its initial clinical trial analysis, Biogen reanalysed the dataset post-hoc and seemingly found an effect in one of the patient subsets. As a considerable surprise to the scientific community, the FDA approved Aduhelm, although it showed no clear efficacy and had considerable safety issues (brain swelling and haemorrhages in 41% of patients). Various reimbursement agencies withheld funding for Aduhelm following the approval of the FDA and Aduhelm was a commercial failure.

Roche's gantenerumab also failed its Phase III trials and missed its target to slow down cognitive decline in patients.

The most recent promising data then came from Biogen/Eisai and their drug lecanemab. Lecanemab was also a mAb to target earlier stages of amyloid maturation, namely A β protofibrils. In a direct comparison with the anti-amyloid antibodies aducanumab and gantenerumab, lecanemab was reported to bind most strongly to A β protofibrils, while the others preferred more highly aggregated forms. During its final Phase III trial, lecanemab was able to demonstrate a statistically significant reduction in cognitive decline by 27% as measured by CDR-SB.

Lecanemab was approved for people with evidence of amyloid plaque build-up and mild cognitive impairment or mild dementia. Although, some researchers and clinicians have called the drug's impact modest and said there's still no definitive evidence of clinical meaningfulness, with the debate ongoing about how big an effect is needed.

In our opinion, the most recent datapoints from lecanemab and its approval reinforce the rationale, that treatment of Alzheimer's at the earlier stages of the amyloid cascade shows considerable potential.

Another interesting future data point will be the release of donanemab's Phase III trial data from Eli Lilly. Donanemab's data release is planned for H1 2023. The antibody is specifically targeting N3pE species of β -amyloid and thus ultimately focusses on the same drug target as varoglutamstat.

Following the positive data release from lecanemab, investors have gained renewed interest in Alzheimer's treatment. With around 8m patients in Europe and 6m patients in the USA, the total addressable market is considerable. On the day of Biogen's Aduhelm FDA approval, Biogen's market capitalization rose by USD 30bn. VVY's varoglutamstat has a unique potential to capture this market due to its early-stage disease attack vector.

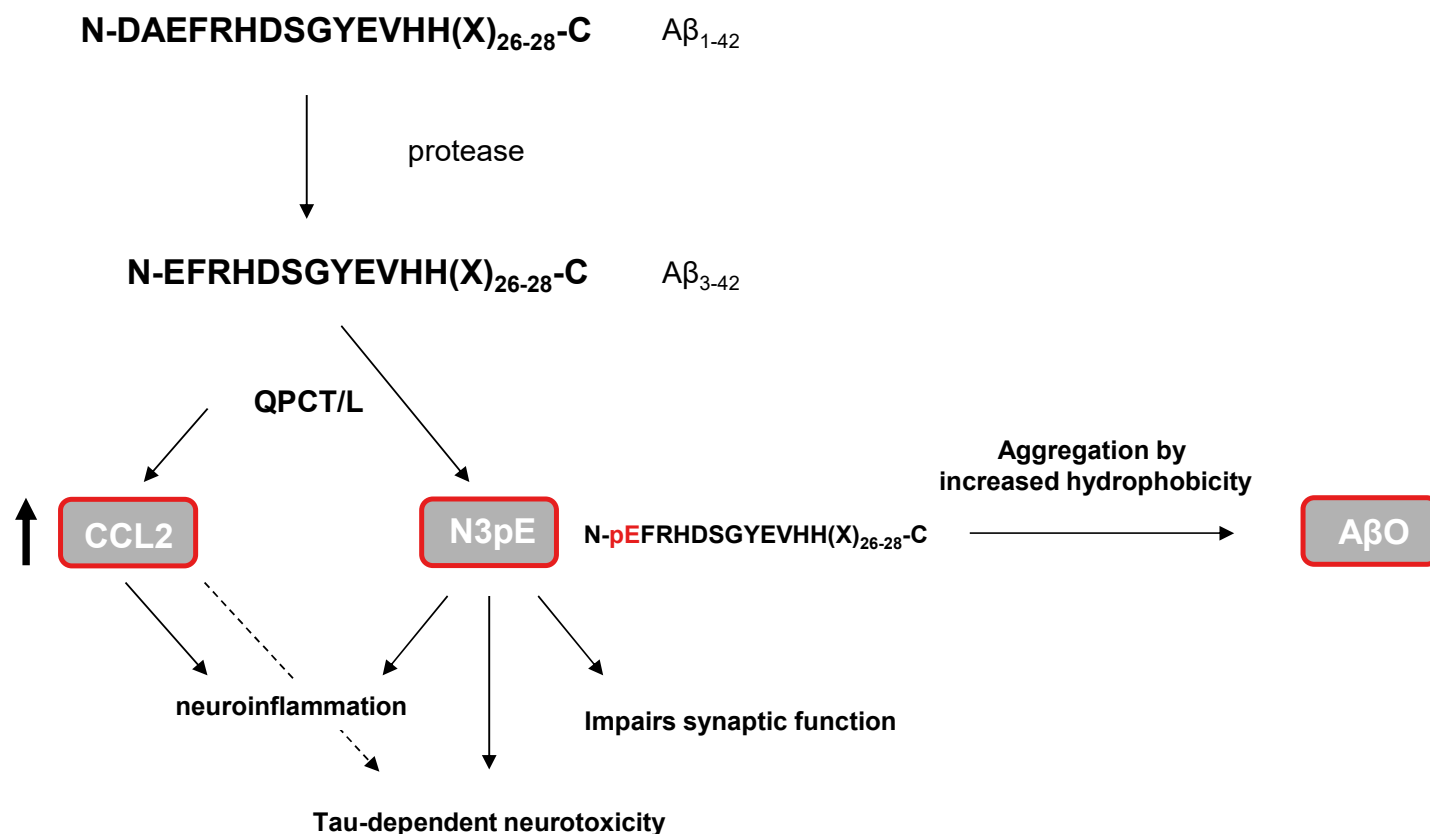
New research focus: Amyloid- β -Oligomers and other upstream drivers of disease

In the earlier decades of Alzheimer's research, A β O was seen rather as transient intermediates from unmodified amyloid- β proteins to the actually cell-toxic amyloid plaques. After nearly 20 years of many unsuccessful attempts to causally treat Alzheimer's disease based on the conventional amyloid hypothesis, the research and therapeutic focus is now back on N3pE/A β O. The following chapter explains the genesis of those early stage amyloid oligomers and transient, highly hydrophobic intermediates to give investors insight into why we regard VVY's approach as very promising:

After cleavage of A β 1-42 by γ -secretases, the peptide is N-terminally modified by another protease (CatB). The resulting A β 3-42 is the substrate of QPCT, which is inhibited by Vivoryon's varoglutamstat. Cyclization of glutamate by QPCT leads to N3pE-A β , which

has greatly increased hydrophobicity due to pyroglutamate function and thus acts as a nucleus for non-cyclized amyloid- β peptides and in this way also increases the toxicity of these peptides. This favours the aggregation of amyloid- β oligomers. Although N3pE-A β peptides most likely occur only as transient intermediate forms and have a short half-life, they exhibit a high neurotoxicity with much higher damage potential than A β O or amyloid- β plaques, according to recent findings.

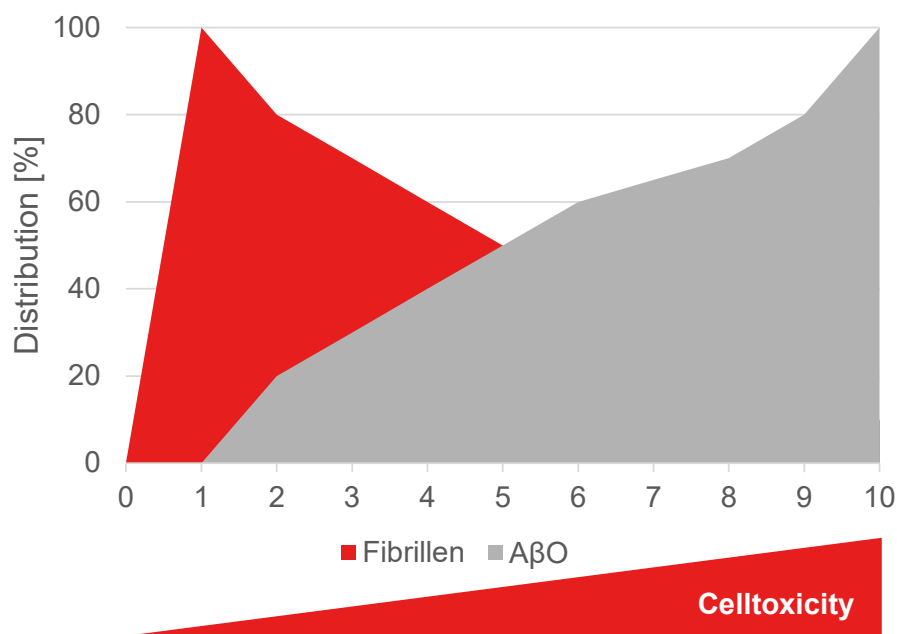
Modification path from amyloid- β proteins to N3pE intermediates and amyloid- β oligomers



Source: Vivoryon Therapeutics, Warburg Research

The inclusion of A β O as a toxic component in the amyloid hypothesis also resolves a major criticism of the hypothesis: to date, no reliable link has been established between the severity of dementia and the amount of amyloid plaques. Moreover, studies in mice have shown that memory loss and other pathological changes in the brain occurred before amyloid plaques were detectable. A β O are therefore increasingly considered the "missing link" of the amyloid hypothesis.

