# **Brain+ (BRAINP)**



### Have Laid the Groundwork for Future Commercial Success

In 2022, Brain+ had a successful commercial introduction of its CST-Therapist Companion dementia product in Denmark and secured the first sales contract. Further, Brain+ attracted new talents within DTx and Alzheimer's, made important advance-ments in R&D pipeline, received positive feedback on core technologies, and secured additional funding. With yet another contract secured in Q2-23, ongoing dialogues with other Danish municipalities and the upcoming market introduction in Germany, Brain+ is now on the path to becoming a commercial business. Analyst Group estimates net sales of EUR 3.0m by 2025, and with an applied EV/S multiple, a potential present value per share of DKK 1.12 is derived in a Base scenario<sup>1</sup>.

#### First (and second) B2B Sale to a Danish Municipality Secured

Shortly after Brain+ introduced its first dementia product *CST-Therapist Companion* to the Danish market for dementia care in November 2022, the first sales contract was established with the Danish municipality of Herning in late December 2022. The contract, worth DKK ~50,000, has since been expanded, both in terms of accessibility and length, which nearly doubled the contract value. As this on one hand illustrates the potential for contractual expansion once a first contract has been established, the first contract value, even after the expansion, fell below are expectations. Hence, we have revised our price assumptions for municipal sales. However, yet another important step was made during Q2-23 with the closing of the Company's second sales contract for CST-TP with a dementia care center in the Danish municipality of Gladsaxe.

#### Upcoming Capital Injection Enables Intensified Commercial Activities

Brain+ announced on March 29, 2023, the intention to carry out a Rights Issue of units, consisting of shares warrants of series TO2 and TO3. Upon full subscription, Brain+ will receive gross proceeds of approx. DKK 15.7m, where accompanied warrants can, if fully subscription, provide additional funding of approx. DKK 15.7-62.9m in total during October 2023, and March 2024. The Rights Issue will provide Brain+ with important fundings to accelerate the commercialization of the CST-TC product as well as support the ongoing development of current pipeline products, CST-Home Care and CST for MCI.

#### Revised Share Price Range

Based on the advancements in the R&D pipeline, enhanced validation and support for CST through recently published publications, the Company's newly formed collaborations, as well as the two commercial deals that lays the groundwork for future commercial success, Analyst Group retains a bullish outlook on Brain+. However, due to a slight delay in the expected time to market for the CST-Home Care and CST for MCI products compared to our previous estimates, we have based our valuation on 2025 financial figures, instead of 2024 as previously. Analyst Group argues that 2025 is a more appropriate time period to value Brain+ because by that time, its product would have been on the market for at least two years, and thus reflect a more matured Brain+ that has started to generate meaningful revenues. We maintain our previous Enterprise Value valuation range for the target year; however, the share price range has been updated in all scenarios due to the capital injection from the rights issue and the subsequent dilution effect.

-		
Bear DKK 0.46	Base DKK 1.12	Bull DKK 1.6
KEY INFORMATION		
Subscription Price Per St	nare, May (DKK)	0.9
Shares Outstanding		45,589,502
Market Cap (MDKK)		22.8
Net cash(-)/debt(+) (MDh	KK)	-14.8
Enterprise Value (MDKK)		8.6
List		First North Copenhage
Interim report 2023		2023-08-3
SHARE PRICE DEVELOPM	IENT	

Brain+ OMX Copenhagen Pl	
4,0	1 600
3,0	1 400
2,0	1 200
10	1 000
1,0	800
0,0	600
- St. y Key, huy, huy shiy shiy, shiy key, key, key, key, kuy, say, key,	)

Owners (Source: Holdings)	
Kim Baden-Kristensen	21.8%²
Ulrik Ditlev Eriksen	11.4%²
Lars Terney	6.6%2
Rasmus Højengaard	5.4%2

Estimates (EURm)	2021A	2022A	2023E	2024E	2025E
Gross Profit	0,5	0,4	0,6	0,9	2,5
Gross Profit Growth	-40,3%	-19,0%	54,5%	37,4%	180,7%
EBIT	-0,9	-1,4	-1,6	-1,8	-0,8
Net Income	-0,9	-1,3	-1,6	-1,8	-0,8
P/S	n.a.	n.a.	52,0	9,4	1,0
EV/S	n.a.	n.a.	12,6	2,3	0,2
EV/EBITDA	neg.	neg.	neg.	neg.	neg.

<sup>&</sup>lt;sup>1</sup> A subscription rate of 95% has been accounted for in announced rights issue in a Base scenario. Given that, net proceeds from the rights issue has been estimated as well as the *burn rate* during January to May 2023, in order to derive the net cash position and Enterprise Value.

<sup>&</sup>lt;sup>2</sup>The Rights Issue is expected to entail changes in the shareholder structure.

# Introduction



#### **Table of Contents**

Comment on Annual Report 2022	3-4
CEO Interview, Kim Baden-Kristensen	5-6
Rights Issue 2023	7
Investment Thesis	8
Company Description	9-12
Pipeline Of Clinical Trials	13
Market Analysis	14-16
Financial Forecast	17-22
Valuation	23-25
Management & Board	26-27
Appendix	28-29
Disclaimer	30

#### **ABOUT THE COMPANY**

**Brain+ A/S** ("Brain+" or "the Company") is a Digital Therapeutic company with the mission to restore patients' independence and quality of life by treating and detecting cognitive decline in Alzheimer's disease and dementia through Digital Therapeutics (DTx), also known as software-as-a-medicine (SaaM) applications. Brain+ has developed a set of DTx technologies, which enable the Company to create a unique and differentiated product offering. These technologies, combined with a strong clinical pipeline, puts Brain+ in a strong position to grow towards a market leader position in the dementia DTx space. Brain+ is listed on First North Copenhagen since October 7, 2021.