Effect of amyloid aggregation level on neuronal toxicity



Source: based on data from Sengupta et al., 2016, EBioMedicine, 6, 42-49; Warburg Research

Because their typical folding allows AβO to interact directly with the lipid membranes of cells, they can spontaneously insert into the membranes. This leads to the formation of new channels/pores in the neuronal membranes, resulting in an uncontrolled influx of ions. This uncontrolled influx leads to neuronal depolarization, affecting the proper function of neurons. Wang and colleagues demonstrated that AβO disrupts the brain's synaptic structure and impedes the formation of long-term memory. Interestingly, Gillman and co-workers showed that the stability and conductance levels of pores formed by N3pE-Aβeta clearly exceed the ones of pores formed by Aβeta 1-42, further corroborating the increased cytotoxicity of N3pE-Aβeta. From the results of the in vitro experiments, it can be concluded that the higher the equilibrium on the oligomer side, i.e. the amyloid peptides have not yet accumulated into fibrils and plaques, the higher the toxic potential of AβO.

Clinical studies analysis

- Varoglutamstat showed encouraging early efficacy data to slow the progression of cognitive decline and also displays a superior safety profile compared to Alzheimer's drugs based on the principle of β -amyloid clearing (such as Aduhelm or lecanemab)
- The VIVIAD and VIVA-MIND studies are set up in a complementary manner to generate a comprehensive dataset and display a potentially convincing efficacy and safety profile

SAPHIR Phase IIa already showed encouraging early-stage data

VIVIAD - EU Phase IIb study

In its Phase IIa study SAPHIR, Varoglutamstat demonstrated significant improvements in the patient's cognitive abilities and working memories after three months (measured by the One Back Test). In addition, notable changes from baseline in attention (Detection Test, Identification Test), a statistically significant reduction in theta power (theta wave, EEG) as well as the reduction of various neuroinflammatory and synaptic biomarkers (neurogranin, pE-CCL2, etc.) were observed. Based on these results, VVY designed two complementary clinical trials to be conducted in the US and EU to gain a comprehensive pathological picture of Alzheimer's diseases and in order to make a broad dataset available for a potential application: VIVIAD and VIVA-MIND.

Those two different multi-centre, randomized, double-blind, placebo-controlled, parallel-group clinical trials are run simultaneously: VIVIAD, the EU Phase IIb study and VIVA-MIND, the US Phase IIa/b study.

VIVIAD includes up to 250 patients with mild cognitive impairment or early-stage Alzheimer's who receive a placebo or either 300mg or 600mg varoglutamstat twice daily. The study started in July of 2020 and will run for up to 96 weeks. This timeframe surpasses the 40-60 weeks' timeframe necessary to show significant treatment effects. The 40 to 60-week time zone is historically associated with strong decreases in perceived drug efficacy as placebo-effects weaken in both treatment and placebo cohorts.

VIVIAD study scheme



Source: Vivoryon Therapeutics, Warburg Research

VIVIAD already showed a very encouraging safety profile

Besides safety, the primary endpoint analyses the development of the patient's cognitive abilities such as attention and working memory (One Back Test of the neurological test battery (NTB)). In addition, VIVIAD examines various secondary and exploratory datapoints such as theta wave power expression and various biomarkers such as neurogranin. An increase in theta wave expression has been shown to be correlated with early stages of Alzheimer's while elevated neurogranin levels have been shown to be associated with a decrease in neurological function.

The study had a very favourable safety readout in mid-2022 based on 188 patients: the highest tested dose of 600mg twice daily was well tolerated and generated far fewer treatment-related discontinuations (1% vs 33%) in contrast to the Phase IIa study at 800mg twice daily, while maintaining a high QPCT target occupancy of 87% (compared to 93% with 800mg).

Most importantly, treatment with varoglutamstat did not result in the emergence of Amyloid-Related Imaging Abnormality (ARIA). ARIA-E (edema) or -H (haemorrhage) are normally associated with monoclonal antibody related to Alzheimer's and represent an important safety flag during the treatment courses of Alzheimer's with those drugs. Lecanemab, the recently approved treatment for Alzheimer's, showed an increased ARIA-E occurrence of 12% and ARIA-H frequency of 17% which necessitates continuous expensive MRI-based patient monitoring during treatment. The study will continue with a dose of 600mg twice daily.

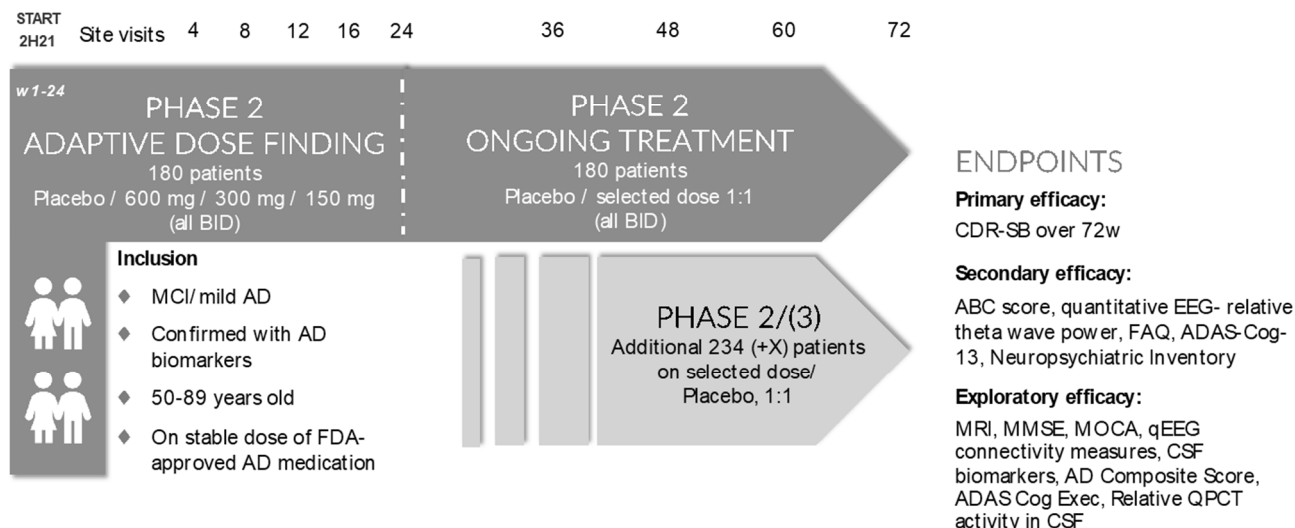
Based on this study design, VVY should make a very comprehensive dataset available for the possibility of accelerated approval, if the study demonstrates a good efficacy profile.

VIVA-MIND - USA Phase IIa/b study

VIVA-MIND in its current stage mimics SAPHIR IIa. The Phase IIa/b trail started in H2 2021 and is currently in its dosage-finding phase. The study initially includes 180 patients on either placebo or 150mg, 300mg and 600mg twice daily of varoglutamstat and also includes patients with mild cognitive impairment or mild/early-stage Alzheimer's. Phase IIa will determine the highest dose that is both safe and well tolerated. During this phase, there is an adaptive dosing evaluation, using a safety stopping boundary, of three dose levels with exposure to varoglutamstat or placebo for a minimum of 24 weeks to help determine which dose will be carried forward in Phase IIb.

VIVA-MIND study scheme

VIVA-MIND PHASE 2 STUDY WITH OPTION TO EXPAND TO PHASE 3



ADAS-Cog: Alzheimer's Disease Assessment Scale- Cognitive Subscale; ADNI ABC: neuropathologic assessment; BID: twice daily; CFC2: cognitive- functional composite; 14
MRI: magnetic resonance imaging; <https://clinicaltrials.gov/ct2/show/NCT03919162>

Source: Vivoryon Therapeutics, Warburg Research

The company recently decided to fully use the in-built flexibility of the study protocol. The first 180 patients will now seamlessly be treated for 72 weeks on the dose selected after 24 weeks. This modulation would allow to continuously randomize patients into the study and even transform it into a Phase III study. This format allows for a significantly increased flexibility in the clinical development of varoglutamstat and could prepare the project very well for the now more stringent FDA guidelines on the accelerated approval process.

The primary efficacy endpoint will include an assessment of the patient's cognitive performance as assessed by clinical dementia rating scale-sum of boxes (CDR-SB, similar to lecanemab). Like VIVIAD, secondary endpoints include a quantitative EEG (theta wave) and in addition the ADNI Battery Composite (ABC, 9-item).

The final dataset of VIVIAD and/or VIVA-MIND should attract the attention of big pharma (if successful)

If we take all important parts into consideration: the resurgence of investor and big pharma interest in Alzheimer's disease following lecanemab's data release and approval, the early Phase IIa dataset from SAPHIR IIa and the pathological disease rationale regarding early-stage Alzheimer's targets such as N3pE fragments, we think that varoglutamstat could already attract considerable suitor interest following the VIVIAD data release following its conclusion in H2 2023. Currently, VVY has enough cash at hand until the end of 2023. further cash inflow is required to finalize both studies, leaving room for additional stake dilution.

Given the enormous unmet medical need, the potential market size of USD 25bn and the more favourable safety profile at the moment, we are under the impression, that a successful VIVIAD trial will invite larger players to in-license varoglutamstat and foot the remaining development bill.

We estimate that VIVA-MIND could run until mid-2024. If both trials are successful, VVY and the potential partner could opt for accelerated approval with those datasets and start marketing the drug to patients in Europe and the US. In parallel, the companies would most likely have to run a confirmatory Phase III trial.

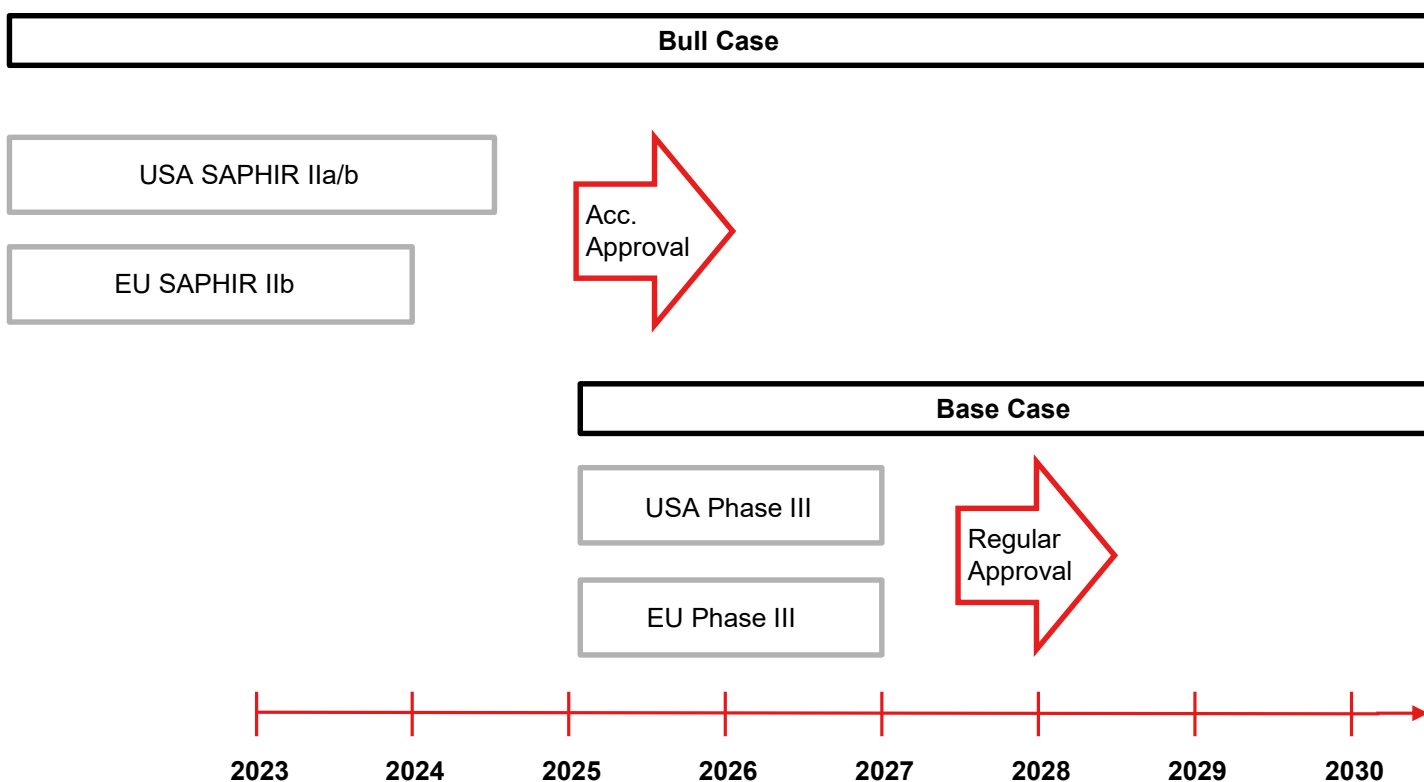
Given the FDA's leeway displayed towards aducanumab, which displayed highly questionable efficacy and safety data, we think conditional approval for varoglutamstat is likely, based on its favourable safety profile.

Market environment Alzheimer's disease and Valuation

- Valuation based on varoglutamstat's EU27+UK and USA market potential
- Base-case scenario: market entry in 2028/2029: rNPV EUR 1,060m
- Bull-case scenario: market entry in 2026/2027: rNPV EUR 1,190m
- rNPV valuation of VVY: EUR 1,083m or EUR 41.34 per share
- rNPV Simcere option: EUR 201m (Base Case) or EUR 251m (Bull Case)

Based on the Alzheimer's Disease Facts and Figures Report 2021, we expect a US patient population of 6.3m, of which approximately 1.9m are in the early phase of Alzheimer's disease and approximately 50% have been diagnosed. Based on the latest models, we assume an annual increase in patient numbers of 2.1% (Tomaskova et al., 2016, Neuropsychiatric Disease and Treatment, 12, 1589-1598). In the base case, our sales calculation is based on a market entry after clinical phase III in 2028 in the US and 2029 in the EU27+UK (base case).

Base Case/Bull Case



Source: Vivoryon Therapeutics, Warburg Research

To assess the market potential in the EU, we assume that 9.4m patients will be affected, 33% of whom are in the early stages of the disease and we assume a 50% diagnosis rate. Of those patients, 67% live in France, Spain, Italy, Germany, UK and Benelux which will be the main addressable market in EU27+UK.

Varoglutamstat has composition of matter patent protection in the EU and USA until 2030. This protection can be extended until 2035 in the US and 2037 in the EU if varoglutamstat remains in one indication (Alzheimer's). As varoglutamstat is a small molecule, we expect

a steep decline in sales volume from those patent expiration dates onwards because of generic competition and therefore forecast FCFs only until those expiration dates.

Base Case: market entry in 2028e/2029e after Phase III

Market potential: Base Case

The drug price watchdog ICER (Institute for Clinical and Economic Review) released a cost-reward-report in preparation for lecanemab's PDUFA event, setting the cost-effective price of lecanemab between USD 8,500 and USD 20,600 per annum and patient, citing the high rate of ARIE-E and ARIA-H as potential triggers of a net harm effect for patients. Eisai itself set the price of lecanemab at USD 26,500 per year. In an initial statement for Aduhelm, ICER set the cost-effective price for Aduhelm at USD 70,000 if effective in treating the disease.

Under the assumption that varoglutamstat has disease-modifying properties and retains its superior safety profile over mAb-based products such as Aduhelm and lecanemab, we assume there would be a considerable increase in demand for varoglutamstat and therefore, a realistic annual price of varoglutamstat would be the midpoint between USD 20,600 and 70,000, **USD 45,300** in a conservative scenario.

ICER's figures are merely recommendations and pricing discussion is expected to begin soon following last week's approval. Should those discussions yield material differences to our assumptions, we will update our model, once more concrete price tags materialize in H1 2023.