CEO AND CHAIRMAN	
CEO	Kim Baden-Kristensen
Chairman	Anders Härfstrand
Analyst	
Name	Christoffer Jennel
Phone	+46 731 58 95 55
E-mail	christoffer.Jennel@analystgroup.se

## **Value Drivers**



Brain+ is a DTx company targeting one of the greatest health challenges of our time – Dementia. While there are plenty of drug development companies on the market, there are other treatments for dementia too and Brain+ is the pioneer in digitizing Cognitive Stimulation Therapy (CST), which already has strong evidence behind it. This gives Brain+ a First Mover Advantage and following a successful partnership with RoX Health (Roche), Brain+ has managed to fast-forward the commercialization phase by two years, and secured its first commercial sales contract in late 2022. DTx is already a billion-dollar market and by being first to market with a digitized CST-product in combination with more collected data from ongoing clinical trials, Brain+ is in a good position to gain market share going forward.

# **Historical Profitability**



Brain+ has since 2020 shifted focus towards the development of regulated and reimbursed DTx products. While several of its current commercial product candidates are in still early trials, Brain+ has had some commercial traction through its first dementia product, CST-Therapist Companion, following the first commercial sale in late 2022. Due to this and the nature of the Company, requiring significant investments in product development and clinical trials, Brain+ has incurred losses ever since its foundation in 2012. The path to profitability is likely a couple of years ahead, where Brain+ aims to be cashflow break-even by the end of 2025. However, the rating is based on historical results and is not forward-looking.

## **Management & Board**



The Management and Board of Brain+ have strong experience within the MedTech industry and startups. The CEO, co-founder, and largest shareholder (~21%, before the rights issue) Kim Baden-Kristensen has shown a strong entrepreneurial spirit. Laying his foundation as a management consultant at BCG, Kim has since been entrusted with roles within leadership, change management, business, and intelligence. For instance, Kim has been VP of Marketing and Strategy at Vestas Wind Systems, the world's largest wind energy company. In 2022, the Executive Board expanded with three new board members, including the Head of R&D at Lundbeck Pharma, which Analyst Group believes will strengthen the Company's competitiveness going forward.

## **Risk Profile**



The business of the Company is new and unproven, and the DTx industry is yet immature as there are still some hurdles to the adoption of DTx products across all stakeholders. Historically, Brain+ has financed much of its R&D activities through public innovation grants, however, while future grant is not guaranteed, the Company has a strong track-record having raised DKK 66m via grants to date. Considering that Brain+ has incurred losses since its inception, the Company may run into liquidity problems to fund further development and operations if the subscription rate in future warrants of series TO2 and TO3 are low.

# **Comment on Annual Report 2022**



ONGOING
DIALOGUES WITH
SEVERAL OF THE
30+ DANISH
MUNICIPALITIES
THAT USE BASIC
CST

NEW GERMAN
COLLABORATION
ESTABLISHED

#### First Commercial Sales Contract With a Danish Municipality Institution

On December 31, 2022, Brain+ announced that it had closed the first commercial sales contract for its CST-Therapist Companion dementia product with the Danish municipality of Herning. The contract, worth DKK 50.000, is for the use of one dementia care facility. Shortly after (on March 20), Herning Municipality decided to expand the agreement to a municipal-wide license, as well as extending the contract length from 1 to 1.5 years. The value of the initial contract nearly doubled as a result of the contractual extension, and Analyst Group claims that this clearly illustrates the potential for Brain+ to expand inside a municipality once the first contract has been established. Since the first commercial contract is always the most challenging during the commercialization phase, Brain+'s future contract sales will be somewhat easier now that they have reached this significant milestone. The company is currently in ongoing discussions several of the 30+ Danish municipalities that are currently using the non-digital version of CST (Cognitive Stimulation Therapy).

While it is important to consider the uncertainties and variations of pricing associated with introducing a new product in an unestablished market, the contract value of the first commercial sale in 2022 fell below Analyst Group's expectations (DKK 155.000), even after accounting for the contractual expansion. Analyst Group will reassess prior price assumptions for municipal sales in the upcoming Equity Research Report update in order to account for these uncertainties as well as the pricing level of the Company's first commercial sale.

An important business activity for Brain+ during 2023 is undoubtedly the commercial introduction of CST-Therapist Companion in Germany during Q2 2023. Brain+ has already made a market entry by partnering with the leading provider of dementia care services in Germany, Malteser Hilfsdienst ("Malteser"), in Q2 2023 through a two-month pilot use of the product. The pilot project covers use in one of Malteser dementia cafés, with the potential to expand CST-TC use across the organization's 100 dementia cafés. The partnership with Malteser comes after Brain+ joined the Danish-German Care Alliance in Q1 2023 with the intention of developing regional lead customers and pilots, like the aforementioned pilot. The partnership will be an important step for the Company to raise awareness and gather feedback for CST-TC in order to improve its usefulness in the German market, and ultimately achieve the first commercial sale in the country going forward.

#### **Delivers a Gross Profit in Line with Guidance and Our Estimates**

Brain+ reported a gross profit of DKK 3.2m (EUR 0.42m) for the full year 2022, matching the upper limit of the previously outlined range of DKK 2-4m. Staff expenses and D&A amounted to DKK 12.7m (EUR 1.65m) and DKK 1.6m (EUR 0.21m), respectively, which resulted in an EBIT of DKK -11.1m. On a Y-Y basis, the gross profit decreased by approx. 19%, mainly due to lower capitalization of development costs during FY2022, and the staff expenses increased by approx. 31%, following the recruitment of new talent to support the Company's accelerated business activities. The outcome was more or less in line with our estimates for the full year of 2022 on each operational IC-item, and we estimate that the gross profit is set to increase going forward following the advancements in current commercialization of CST-TC in the Danish and German market, while staff expenses are expected to increase as well due to key recruitments during 2022, albeit in a slower pace.