For the EU27+UK, we use the relative pricing of multiple sclerosis drug Ocrevus between US and EU27+UK as the basis for our varoglutamstat price point. Compared to the US, Ocrevus is sold in the EU at a 34% discount. Thus, we assume a EU27+UK price of EUR 28,748 per year per patient for varoglutamstat.

Base Case: sales forecasts

USA	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035		
Patients (m)	6.3	6.5	6.6	6.7	6.9	7.0	7.2	7.3	7.5	7.6	7.8	8.0	8.1		
% growth	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%		
% adj.	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%		
APP (m)	1.0	1.1	1.1	1.1	1.1	1.2	1.2	1.2	1.2	1.3	1.3	1.3	1.3		
% market share						5%	10%	20%	30%	40%	40%	40%	40%		
market share varoglutamstat (m)						0.06	0.12	0.24	0.37	0.50	0.51	0.53	0.54		
price per patient per year (EUR)						42,736	42,736	42,736	42,736	42,736	42,736	42,736	42,736		
Sales varoglutamstat (EURm)						2,476	5,056	10,325	15,813	21,527	21,979	22,441	22,912		
EU27+UK	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037
Patients (m)	9.4	9.6	9.8	10.0	10.2	10.4	10.6	10.9	11.1	11.3	11.6	11.8	12.1	12.3	12.6
% growth	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%
% adj.	7%	7%	7%	7%	7%	7%	7%	7%	7%	7%	7%	7%	7%	7%	7%
APP (m)	0.6	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.8	0.8	0.8	0.8	0.8	0.8	0.9
% market share							5%	10%	20%	30%	40%	40%	40%	40%	40%
market share varoglutamstat (m)							0.04	0.07	0.15	0.23	0.32	0.32	0.33	0.34	0.34
price per patient per year (EUR)							28,206	28,206	28,206	28,206	28,206	28,206	28,206	28,206	28,206
Sales varoglutamstat (EURm)							1,025	2,093	4,274	6,546	8,912	9,099	9,290	9,485	9,684

Source: Warburg Research

In this scenario, we further assume that VVY will out-license varoglutamstat to an interested big pharma company (Eli Lilly, Roche, Pfizer, etc.) following a successful Phase III trial. In that case, we forecast, that VVY will receive milestones and royalties on net sales at a rate of 22%. We further discount those future cashflows with a standard biotech WACC of 15%. Finally, we attribute a probability of success (PoS) of 12.3%, which is the current PoS for neurological Phase II drug assets in development (Clinical Development Success Rates and Contributing Factors 2011–2020). Taken together our base-case model yields a risk-adjusted NPV of VVY and varoglutamstat of EUR 1,060m.

Base Case rNPV model

	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037
Sum sales varoglutamstat (EURm)	0	0	0	0	2,476	6,082	12,419	20,088	28,073	30,891	31,539	32,202	9,485	9,684	
% royalty rate	22%	22%	22%	22%	22%	22%	22%	22%	22%	22%	22%	22%	22%	22%	
Royalties VVY (EURm)	0	0	0	0	545	1,338	2,732	4,419	6,176	6,796	6,939	7,084	2,087	2,130	
Upfronts and milestones VVY (EURm)	0	0	0	350	350	0	0	0	0	0	0	0	0	0	
Taxes (EURm)	0	0	0	-105	-268	-401	-820	-1326	-1853	-2039	-2082	-2125	-626	-639	
% tax rate	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	
FCF (EURm)	0	0	0	245	626	937	1,912	3,093	4,323	4,757	4,857	4,959	1,461	1,491	
NPV (EURm)	0	0	0	163	362	471	836	1,177	1,430	1,368	1,215	1,078	276	245	
% PoS	12.3%	12.3%	12.3%	12.3%	12.3%	12.3%	12.3%	12.3%	12.3%	12.3%	12.3%	12.3%	12.3%	12.3%	
rNPV (EURm)	0	0	0	20	45	58	103	145	176	168	149	133	34	30	

Source: Warburg Research

Bull Case: market entry in 2026e/2027e after Phase IIb

Market potential: Bull Case

In December 2021, varoglutamstat received the FDA's fast-track designation. This will expedite the review of drugs with the potential to treat serious conditions and fill an unmet medical need, aiming to bring important new drugs to the patient earlier, such as potentially varoglutamstat.

Provided that varoglutamstat can already show convincing efficacy data in phase IIb, conditional approval by the health authorities of the US and EU markets is possible. In this case we assume market entry of varoglutamstat in 2026e in the US and 2027e in the EU27+UK (bull case). Conditional approval would most likely be followed by a confirmatory Phase III clinical trial which would run in parallel to market sales of varoglutamstat.

Bull Case: sales forecasts

USA	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035		
Patients (m)	6.3	6.5	6.6	6.7	6.9	7.0	7.2	7.3	7.5	7.6	7.8	8.0	8.1		
% growth	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%		
% adj.	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%	17%		
APP (m)	1.0	1.1	1.1	1.1	1.1	1.2	1.2	1.2	1.2	1.3	1.3	1.3	1.3		
% market share				5%	10%	20%	30%	40%	45%	45%	45%	45%	45%		
market share varoglutamstat (m)				0.06	0.11	0.23	0.35	0.48	0.56	0.57	0.58	0.59	0.60		
price per patient per year (EUR)				42,736	42,736	42,736	42,736	42,736	42,736	42,736	42,736	42,736	42,736		
Sales varoglutamstat (EURm)				2,375	4,851	9,905	15,169	20,651	23,720	24,218	24,727	25,246	25,776		
EU27+UK	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037
Patients (m)	9.4	9.6	9.8	10.0	10.2	10.4	10.6	10.9	11.1	11.3	11.6	11.8	12.1	12.3	12.6
% growth	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%
% adj.	7%	7%	7%	7%	7%	7%	7%	7%	7%	7%	7%	7%	7%	7%	7%
APP (m)	0.6	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.8	0.8	0.8	0.8	0.8	0.8	0.9
% market share					5%	10%	20%	30%	40%	45%	45%	45%	45%	45%	45%
market share varoglutamstat (m)					0.03	0.07	0.15	0.22	0.30	0.35	0.36	0.36	0.37	0.38	0.39
price per patient per year (EUR)					28,206	28,206	28,206	28,206	28,206	28,206	28,206	28,206	28,206	28,206	28,206
Sales varoglutamstat (EURm)					983	2,008	4,100	6,280	8,549	9,819	10,025	10,236	10,451	10,670	10,894

Source: Warburg Research

At this earlier stage, we also assume, that VVY will out-license varoglutamstat to an interested big pharma company to receive milestones and royalties on net sales, albeit at a lower rate of 15% due to the earlier clinical stage. All other important model parameters remain the same (WACC 15%, PoS 12.3%, drug pricing). Based on these assumptions our bull-case rNPV model yields a risk-adjusted NPV of EUR 1,190m.

Bull Case rNPV model

	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037
Sum sales varoglutamstat (EURm)	0	0	2,375	5,834	11,913	19,270	26,930	32,269	34,037	34,752	35,482	36,227	10,670	10,894	
% royalty rate	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	
Royalties VVY (EURm)	0	0	356	875	1,787	2,890	4,040	4,840	5,106	5,213	5,322	5,434	1,601	1,634	
Upfronts and milestones VVY (EURm)	100	200	200	250	0	0	0	0	0	0	0	0	0	0	
Taxes (EURm)	-30	-60	-167	-338	-536	-867	-1212	-1452	-1532	-1564	-1597	-1630	-480	-490	
% tax rate	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	
FCF (EURm)	70	140	389	788	1,251	2,023	2,828	3,388	3,574	3,649	3,726	3,804	1,120	1,144	
NPV (EURm)	71	123	298	524	724	1,018	1,237	1,289	1,182	1,049	932	827	212	188	
% PoS	12.3%	12.3%	12.3%	12.3%	12.3%	12.3%	12.3%	12.3%	12.3%	12.3%	12.3%	12.3%	12.3%	12.3%	
rNPV (FIRRm)	9	15	37	64	89	125	152	159	145	129	115	102	26	23	

Source: Warburg Research

Simcere Pharmaceuticals: China market

VVY signed a licensing deal with Simcere Pharmaceuticals for the development of varoglutamstat and N3pE-antibody PBD-C06 in China. VVY received combined upfront and early milestone payments of USD 12.8m and is eligible for additional payments of USD 554m. We assume that VVY would be able to receive 12% royalties on net sales of varoglutamstat in China should it be approved.