	(Actual)	(Estimates)	
Income Statement (MEUR)	2022A	2022E	Change (%)
Gross Profit	0,42	0,45	-5,7%
Staff Expenses	-1,65	-1,70	-3,2%
Depreciation, Amortization & Impairment	-0,21	-0,21	1,4%
EBIT	-1,44	-1,47	-1,8%
Other Finance Income	0,00	0,00	n.a.
Finance Expenses	-0,01	-0,01	-35,90%
EBT	-1,44	-1,48	-0,02
Tax Expense	0,19	0,36	-48,1%
Net income	-1,26	-1,12	12,6%

# **Comment on Annual Report 2022**



STRONG MOMENTUM FOR CST

#### **Positive Results in Clinical Studies**

In 2022, Brain+ received early positive clinical results on its three core technologies (CST, CTT and Starry Night), and during Q1 2023, Brain'+ was provided with additional validation on its technologies, following promising clinical results for Brain+'s CCT technology for cognitive training, (which we followed up with a comment and an interview with CEO Kim Baden-Kristensen, read here.) With a maturing R&D and product pipeline, together with an increasing support as well as validation for CST (which is the foundation for Brain+'s most matured product technology) from recently published critical policy papers such as the World Alzheimer's Report 2022, A Blueprint for Dementia (WHO) and a 2nd systematic Cochrane review, Brain+ is in a unique position to benefit from this positive momentum behind CST as a non-pharmaceutical therapy for Alzheimer's dementia.

Currently, Brain+ is in two ongoing trials for the Company's CCT and Starry Night Cognitive test products, with readouts expected in 2023 and 2024. Additionally, Brain+ has three planned trials for the CST product suite during 2023-2024, where the claims trial for the second iteration of CST-TC that Brain+ is developing, will be taking place in 2023. This trial is important, as with the other two planned trials, since a positive readout would not only enable reimbursement coverage of CST-TC, but also facilitate a UK market entry and pave the way for big pharma deals. The results of the aforementioned studies will therefore be closely monitored by Analyst Group moving forward, as they will serve as an indicator of the success of the Company's commercialization.

#### **Continue to Build on its Track Record of Funding via Grants**

In 2022, Brain+ completed the two grant-funded projects Horizon and Eurostars AD Shield in collaboration with partners. The Company's collaborative approach enables grant-funding of clinical trials, and strategic alliances have also greatly contributed to Brain+'s operations. This approach has provided Brain+ with access to resources and expertise, as well as non-dilutive funding, which increases efficiency and cost-savings. Since the inception of Brain+ in 2014, the Company has raised approximately DKK 100 million in funding, of which DKK 66 million is through innovation grant funded research.

In Q1 2023, Brain+ added to this early strong track record by receiving, along with a consortium of respected dementia experts, a grant worth approx. SEK 0.5m from the EU Joint Programmme – Neurodegenerative Disease Research, that covers the research into the Company's two main therapeutic technologies (CST and CTT). The grant will also cover the examination of the hypothesized synergy effect of combining CST and CCT, which is a key research step for the third product in Brain+ CST-suite, CST for MCI. The project will be structured into three different groups, all contributing to the development of Brain+s pipeline. Analyst Group is optimistic about Brain+'s ability to secure grant after grant in order to fund the Company's R&D, as this demonstrates not only the support and interest that exist for Brain+ from

Ongoing Rights Issue will Strengthen the Balance Sheet and Enable Brain+ to Proceed With Outlined Commercial Activities.

the stakeholders within the Alzheimer's space but also validate the relevance of its offering.

Brain+ has historically been largely funded by grants, and by entering the commercialization phase in late 2022, whilst still advancing the product pipeline via clinical trials, additional resources were expected to be required, according to Analyst Group. Hence, the announcement of the rights issue on March 29, came as a no surprise, and the proceeds are necessary for Brain+ to execute on the planned commercial activities to increase sales and make further advancements in R&D. For more information on the Rights Issue and our view on it, we refer to our previous comment on the rights issue here.

The Company's cash balance at the end of 2022 amounted to DKK 6.4m, a decrease from approx. DKK 10m at the end of 2021, despite a capital injection (net) of approx. DKK 5.5m for warrants of series TO1 in Q4 2022. The ongoing rights issue has been secured to approx. 85%, hence providing Brain+ with sufficient capital to cover up for working capital needs and further investments in R&D, where accompanying warrants of series TO2 and TO3 will play a significant role going forward. Grant financing will continue to be a supplementary source of funding for the Company's R&D pipeline, as well as allowing Brain+ to make existing cash levels and the upcoming cash injection from the rights issue last for a longer period of time. To summarize, Analyst Group maintains a positive view on Brain+ based on the pipeline's maturation, improved validation and support for CST via recently published reports, the Company's newly established partnerships, as well as the first commercial sale that lays the foundation for further commercial success.

RECIEVES EU GRANT TO RESEARCH ON MAIN TECHNOLOGIES

RIGHTS ISSUE ENABLES EXECUTION ON PLANNED COMMERICAL ACTIVITIES

# **CEO Interview, Kim Baden-Kristensen**





The books for 2022 have now been revealed, showing a Gross Profit of DKK 3.2m for the full year 2022, in line with your guidance of DKK 2-4m, but at the same time slightly lower than in 2021, mainly due to lower capitalization of development costs. On the other hand, a lot has happened not only in 2022, but also at the beginning of 2023. How would you sum up 2022 and the beginning of 2023?

2022 has been a step-change year, in which we made commercial introduction of our first digital dementia product, the CST – Therapist Companion, 2 years earlier than expected at the time of the IPO and succeeded in closing also our first Danish public sector health care B2B sales contract, thus transitioning Brain+ from a pure R&D company to an early-stage commercial operation. Also, we successfully concluded numerous clinical trials with our academic partners which have provided positive feasibility and proof of concept results on our core products and technologies. In addition, we strengthened the board of directors and our team with veteran life science, digital therapeutic and life science profiles. So far in 2023, the positive 'takter' have continued with expansion of our first sales contract, signing of a the second contract in Denmark, partnership with one of the largest dementia care organizations in Germany to create early awareness of our German CST-TC version, extended our collaborations with leading experts and key opinion leaders in our field in Denmark, Sweden, Germany and the UK – and launched an 85% preguaranteed capital increase to finance the next two years growth.

Patient data security is a critical concern in the digital therapeutics (DTx) industry, given that these solutions involve storing and processing sensitive patient information. Could you provide some color on how Brain+ works to ensure patient data security in your DTx-products?

From the beginning of our product design process, our team of IT and regulatory specialists build our system architecture and products to comply with all relevant ICT and patient data security requirements, as well as with other applicable quality and regulatory standards. We consider ICT security and customer data protection to be an integral part of our products and of our intellectual property (code and methods). We deploy best-practice technical measures to prevent malicious intrusion in our systems, including two-factor access for all developers, use of data storage solutions complying with SOC 1 2 & 3, and integration of best-practice standards for secure development in all our products, including use of IEC 82304 and CIS18 controls.

The digital therapeutics market currently is still in its early development. Most digital therapeutics are paid for on a fee-for-service basis, which can be difficult to sustain for the providers and payers alike. How does Brain+ intend to address the challenges associated with a sustainable revenue model in the DTx industry?

Large scale DTx reimbursement frameworks are becoming available in more and more countries these years and these will help to sustain a sustainable and attractive revenue model for DTx products. In 2022, Germany opened its 2nd DTx reimbursement channel, and here in May 2023, France went live with its new DTx assessment process for national reimbursement. The UK already has such system in place, and more markets are preparing to open similar reimbursement routes for DTx. In the meantime, we see it as both valuable and competitively sound to begin scaling based on fee-for-service models, or as in our case on a SaaS model as applied for CST-TC.

Pear Therapeutics, which has three FDA-cleared prescription apps to help treat substance use disorder and insomnia, filed for Chapter 11 bankruptcy in April 2023 after facing major financial challenges. What is your view on Pear Therapeutics' recent bankruptcy filing and what do you think it means for the DTx industry?

Pear Therapeutics has been a first mover and been playing a very important part in maturing the DTx industry and in particular the US DTx ecosystem. Just as we are seeing it in biotech and other high tech industries, it often takes time for innovative companies in new markets to scale to profitability. The financial market conditions for those companies are just tough, and regardless of whether the business fundamentals are sound, some companies will run into trouble getting sufficient funding due to timing, cost base, and in particular financing structure. This seems to have happened to Pear. I hope Pear will end being picked-up by a stronger player and continue its journey, but even if this will not be the case, there case is a foreseeable bump in the road, when building a new business model around a new product category like DTx. I cannot in any way see, how the challenges of Pear Therapeutics change the perspective that DTx will become an important and integral part of how health care will be delivered in the future.

# **CEO Interview, Kim Baden-Kristensen**





Brain+'s main objective in 2023 will be to expand CST-Therapist Companion sales in Denmark and to launch the product in Germany, while also developing new features and maturing the product pipeline. Could you perhaps comment on Brain+'s strategy for increasing CST - Therapist Companion sales, as well as how Brain+ intends to handle regulatory constraints and market hurdles as you expand into Germany? Also, could you provide more details on the additional features and product pipeline that Brain+ is currently developing, as well as what they will enable?

In Denmark, we are targeting in first instance the about 30 municipalities already using basic CST (Cognitive Stimulation Therapy) in their dementia care, and this is what CST – Therapist Companion supports. The first two sales contracts have been closed with two different municipalities, and getting the first foot in the door is key in this market with a view to further expansion. We are in dialogue with several other municipalities – and even some, which are not yet using basic CST. Considering the traditional municipal sales cycle of 12-24 months, we are encouraged by the interest, we are being met, and expect to close several additional contracts in 2023 – even if most likely not until Q4.

In Germany, we have worked with Rox Health, a daughter company of Roche Germany, on preparing the regulatory pathway for our type of products, so here a lot of the market access work has been done. Some of the remaining hurdles are first to be approved for reimbursement then to get acceptance from dementia clinicians. We are working on the reimbursement model for Germany, looking at the national framework of DiPA and others, and will share more this year. To address the clinician adoption barrier, we have deliberately chosen to market adapt our products in close collaboration with the leading German key opinion leaders in dementia and currently with a focus on CST-specialists.

The second product in our pipeline, CST - Home Care, will extend the delivery of Cognitive Stimulation Therapy into people's own homes, which we foresee will significantly increase access to this therapy and extend our market potential. The third product in the pipeline, CST-for-MCI, is for people in the earlier disease stage of Mild Cognitive Impairment. The earlier we can treat the better, because we may be able to delay the onset of dementia and thus improve quality of life for people for many years, while saving considerable health care costs. This early stage segment is also what the new Alzheimer's drugs, which recently have shown positive clinical effects, are where there are highly attractive prospects for combining our DTx solutions with medicine.

On March 29, Brain+ announced a right issue of units amounting to approximately DKK 15.7 million (gross proceeds) in order to primarily advance in clinical trials and expand commercial activities. Could you give three reasons as to why Brain+ is a good investment today?

The fundamental business case of Brain+ has only strengthened since the IPO; the main therapy we are working with, CST, has gained international support by the WHO and Alzheimer's Disease International; we have strengthened our position with global key opinion leaders in all our target markets; and we have delivered in terms of product development and market introduction on our objectives set out at the IPO. We have embarked on our commercial journey, and will be hitting a number of major value inflection points in the coming years, including proof of business, medical device certifications, new product launches to mention some of them. From this perspective, one can consider the prospects of our company and compare the IPO valuation with the price of buying new shares via the unit offering, and make ones choice about the investment attractiveness of Brain+.

# **Rights Issue 2023**





USE OF PROCEEDS (Right Issue):

# Commercial Activities

Scale sales of CST-TC in Denmark, Germany and the UK.

#### **Clinical Program**

CST-Home Care and CST for MCI

#### **Development**

Of the UK version of the CST-Therapist Companion (TC)

#### **Working Capital**

Cover other operating expenses through November 2024 On March 29, 2023, Brain+ announced that the Company intends to carry out a preferential Rights Issue of shares and warrants of series TO 2 and TO 3. The Rights Issue compromises a maximum of 15,720,518 units where each unit consists of two (2) shares, two (2) warrants of series TO 2, and two (2) warrants of series TO 3. The subscription price is set to DKK 1.00 per unit, which corresponds to DKK 0.50 per share, and the warrants are issued free of charge. Given a full subscription of the Rights Issue, Brain+ will receive approx. DKK 15.7 million before transaction-related costs. Subsequently warrant exercise of TO 2 and TO 3 can, if fully subscribed, provide the Company with an additional amount of approx. DKK 6.3-25.2 million and DKK 9.4-37.7 million in gross proceeds. If the Rights Issue is fully subscribed, the Board of Directors has the option to resolve an Over-Allotment Issue of up to 5,821,544, which would correspond to additional issue proceeds (gross) of approx. DKK 5.8 million and thus enable a further acceleration in clinical and commercial activities.