We further assume, that Simcere would be able to piggyback on the dataset of VIVIAD and VIVA-MIND for a Chinese approval, as the studies include patient cohorts of Chinese ethnicity. Therefore, it is likely that Simcere will not need to follow through with a complete clinical development timeline and would be able to apply for approval in a similar timeframe as VVY in the EU and USA.

rNPV option value of China license in Base Case: EUR 201m

Adjusted for relative pricing of China vs the US and similar parameters, as outlined above, we derive a rNPV-based value for the Simcere option of EUR 201m in the base-case scenario with market entry in 2030.

Market forecast China option with Simcere (Base Case)

China	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037
Patients (m)	14.2	14.5	14.8	15.2	15.5	15.8	16.1	16.5	16.8	17.2	17.5	17.9	18.3	18.7	19.0
% growth	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%
% adj.	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%
APP (m)	1.4	1.4	1.5	1.5	1.5	1.6	1.6	1.6	1.7	1.7	1.7	1.8	1.8	1.8	1.9
% market share								5%	10%	20%	30%	40%	40%	40%	40%
market share varoglutamstat (m)								0.08	0.17	0.34	0.52	0.71	0.72	0.74	0.75
price per patient per year (EUR)								16,368	16,368	16,368	16,368	16,368	16,368	16,368	16,368
Sales varoglutamstat (EURm)								1,334	2,724	5,562	8,519	11,597	11,840	12,089	12,343
Sales varoglutamstat (EURm)	0	0	0	0	0	0	0	1,334	2,724	5,562	8,519	11,597	11,840	12,089	12,343
% royalty rate	12%	12%	12%	12%	12%	12%	12%	12%	12%	12%	12%	12%	12%	12%	12%
Royalties VVY (EURm)	0	0	0	0	0	0	0	160	327	667	1,022	1,392	1,421	1,451	1,481
Upfronts and milestones VVY (EURm)	10	50	0	100	125	130	139	0	0	0	0	0	0	0	0
Taxes (EURm)	-3	-15	0	-30	-38	-39	-42	-48	-98	-200	-307	-417	-426	-435	-444
% tax rate	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
FCF (EURm)	7	35	0	70	88	91	97	112	229	467	716	974	995	1,015	1,037
NPV (EURm)	8	35	0	54	58	53	49	49	87	155	206	244	216	192	170
% PoS	100.0%	12.3%	12.3%	12.3%	12.3%	12.3%	12.3%	12.3%	12.3%	12.3%	12.3%	12.3%	12.3%	12.3%	12.3%
rNPV (EURm)	8	4	0	7	7	6	6	6	11	19	25	30	27	24	21

Source: Warburg Research

rNPV option value of China license in Bull Case: EUR 251m

In a bull-case scenario, we estimate that VVY would receive a royalty rate of 10% after a potential market entry in 2028, yielding a risk-adjusted NPV of EUR 251m.

Market forecast China option with Simcere (Bull Case)

China	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037
Patients (m)	14.2	14.5	14.8	15.2	15.5	15.8	16.1	16.5	16.8	17.2	17.5	17.9	18.3	18.7	19.0
% growth	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%
% adj.	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%
APP (m)	1.4	1.4	1.5	1.5	1.5	1.6	1.6	1.6	1.7	1.7	1.7	1.8	1.8	1.8	1.9
% market share						5%	10%	20%	30%	40%	40%	40%	40%	40%	40%
market share varoglutamstat (m)						0.08	0.16	0.33	0.50	0.68	0.69	0.71	0.72	0.74	0.75
price per patient per year (EUR)						16,368	16,368	16,368	16,368	16,368	16,368	16,368	16,368	16,368	16,368
Sales varoglutamstat (EURm)						1,280	2,613	5,336	8,172	11,125	11,358	11,597	11,840	12,089	12,343
Sales varoglutamstat (EURm)	0	0	0	0	0	1,280	2,613	5,336	8,172	11,125	11,358	11,597	11,840	12,089	12,343
% royalty rate	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%
Royalties VVY (EURm)	0	0	0	0	0	128	261	534	817	1,112	1,136	1,160	1,184	1,209	1,234
Upfronts and milestones VVY (EURm)	10	50	100	125	130	139	0	0	0	0	0	0	0	0	0
Taxes (EURm)	-3	-15	-30	-38	-39	-80	-78	-160	-245	-334	-341	-348	-355	-363	-370
% tax rate	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
FCF (EURm)	7	35	70	88	91	187	183	374	572	779	795	812	829	846	864
NPV (EURm)	8	35	62	67	61	108	92	163	218	258	229	203	180	160	142
% PoS	100.0%	12.3%	12.3%	12.3%	12.3%	12.3%	12.3%	12.3%	12.3%	12.3%	12.3%	12.3%	12.3%	12.3%	12.3%
rNPV (EURm)	8	4	8	8	7	13	11	20	27	32	28	25	22	20	17

Source: Warburg Research

rNPV model and valuation

Our valuation of VVY is based on the **Base Case** of varoglutamstat's potential market entry. VVY currently has other assets at various clinical stages in its pipeline but is focusing its resources solely on the successful conclusion of the two ongoing clinical trials in Alzheimer's disease. Therefore, we base our valuation of VVY on the market potential of an efficacious Alzheimer's disease drug in the USA and EU27+UK.

While traditional market entry after a successful Phase III trial in 2028e is the main basis for our valuation, conditional approval of varoglutamstat following a successful Phase IIb trial is likely due to the high unmet medical need of Alzheimer's patients for efficacious and safe treatment options. This would then allow for market entry in 2026e.

While providing investors with an indication of the potential value of such a scenario, we base our price target of EUR 41.00 on our base-case scenario. We assume that Claus Christiansen and KKR will execute their option to buy additional shares at EUR 7.30 in accordance with the released prospectus, thereby fully diluting the share count to 26.2m. To this, we add estimated cash at EOY 2022e and arrive at a rNPV-based valuation of EUR 41.34 per share, which serves as the basis for our price target.

At the moment, we do not include a potential market authorization of varoglutamtstat with VVY's partner Simcere Pharmaceuticals in our valuation and view it as optional upside.

Sum of the parts valuation			
		weight	weighted
rNPV base case (EURm)	1,060	100%	1,060
rNPV bull case (EURm)	1,190	0%	0
VVY rNPV (EURm)			1,060
shares fully diluted (m)			26.2
Cash/debt (EURm)			22.6
Cash per share (EUR)			0.86
EV (EURm)			1,083
EV per share (EUR)			41.34

Source: Warburg Research

Financial situation

We estimate that VVY should close the year with EUR 22.6m in cash on its balance sheet. The company raised capital twice this year: EUR 21m in early 2022 and an additional EUR 15m with its anchor investor Claus Christiansen and a KKR biotech fund (Dawn) as the first tranche of a two-part warrant (EUR 30m in total). We also assume that VVY will receive a milestone of EUR 10m in 2023 from its partner Simcere Pharmaceuticals for the launch of the Phase I clinical trial in China. In addition, we estimate that the second part of the KKR/Claus Christiansen warrant will be triggered at the latest with the completion of the VIVIAD study in H2 2023, yielding an additional EUR 15m with the issuance of 2.05m additional shares at a price of EUR 7.30. We have included that payment in our cash-flow forecasts for 2024 and, as mentioned above, base our per-share value of VVY on this fully diluted share count of 26.2m.

We have modelled additional debt of EUR 25m as positive cashflow in 2024. Non-commercial stages companies such as VVY are normally not eligible for debt and we therefore assume that VVY will need additional financing in the future. As the conditions of such a potential capital increase are difficult to forecast, we choose to model additional debt.