The Company has received pre-subscription commitments amounting to approx. DKK 4.4 million, or ~28% of the initial part of the Rights Issue, and guarantee commitments amounting to approx. DKK 8.9 million, or ~57%. Hence, the Rights Issue is secured to approximately DKK 13.4 million, or ~ 85 %.

The dilution effect from the Rights Issue for shareholders that do not choose to participate, assuming fully subscribed, amounts to approx. 66.7%, and in case of full subscription of the warrants of series TO 2 and series TO 3, additional dilution of approx. 40.0 % and approx. 28.6 % will occur.

#### **Brain+'s Upcoming Rights Issue At A Glance**

~ DKK 15.7 M

In gross proceeds upon full subscription to the Rights Issue **DKK 1.00** 

Price per Unit

May 10 to 25, 2023

**Subscription Period** 

#### **About Warrants of Series T02**

The exercise price in the warrant exercise of series TO 2 will amount to 70% of the average volume-weighted price for the share according to Nasdaq First North Growth Market's official price statistics during the period of 20 trading days ending two (2) banking days before the exercise period begins. The Company will publish the exercise price the day before the first day of the exercise price the day before the first day of the exercise price the exercise price shall not exceed DKK 0.80. The exercise price shall not fall below DKK 0.20. One (1) warrant of series TO 2 gives the right to subscribe for one (1) new share in the Company during the exercise period that is planned to be from October 2 - October 16, 2023.

#### **About Warrants of Series TO3**

The exercise price in the warrant exercise of series TO 3 will amount to 70% of the average volume-weighted price for the share according to Nasdaq First North Growth Market's official price statistics during the period of 20 trading days ending two (2) banking days before the exercise period begins. The Company will publish the exercise price the day before the first day of the exercise period. The exercise price shall not exceed DKK 1.20. The exercise price shall not fall below DKK 0.30. One (1) warrant of series TO 3 gives the right to subscribe for one (1) new share in the Company during the exercise period that is planned to be from March 8 - March 22, 2024.

#### **Pre-Money Valuation**

15,720,518

Shares outstanding Pre-Right Issue



**DKK 0.5** 

Subscription price per share



~DKK 7.9 m

Market Cap (Pre-Money)

#### ~DKK 15.7 m

Upon full subscription (before transaction-related costs



#### **Post-Money Valuation**

47,161,554

Shares outstanding Post-Right Issue (upon full subscription)



**DKK 0.5** 

Subscription price per share



~DKK 23.6 m

Market Cap (Post-Money)

## **Investment Thesis**



~140M PEOPLE WITH DEMENTIA IN 2050

CST GAINS FURTHER SUPPORT FROM CRITICAL POLICY PAPERS

FURTHER
MILESTONES HAVE
BEEN REACHED
WITHIN DTX DURING
2022

COMMERCIAL ROLL-OUT













EUR 3.0M REVENUES 2025E

THE DTX MARKET IS STILL IMMATURE

Nordic Digital Health and Evaluation
 Oritoria

 $^2$ A 95% subscription rate has been modelled for in a Base scenario, corresponding to a dilution effect of  $\sim$  66%.

Ag Analyst Group

**Unique Product Offering That Addresses A Billion Dollar Market** 

USD 1.3 trillion. That was the estimated total global society cost of dementia in 2019 and this figure is posed to more than double by 2030. Dementia is a massive unmet clinical need and is, as such, a growing health concern on a global basis, where the number of people with dementia is set to exceed 139 million by 2050, from 55 million in 2019. There is currently no treatment available to cure dementia, instead there are treatments that can help to temporarily reduce or alleviate symptoms, which is why biopharma has over 140 drugs in the pipeline. While medicines for dementia symptoms are important, they are only one part of the care for a person with dementia and combining drugs with DTx is a major opportunity for the future, pharma companies are therefore seen as potential partners rather than competitors for Brain+ and DTx in general. Today, the leading non-pharmacological treatment of dementia is CST, which is a guided talk therapy to stimulate cognition that has been adopted in 35 countries and is also e.g., the recommended standard of care in Germany, Denmark, and UK, for treating people living with mild to moderate dementia. Moreover, CST was highlighted in the World Alzheimer's Report (2022) as a cost-effective and evidence-based therapy for dementia that should be further researched and implemented globally. In its most recent policy paper, A Blueprint for Dementia Research (2022), WHO also highlighted the advantages of CST, stating that evidence suggests that CST, among other rehabilitative interventions, can, for example, improve cognition and quality of life and that psychosocial interventions are effective when delivered digitally. Brain+ is the pioneer in digitizing CST, which already has rigorous clinical evidence behind it, including a two Cochrane reviews.

#### Digital Therapeutics Is A Fast-Growing Segment Within The Healthcare Sphere

DTx are a novel category of medical interventions that have gained market traction within the healthcare sphere in recent years. The value-proposition of DTx stretches all the way from patients and caregiver, to clinicians and payors, as it, for example, makes health care more convenient and accessible for the former two, and reduces the overall cost of care as well as optimize patient engagement for the latter two. DTx are increasingly becoming an integrated part of healthcare and policymakers at the local, national, and regional levels have, to a larger extent, established DTx reimbursement and regulatory pathways which, in turn, paves the way for a faster adoption of DTx products going forward. In 2022 alone, there have been several breakthroughs on this subject such as revised FDA regulations, the establishment of DiPA in Germany, and the creation of the NordDEC¹, to name a few. On top of that, the number of apps approved for national reimbursement via DiGA in Germany grew to 32.

#### First Commercial Sales Contracts Has Been Secured - Two Years Ahead Of Plan

On December 31, 2022, just two months after the market introduction of the Company's first dementia product *CST-Therapist Companion*, Brain+ secured the first commercial sales contract, and in Q2-23 Brain+ secured yet another sales contract. Considering the usual 1-2 year sell cycle to municipalities, securing two sales contract within six months after the initial market introduction is a sign of strength according to Analyst Group, and showcases the importance of Brain+'s dementia products. The first commercial sales represents an important milestone for the Company and marks a two-year market acceleration relative to the commercial roadmap projection during the IPO in 2021. In addition to expanding the market share in Denmark, where Brain+ currently engages in dialogues with 30+ Danish municipalities that already use CST, the company is targeting Germany for the next commercial roll-out in Q2 2023. Brain+ has the prerequisites needed to succeed with the commercialization in Germany moving forward as a result of the Company's already established partnership with RoX Health (a Roche subsidiary), a current strong network of KOLs, and initiated collaborations with the German medical distributor Coopmed as well as Germany's top provider of dementia care services Malteser Hilfsdient.

#### Forecast And Valuation: a Summary

In a Base Scenario, Brain+ is estimated to reach net sales of EUR 3.0m in 2025 following further commercial traction in Denmark and upcoming commercial introductions in Germany and the UK. With a target multiple of EV/S 2.9x on estimated net sales in 2025, and a conservative discount rate of 16%, which accounts for the time-specific risk of events that are far away and have not yet occurred, this yields, in a Base scenario, a potential net present value per share of DKK 1.12.

#### DTx Is Still An Immature Industry And Faces Hurdles To The Adoption Of DTx

While the DTx market has gained traction within the healthcare space and reached several important reimbursement and regulatory milestones recently, it faces several risks and challenges going forward as it is still an immature industry. The future of DTx will depend on the ability of companies to overcome fundamental challenges such as the ability to demonstrate its impact, the optimization of pricing and reimbursement, as well as general structural behavioral change across the stakeholders and their mindset about DTx. As with many other DTx companies, the path to profitability lies a couple of years away for Brain+, and even though Brain+ has a strong track-record of receiving grant funding to finance much of its R&D activities in the past, it is not a guarantee for the future.





**Brain+** is a Digital Therapeutic ("DTx") company that develops medical software applications to detect and treat the cognitive symptoms of dementia, with a particular focus on Alzheimer's disease, the most common form of dementia. Since its inception in 2012, Brain+ has gained a strong knowledge base, attracted a broad network of global expert collaborators, and landed the company's first large pharma deal with RoX Health, a subsidiary of the global pharma company Roche, in 2021. Brain+ has also gained some commercial traction by securing its first commercial sales contract with the Danish municipality of Herning in late 2022 regarding the Company's first dementia product on the market – *CST-Therapist Companion*.

#### **Overview of Core Technologies**

Brain+ has developed three core DTx technologies, which are undergoing clinical validation and further iterative development, where each technology targets specific modes of action to not only treat but also prevent brain disorders and cognitive dysfunctions. Dementia is a disease that undergoes different stages, from mild to severe, and Brain+ initial product technology to market, a digitized Cognitive Stimulation Therapy ("CST") solution, targets the Mild-Moderate stage, while future product technologies (Computerized Cognitive Training "CCT" and Starry Night) targets the Mild Cognitive Impairment Stage, which can be seen as the "Pre-Phase" of dementia, in order to detect early symptoms of dementia. Based on the product technologies, Brain+ develops commercial products, where each are represented in two parts, one application for the patient to interact with and receive the therapies, and one application for the clinicians, which offers progress analytics of the patients. The three core technologies that Brain+ has developed are:

#### **Current stage: Introduced in Q4-22**

Digital Cognitive Stimulation Therapy ("CST") is a DTx product technology delivered as a dementia therapy that treats the main symptoms of dementia, namely cognitive decline. It works like a guided talk therapy which facilitates deep thinking and social interaction that stimulates cognition. CST as a treatment has proven to move patients two points on the Mini Mental State Examination test, which is a significant improvement in a person's abilities, which is also why CST is the recommended standard of care for dementia in e.g., Denmark, Germany, and UK. This treatment has been digitized by Brain+ together with leading clinical experts and the first product in Brain+ CST-product technology suite, CST-Therapist Companion, is a digital tool used in a clinic where the therapy is led by a trained CST professional. This product enables therapists to reduce the preparation time by around 80%, standardize CST group sessions in high quality, and enhance the consistency in therapeutic delivery. The second product is the CST-Home Care which relies on a caregiver to interact with the person with dementia when the CST therapy is performed at home. The third product, CST for MCI, targets people with Mild Cognitive Impairment, a pre-phase of dementia that is 3-4x more prevalent than dementia, and is intended to allow the prescription of CST therapy right after diagnosis for home use without patient having to attend group sessions first. While the first product, CST-Therapist Companion, has already been commercial introduced in Q4 2022, the second and the third CST-products are under development. The time to market for the CST-Home Care product is expected to be in 2025.



Cognitive Stimulation Therapy (CST)

## **Current stage: In developement**

**Computerized Cognitive Training** ("CCT") is in simple terms a product that can be likened to a fitness exercise for the brain and the 2<sup>nd</sup> generation of this technology is currently being developed for use in the pre-stages of dementia, like mild cognitive impairment or in people who are in high-risk groups for developing dementia and will be targeting the regulated market. The 2<sup>nd</sup> generation of this product will not only add new mechanisms of action, which target specific neural pathways in the brain relevant in dementia, but also build on the technologies already developed in the 1<sup>st</sup> generation.



Computerized Cognitive Training (CCT)

## Current stage: In developement

**Starry Night** is an app-based memory test which is designed to detect early cognitive decline related to Alzheimer's and to monitor disease progression. The test measures binding errors in the working memory and is sensitive to changes in hippocampal volume, where hippocampus is a part of the limbic system in the brain that plays an important role in regulating learning, memory encoding, memory consolidation and spatial navigation. The memory test was originally developed at Oxford University and then further co-developed, gamified and made scalable with Brain+.