Company & Products

History

Vivoryon Therapeutics N.V. was founded in 1997 and is headquartered in Halle (Saale) and in Munich, Germany. It was originally founded as a research and discovery business with a focus on diabetes and later on Alzheimer's disease. Throughout its history, Vivoryon underwent the following stages and reached the following milestones:

- 1997: Foundation under the name „ProBioTec GmbH“ with a focus on diabetes medication
- 1999 – 2004: Research on enzymology and physiology of the DP4 enzyme, which goes on to provide the basis for the development of a breakthrough generation of gliptin antidiabetics (DPP-4 inhibitors). Licensing agreements with Merck & Co., Ferring and Orth McNeil Pharmaceuticals as well as Novartis. In 2004, the company's diabetes research division and all related rights are sold to OSI Pharmaceuticals
- 1999 – 2006: Discovery of the enzyme glutaminyl cyclase (QC) and research for its role in Alzheimer's disease. In 2004, the company demonstrates that QC catalyses the formation of certain β -amyloid species with a pyroglutamyl residue, or “pGlu-Abeta”, which is said to play a role in the development of Alzheimer's disease.
- 2001: Name change to “Probiodrug AG”
- 2007 – 2011: Discovery and preclinical development of QC-Inhibitors as well as first financing rounds
- 2011 – 2014: Clinical Phase I studies of its QC-Inhibitor varoglutamstat along with the preparation of preclinical development of the pGlu-Abeta antibody PBD-C06 and the follower QC-Inhibitor PQ1565. Transformation of the company from a research-oriented business to a development business
- 2014: IPO at the Euronext Amsterdam
- 2015: varoglutamstat successfully completes Phase IIa safety and tolerability study for patients with early Alzheimer's disease
- 2019: varoglutamstat enters Phase IIa/b efficacy and safety study for patients with early Alzheimer's disease (expected completion 05/2023)
- 2020: varoglutamstat enters Phase IIb safety, tolerability, and efficacy study for patients with mild Alzheimer's disease (expected completion 06/2023)
- 2022: Independent DSMB decides on 600mg BID of varoglutamstat as the dose to be used in the remainder of the European Phase II study (VIVIAD, expected completion Q1 2024)

Management

Ulrich Dauer, PhD (CEO)



Dr. Ulrich Dauer was appointed CEO in May 2018. He has more than 20 years of experience in the biopharmaceutical industry in both public and private companies. He was a co-founder and served as the CEO of 4SC AG for 14 years and took the company public in 2005. In subsequent leadership positions in the biotech industry, Dr. Dauer executed the EUR 130m trade sale of Activaero in 2014 and later took up CEO positions of two privately held biotech companies (Omeicos GmbH, Ventaleon GmbH). He is also a non-executive board member of Atriva Therapeutics GmbH. Dr. Dauer holds a PhD in Chemistry from the Julius Maximilians University of Würzburg, Germany.

Florian Schmid (CFO)



Florian Schmid was appointed CFO in April 2021, following over 20 years of leadership experience in biopharmaceutical, technology, and consulting businesses. He previously worked at InflaRx N.V., where he served as Director Finance & Controlling. Prior to that, he spent six years at T-systems International GmbH, where he led the Global Deal & Business Support department. He started his career as a certified tax advisor and public accountant at Arthur Andersen and EY. Florian Schmid holds a degree in business economics from the Ludwig Maximilians University in Munich, Germany.

Michael Schaeffer, PhD (Chief Business Officer)



Dr. Michael Schaeffer has been Chief Business Officer since October 2018. He has almost 20 years of experience in strategic business development across pharma and biotech, as well as scientific project and alliance management. Prior to joining Vivoryon, he was founder, CEO, and Managing Director of the biotech companies SiREEN AG and CRELUX GmbH, where he was responsible for the integration into WuXiAppTec, a leading Shanghai based CRO with over 20,000 employees globally. Dr. Schaeffer received his PhD in Molecular Biology from the Ludwig Maximilians University in Munich, Germany.

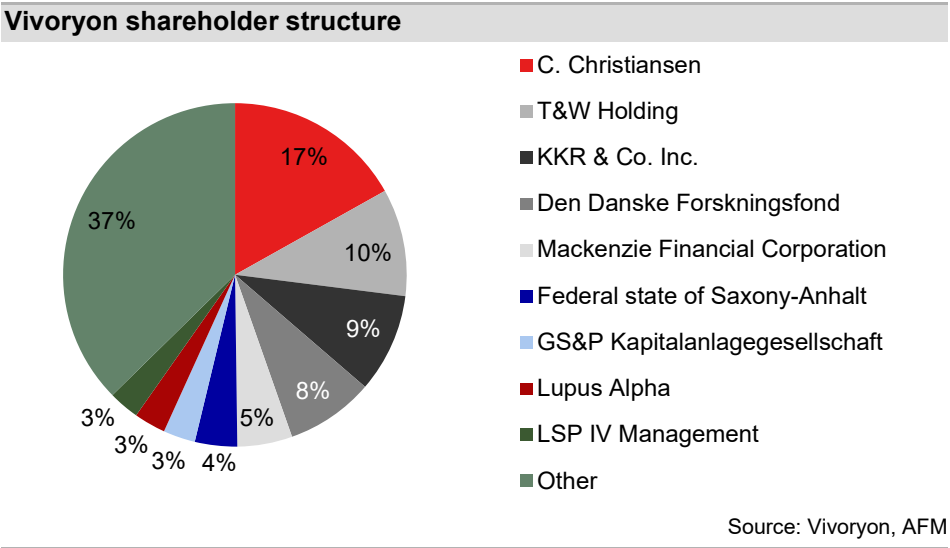
Frank Weber, MD (Chief Medical Officer)



Dr. Frank Weber has been serving as Vivoryon's Chief Medical Officer since 2012 and has more than 30 years of experience in the pharmaceutical and life-science industry. Before working at Vivoryon, he served as Chief Medical Officer at Merck KGaA in Germany and Switzerland, joining Californian InterMune (Genentech/Roche) as Global Clinical Advisor. He began his career with various management positions in medical affairs and clinical development at American Cyanamid (Lederle) in the USA and Synthelabo (Sanofi) in France. Dr. Weber holds an MD in Cancer Immunology from the Medical University Cologne, Germany.

Shareholder Structure

Vivoryon N.V. is owned by a mix of asset management firms, government funds, as well as private individuals. The authorized share capital amounts to EUR 60,000,000 and the issued share capital amounts to EUR 20,050,482. The largest shareholder with 16.88% is C. Christiansen. Approximately 37% of the company is owned by shareholders with a stake of less than 3% each.



Sum of the parts			
		weight	weighted
rNPV base case (EURm)	1,060	100%	1,060
rNPV bull case (EURm)	1,190	0%	0
VVY rNPV (EURm)			1,060
shares fully diluted (m)			26.2
Cash/debt (EURm)			22.6
Cash per share (EUR)			0.86
EV (EURm)			1,083
EV per share (EUR)			41.34

■ We base our SOTP-derived value of VVY on our Base Case scenario for varoglutamstat

Valuation	2018	2019	2020	2021	2022e	2023e	2024e
Price / Book	42.2 x	1.3 x	3.9 x	20.4 x	10.2 x	45.1 x	n.a.
Book value per share ex intangibles	0.15	2.14	1.28	0.80	1.09	0.23	-0.09
EV / Sales	n.a.	n.a.	n.a.	30.0 x	n.a.	27.3 x	n.a.
EV / EBITDA	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
EV / EBIT	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
EV / EBIT adj.*	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
P / FCF	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
P / E	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
P / E adj.*	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Dividend Yield	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
FCF Potential Yield (on market EV)	-15.4 %	-46.3 %	-20.7 %	-4.1 %	-11.9 %	-6.6 %	-7.5 %
*Adjustments made for: -							