#### The Relevance Of Brain+ Technology And Product Offering

With more than 140 drugs in the pipeline for Alzheimer's disease, over 80% of these focus on disease modification and the candidate treatments are often backed by well-funded pharmaceutical companies. While drugs cannot strengthen the neural networks of the brain directly, they can, however, facilitate that the biological systems are not dysfunctional and that they are in a state of readiness and plasticity, meaning the ability to change. The digitized treatments that Brain+ develops address the cognitive decline that people with dementia experience and will be complementary to drugs that target the underlying pathology, much like how it works today for a, for instance, stroke patient. To add additional color to this, these patients need to take blood thinners to avoid further strokes (in the case of Alzheimer's this can be compared with taking a drug), while at the same time exercising to strengthen their cardiovascular system (in this case Brain+ products' treatment of cognitive decline). Given this, pharma companies can therefore be seen as potential partners to Brain+ rather than competitors, given that the modes of action are different as mentioned above, and could therefore be used as value-added services or a synergistic service when conducting the two treatments simultaneously to achieve an even bigger effect. Breakthroughs within Alzheimer's and Dementia are rare, which is why pharma companies are continuing to invest heavily in the indication. This results in a significant strategic partnership potential for Brain+ who, to date, has ongoing dialogues with leading pharmaceutical companies within Alzheimer's and dementia.

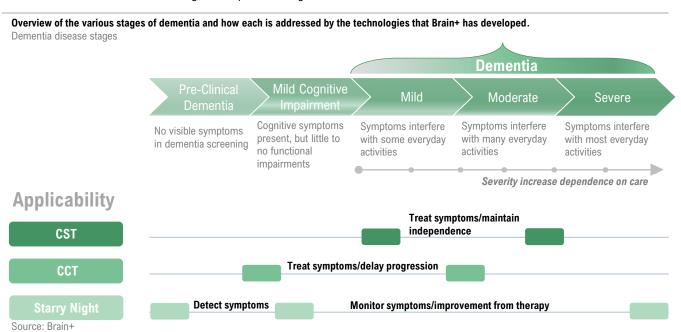
BIG PHARMA ARE POTENTIAL PARTNERS TO BRAIN+

Furthermore, the Alzheimer's targeted memory test developed by Brain+, Starry Night, is of high relevance for potential pharmaceutical partners as the drugs they are developing are likely to be more effective if it is used earlier in the dementia disease stage, which Starry Night is developed to do.

Currently, there are several so-called "brain training apps" on the market to function as a "brain fitness center", however, they are non-regulated and do not have the rigorous evidence-based approach necessary for becoming a regulated digital therapeutic. Brain+ is thus differentiating itself from these apps, due to its DTx approach, with clinical validation, regulation, and reimbursement.

#### **Brain+'s Technologies Targets Multiple Disease Stages**

Dementia is categorized into different phases based on the progression of brain changes. The three broad phases are Pre-Clinical Dementia, Mild Cognitive Impairment (MCI) and Dementia, which is further subcategorized into mild, moderate and severe. The length of time spent in each stage varies and is influenced by factors such as age, genetics, and biological sex, to name a few. Brain+'s developed technologies - CST, CTT and Starry Night – are applicable across multiple of abovementioned disease stages, where the initial introduced product, CST, targets the Mild to Moderate-stage, while upcoming products will target the Mild Cognitive Impairment stage.





#### **Business Model**

The primary business model of Brain+ is to bring prescribed and reimbursed DTx-products to the market as a *Software-as-a-Medical-Device* ("SaMD") solution. Since the digital software apps that Brain+ develops are specifically designed to have a health impact on patients, Brain+ products needs, as a DTx-company, to go through very rigorous standards and regulatory processes to become a reimbursement product, much like how it works in the Life Science sphere when developing a new drug. This means that DTx-products are evidence-based and go through clinical trials similar to normal medicine. Brain+, therefore, needs to comply with medical regulations for its DTx medical products, and apply for reimbursement, before they can be prescribed by clinicians, and, similar to a drug, be paid for by e.g., national or private health insurance systems. If the products become regulated and prescribed as a drug, they do not necessarily always become reimbursed, and in that case, the end customers (i.e. the patients) will need to pay for the treatment themselves. Reimbursement trends are, nonetheless, positive, and an increasing number of healthcare payers express readiness to reimburse DTx products. Brain+ initial commercial introduction of the *CST-Therapist Companion* will, however, come in the form of a B2B SaaS solution, by selling directly to either municipalities or care homes/givers, as it will be introduced as a digital health tool to support therapists and therefore does not require a regulatory certification.

The initial business model for Brain+ will come in the form of a B2B SaaS solution, while the primary business model of Brain+ in the future is expected to be a SaMD-solution, supported by products with medical claims.

The initial and primary business model of Brain+



Initial market approach

B2B-SaaS



Aimed market approach

Software as a Medical Device Solution

Source: Brain+

#### **Cost Drivers**

Unlike most public companies, Brain+ shows the gross profit as the top line in the P&L, including items of revenue, work by the Entity, other operating income, and other external expenses. The latter includes for example costs for distribution, sales, advertising, administration, and premises, loss of debtors, and operating leasing costs. So, while Brain+ way of accounting drives lower gross margins per se, the operating income will be the same, regardless if Brain+ used the same accounting metrics as other listed companies.

On an operational level, staff expenses are the main cost driver for Brain+ and since the IPO in 2021, Brain+ has been expanding the team to strengthen finance, quality and compliance management, research, and software engineering. Currently, Brain+ has sufficient in-house capacity to manage the sales efforts required to enable additional contracts for the first dementia product *CST-Therapist Companion* in Denmark throughout 2023. However, as Brain+ progresses with the R&D pipeline and commercialization phase, staff expenses are expected to increase in the following years to manage further clinical trials as well as product development. Further, Brain+ intends, to a large extent, to rely on partnerships to scale sales internationally rather than building an international sales force *in-house* which, in turn, enables Brain+ to keep increases in staff expenses at a slower pace, as these sales-partnering costs will be recognized as a gross expense for Brain+, due to revenue share.