Consolidated profit and loss

In EUR m	2018	2019	2020	2021	2022e	2023e	2024e
Sales	0.00	0.00	0.00	10.76	0.00	10.00	0.00
Change Sales yoy	n.a.	n.a.	n.a.	n.a.	-100.0 %	n.a.	-100.0 %
COGS	0.01	0.01	0.01	1.57	0.01	1.00	0.01
Gross profit	-0.01	-0.01	-0.01	9.20	-0.01	9.00	-0.01
<i>Gross margin</i>	<i>n.a.</i>	<i>n.a.</i>	<i>n.a.</i>	<i>85.4 %</i>	<i>n.a.</i>	<i>90.0 %</i>	<i>n.a.</i>
Research and development	4.84	4.75	13.21	17.45	21.46	21.50	17.00
Sales and marketing	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Administration expenses	2.89	3.02	2.81	4.55	5.60	5.50	5.50
Other operating expenses	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Other operating income	0.03	0.00	0.00	0.00	0.00	0.00	0.00
Unfrequent items	0.00	0.00	0.00	0.00	0.00	0.00	0.00
EBITDA	-7.71	-7.78	-16.03	-12.81	-27.07	-18.00	-22.51
<i>Margin</i>	<i>n.a.</i>	<i>n.a.</i>	<i>n.a.</i>	<i>-119.0 %</i>	<i>n.a.</i>	<i>-180.0 %</i>	<i>n.a.</i>
Depreciation of fixed assets	0.00	0.00	0.00	0.00	0.00	0.00	0.00
EBITA	-7.71	-7.78	-16.03	-12.81	-27.07	-18.00	-22.51
Amortisation of intangible assets	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Goodwill amortisation	0.00	0.00	0.00	0.00	0.00	0.00	0.00
EBIT	-7.71	-7.78	-16.03	-12.81	-27.07	-18.00	-22.51
<i>Margin</i>	<i>n.a.</i>	<i>n.a.</i>	<i>n.a.</i>	<i>-119.0 %</i>	<i>n.a.</i>	<i>-180.0 %</i>	<i>n.a.</i>
EBIT adj.	-7.71	-7.78	-16.03	-12.81	-27.07	-18.00	-22.51
Interest income	0.00	0.00	0.11	0.97	0.00	0.00	0.00
Interest expenses	0.04	0.00	0.60	0.39	0.50	0.50	0.50
Other financial income (loss)	0.00	0.00	0.00	0.00	0.00	0.00	0.00
EBT	-7.75	-7.94	-16.62	-12.23	-27.57	-18.50	-23.01
<i>Margin</i>	<i>n.a.</i>	<i>n.a.</i>	<i>n.a.</i>	<i>-113.6 %</i>	<i>n.a.</i>	<i>-185.0 %</i>	<i>n.a.</i>
Total taxes	0.00	0.00	0.00	0.43	0.00	0.00	0.00
Net income from continuing operations	-7.75	-7.94	-16.62	-12.66	-27.57	-18.50	-23.01
Income from discontinued operations (net of tax)	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Net income before minorities	-7.75	-7.94	-16.62	-12.58	-27.57	-18.50	-23.01
Minority interest	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Net income	-7.75	-7.94	-16.62	-12.58	-27.57	-18.50	-23.01
<i>Margin</i>	<i>n.a.</i>	<i>n.a.</i>	<i>n.a.</i>	<i>-116.9 %</i>	<i>n.a.</i>	<i>-185.0 %</i>	<i>n.a.</i>
Number of shares, average	8.21	12.55	19.98	19.98	22.05	24.10	25.15
EPS	-0.94	-0.63	-0.83	-0.63	-1.25	-0.77	-0.91
EPS adj.	-0.94	-0.63	-0.83	-0.63	-1.25	-0.77	-0.91

*Adjustments made for:

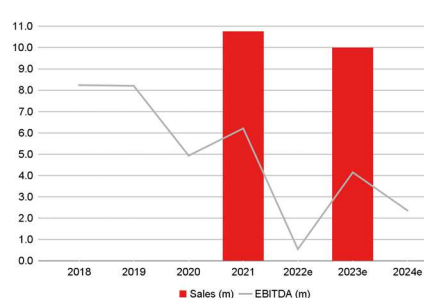
Guidance: Sufficient cash to fund R&D and operations at least until December 2023

Financial Ratios

	2018	2019	2020	2021	2022e	2023e	2024e
Total Operating Costs / Sales	n.a.	n.a.	n.a.	204.4 %	n.a.	270.0 %	n.a.
Operating Leverage	n.a.	n.a.	n.a.	n.a.	-1.1 x	n.a.	-0.3 x
EBITDA / Interest expenses	n.m.	n.a.	n.m.	n.m.	n.m.	n.m.	n.m.
Tax rate (EBT)	0.0 %	0.0 %	0.0 %	-3.5 %	0.0 %	0.0 %	0.0 %
Dividend Payout Ratio	0.0 %	0.0 %	0.0 %	0.0 %	0.0 %	0.0 %	0.0 %
Sales per Employee	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

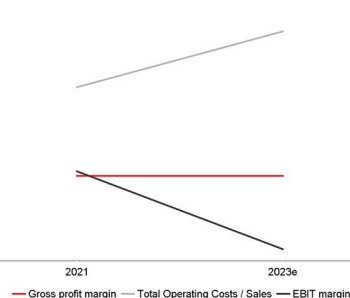
Sales, EBITDA

in EUR m

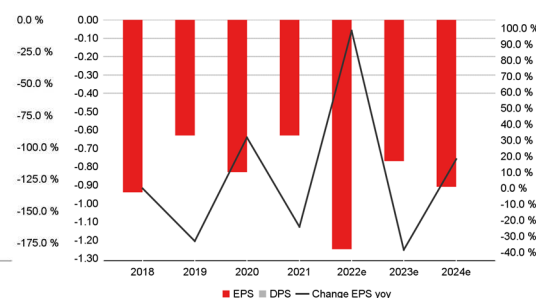


Operating Performance

in %



Performance per Share



Source: Warburg Research

Source: Warburg Research

Source: Warburg Research

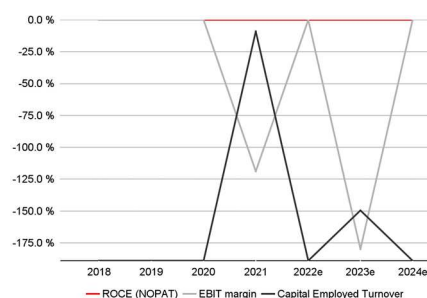
Consolidated balance sheet

In EUR m	2018	2019	2020	2021	2022e	2023e	2024e
Assets							
Goodwill and other intangible assets	0.01	0.00	0.57	0.53	0.53	0.53	0.53
thereof other intangible assets	0.01	0.00	0.57	0.53	0.53	0.53	0.53
thereof Goodwill	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Property, plant and equipment	0.06	0.56	0.08	0.07	0.07	0.07	0.07
Financial assets	0.00	0.00	0.00	3.47	3.47	3.47	3.47
Other long-term assets	0.00	0.00	0.31	0.22	0.22	0.22	0.22
Fixed assets	0.06	0.56	0.96	4.29	4.29	4.29	4.29
Inventories	0.00	0.00	0.00	0.00	0.00	1.40	0.00
Accounts receivable	0.00	0.00	0.00	0.00	0.00	1.60	0.00
Liquid assets	3.78	41.52	26.31	17.74	25.72	4.21	24.21
Other short-term assets	0.20	3.85	2.49	2.49	2.49	2.49	2.49
Current assets	3.98	45.38	28.79	20.23	28.21	9.71	26.70
Total Assets	4.00	45.90	29.70	24.50	32.50	14.00	31.00
Liabilities and shareholders' equity							
Subscribed capital	8.21	19.98	19.98	20.05	24.11	24.11	26.16
Capital reserve	48.74	86.39	82.14	83.21	115.16	115.16	128.10
Retained earnings	-55.31	-63.14	-79.65	-92.30	-119.87	-138.37	-161.38
Other equity components	-0.41	-0.56	3.75	5.60	5.20	5.20	5.20
Shareholders' equity	1.23	42.67	26.22	16.56	24.59	6.09	-1.92
Minority interest	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Total equity	1.23	42.67	26.22	16.56	24.59	6.09	-1.92
Provisions	0.00	0.00	2.21	1.96	1.96	1.96	1.96
thereof provisions for pensions and similar obligations	0.00	0.00	1.98	1.82	1.82	1.82	1.82
Financial liabilities (total)	1.85	2.27	0.30	0.30	0.30	0.30	25.30
Short-term financial liabilities	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Accounts payable	0.00	0.00	0.91	4.36	4.36	4.36	4.36
Other liabilities	0.96	0.93	0.10	1.30	1.30	1.30	1.30
Liabilities	2.82	3.20	3.52	7.91	7.91	7.91	32.91
Total liabilities and shareholders' equity	4.00	45.90	29.70	24.50	32.50	14.00	31.00

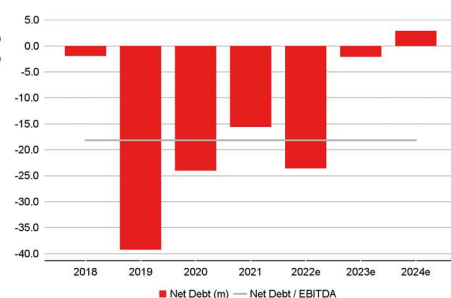
Financial Ratios

	2018	2019	2020	2021	2022e	2023e	2024e
Efficiency of Capital Employment							
Operating Assets Turnover	0.0 x	0.0 x	0.0 x	-2.5 x	0.0 x	-7.7 x	0.0 x
Capital Employed Turnover	0.0 x	0.0 x	0.0 x	11.4 x	0.0 x	2.5 x	0.0 x
ROA	-12300.0 %	-1408.0 %	-1740.2 %	-293.2 %	-642.5 %	-431.1 %	-536.2 %
Return on Capital							
ROCE (NOPAT)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
ROE	n.a.	-36.2 %	-48.3 %	-58.8 %	-134.0 %	-120.6 %	-1105.3 %
Adj. ROE	n.a.	-36.2 %	-48.3 %	-58.8 %	-134.0 %	-120.6 %	-1105.3 %
Balance sheet quality							
Net Debt	-1.93	-39.26	-24.03	-15.61	-23.59	-2.09	2.92
Net Financial Debt	-1.93	-39.26	-26.01	-17.44	-25.42	-3.91	1.10
Net Gearing	-156.8 %	-92.0 %	-91.6 %	-94.3 %	-96.0 %	-34.4 %	-151.7 %
Net Fin. Debt / EBITDA	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Book Value / Share	0.1	2.1	1.3	0.8	1.1	0.3	-0.1
Book value per share ex intangibles	0.1	2.1	1.3	0.8	1.1	0.2	-0.1

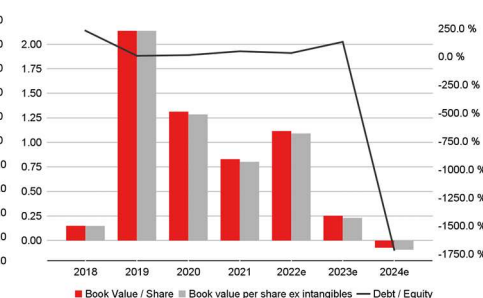
ROCE Development



Net debt in EUR m



Book Value per Share in EUR



Source: Warburg Research

Source: Warburg Research

Source: Warburg Research

Consolidated cash flow statement

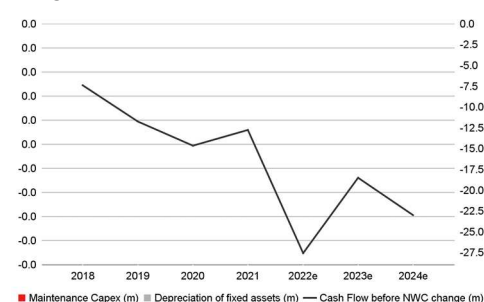
In EUR m	2018	2019	2020	2021	2022e	2023e	2024e
Net income	-7.75	-7.94	-16.62	-12.58	-27.57	-18.50	-23.01
Depreciation of fixed assets	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Amortisation of goodwill	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Amortisation of intangible assets	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Increase/decrease in long-term provisions	0.16	-0.16	1.98	-0.16	0.00	0.00	0.00
Other non-cash income and expenses	0.20	-3.65	0.00	0.00	0.00	0.00	0.00
Cash Flow before NWC change	-7.39	-11.76	-14.64	-12.74	-27.57	-18.50	-23.01
Increase / decrease in inventory	0.00	0.00	0.00	0.00	0.00	-1.40	1.40
Increase / decrease in accounts receivable	0.00	0.00	0.00	0.00	0.00	-1.60	1.60
Increase / decrease in accounts payable	0.42	-0.23	0.91	3.45	0.00	0.00	0.00
Increase / decrease in other working capital positions	0.00	0.40	-0.30	-2.00	0.00	0.00	0.00
Increase / decrease in working capital (total)	0.42	0.17	0.61	1.45	0.00	-3.00	3.00
Net cash provided by operating activities [1]	-6.97	-11.59	-14.03	-11.29	-27.57	-21.50	-20.01
Investments in intangible assets	0.00	0.00	-0.58	0.00	0.00	0.00	0.00
Investments in property, plant and equipment	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Payments for acquisitions	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Financial investments	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Income from asset disposals	0.48	-0.05	0.00	0.00	0.00	0.00	0.00
Net cash provided by investing activities [2]	0.48	-0.05	-0.58	0.00	0.00	0.00	0.00
Change in financial liabilities	0.00	0.00	-1.97	0.00	0.00	0.00	25.00
Dividends paid	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Purchase of own shares	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Capital measures	0.00	51.24	0.00	-0.74	35.55	0.00	15.00
Other	0.00	-1.83	0.00	-0.10	0.00	0.00	0.00
Net cash provided by financing activities [3]	0.00	49.41	-1.97	-0.84	35.55	0.00	40.00
Change in liquid funds [1]+[2]+[3]	-6.50	37.77	-16.57	-12.13	7.98	-21.50	19.99
Effects of exchange-rate changes on cash	0.00	0.00	-0.48	0.47	0.00	0.00	0.00
Cash and cash equivalent at end of period	3.80	41.52	24.48	14.65	22.64	1.14	21.13

Financial Ratios

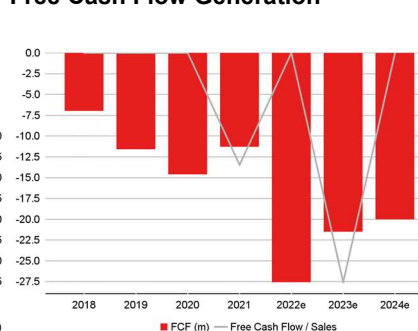
	2018	2019	2020	2021	2022e	2023e	2024e
Cash Flow							
FCF	-6.97	-11.59	-14.60	-11.29	-27.57	-21.50	-20.01
Free Cash Flow / Sales	n.a.	n.a.	n.a.	-104.9 %	n.a.	-215.0 %	n.a.
Free Cash Flow Potential	-7.71	-7.94	-16.12	-13.16	-27.07	-18.00	-22.51
Free Cash Flow / Net Profit	90.0 %	145.9 %	87.9 %	89.7 %	100.0 %	116.2 %	87.0 %
Interest Received / Avg. Cash	n.a.	0.0 %	0.3 %	4.4 %	0.0 %	0.0 %	0.0 %
Interest Paid / Avg. Debt	n.a.	0.0 %	47.1 %	130.7 %	166.7 %	166.7 %	3.9 %
Management of Funds							
Investment ratio	n.a.	n.a.	n.a.	0.0 %	n.a.	0.0 %	n.a.
Maint. Capex / Sales	n.a.	n.a.	n.a.	0.0 %	n.a.	0.0 %	n.a.
Capex / Dep	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Avg. Working Capital / Sales	n.a.	n.a.	n.a.	-24.5 %	n.a.	-28.6 %	n.a.
Trade Debtors / Trade Creditors	n.a.	n.a.	0.0 %	0.0 %	0.0 %	36.7 %	0.0 %
Inventory Turnover	n.a.	n.a.	n.a.	n.a.	n.a.	0.7 x	n.a.
Receivables collection period (days)	n.a.	n.a.	n.a.	0	n.a.	58	n.a.
Payables payment period (days)	0	0	33,252	1,014	159,140	1,591	159,140
Cash conversion cycle (Days)	n.a.	n.a.	n.a.	n.a.	n.a.	-1,022	n.a.

CAPEX and Cash Flow

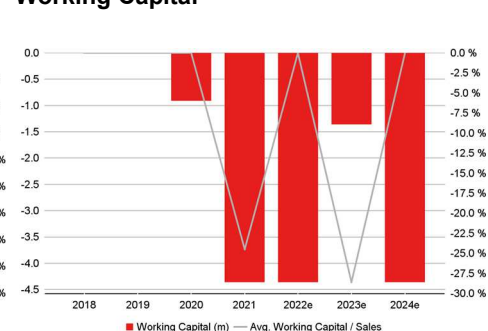
in EUR m



Free Cash Flow Generation



Working Capital



Source: Warburg Research

Source: Warburg Research

Source: Warburg Research

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Company	Disclosure	Link to the historical price targets and rating changes (last 12 months)
Vivoryon Therapeutics	5	http://www.mmwarburg.com/disclaimer/disclaimer_en/NL00150002Q7.htm

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-H-	Hold:	The price of the analysed financial instrument is expected to remain mostly flat over the next 12 months.
-S-	Sell:	The price of the analysed financial instrument is expected to fall over the next 12 months.
“-“	Rating suspended:	The available information currently does not permit an evaluation of the company.

WARBURG RESEARCH GMBH – ANALYSED RESEARCH UNIVERSE BY RATING

Rating	Number of stocks	% of Universe
Buy	160	75
Hold	44	21
Sell	6	3
Rating suspended	3	1
Total	213	100

WARBURG RESEARCH GMBH – ANALYSED RESEARCH UNIVERSE BY RATING ...

... taking into account only those companies which were provided with major investment services in the last twelve months.

Rating	Number of stocks	% of Universe
Buy	44	86
Hold	6	12
Sell	0	0
Rating suspended	1	2
Total	51	100

PRICE AND RATING HISTORY VIVORYON THERAPEUTICS AS OF 09.01.2023



Markings in the chart show rating changes by Warburg Research GmbH in the last 12 months. Every marking details the date and closing price on the day of the rating change.

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