Brain+ also intends to enter licensing deals with pharma counterparts for its products or tech, which would be associated with royalties in connection with product sales and, as such, provide a cost-efficient scale-up and enables Brain+ to further capitalize on the potential commercial success of its products. By developing scalable software products from its current R&D setup and core technologies, the incremental unit economics are attractive, creating strong operating leverage as the product sales start to take off. However, the upfront investments are lumpy and the path to profitability is a few years away.

STRONG OPERATING LEVERAGE





ONGOING
CLINICAL TRIALS
ARE IMPORTANT
FOR FUTURE
COMMERCIAL
SUCCESS

#### Strategic Outlook

The development and commercial success of Brain+ products rely on getting positive results from scientific and clinical trials. The two ongoing trials, both paid for by grants, are at early stages including the feasibility studies and Proof of Concept. Additionally, Brain+ has three trials scheduled for the CST product line, with the first two is intended to gather information for regulatory compliance and meet reimbursement requirements, and the third is intended to conduct a Proof of Concept study to assess effectiveness and safety. As Brain+ collects more clinical data, the Company can move its products into the medical class with medical claims and reimbursement. To reach large-scale commercialization and reimbursement for its products, Brain+ must show positive outcomes in future pivotal stages as well as receiving regulatory approval and public certifications. The path to reimbursement is, in general, time-consuming and accompanied with not only regulatory processes, but processes that involves garnering real-world evidence that showcase that the DTx-product still perform well outside of a clinical trial setting and publishing studies that emphasizes the product's therapeutic benefit for patients, as well as its economic benefits. What has been seen in the DTx-space is that while some DTx are both regulated and prescribed, it distinguishes whether a DTx product is reimbursed, or is selling via a non-reimbursed model.

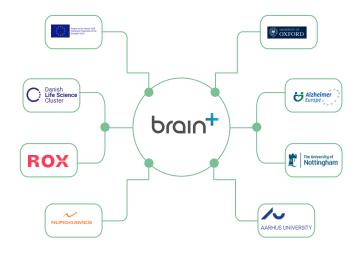
By commercializing its first dementia product in Denmark in Q4 2022 and Germany in Q2 2023, Brain+ will receive important data, outside clinical trials, which will be valuable for the path to reimbursement and large-scale commercialization. The data collected from commercial introductions will also enable Brain+ to not only further adapt and personalize treatments, but build algorithms, which together with machine learning, makes Brain+ technology harder to copy.

# Commercial Road Map



By working with a strong network of experts and key opinion leaders (KOL's) in ongoing trials, together with current established partnership with RoX Health and other valuable collaborations, Analyst Group argue that Brain+ is in good position to yield expected results in clinical trials. However, it should be noted that the nature of highly innovative technologies, such as Brain+ DTx product, carries a high risk were any delays or negative readouts in ongoing and planned trials could have a significant impact on the Company's financial and market position.

The core of the Brain+ strategy involves partnerships since they strengthen the organization's inherent capabilities. A selection of Brain+ current network of KOL's and partnerships

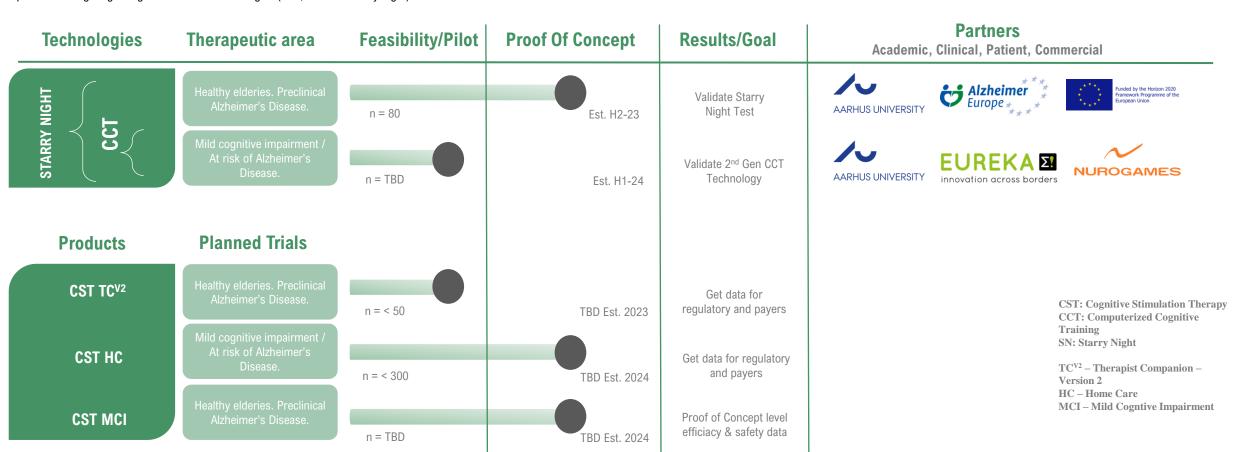


Source: Brain+

## PIPELINE OF CLINICAL TRIALS

Brain+ has two ongoing and three planned trials, where the CST-Therapist Companion version 2 will be tested in 2023 to document its benefits, with an emphasis on satisfying reimbursement-required endpoints that validate its clinical benefits connected to treatment. This trial will also give data to assure regulatory compliance as a medical device that is MDR compliant. Similarly, CST-Home Care has a planned trial to determine its benefits in 2024, with the goal of satisfying reimbursement-required goals that validate clinical benefits related to reducing cognitive decline and improving quality of life for both caregivers and users. This trial will also give data to assure regulatory compliance as a medical device that is MDR compliant. In addition, a Proof-of-Concept Study (Phase 2) for the CST-for-MCI study is being planned to investigate efficacy and safety.

The ongoing trials are conducted in collaboration with a strong network of experts and key opinion leaders (KOL's), and these are all paid for by grants. To date, Brain+ has raised approximately DKK 100m in fundings (of which DKK 66m were grants) and are continuing to work with grants, where Brain+ have a number of ongoing of grant projects with the Company's university partners. As of April 2023, Brain+ and its partners have completed six feasibility and proof-of-concept ("POC") trials with positive findings regarding its three core technologies (CST, CCT and Starry night).



# **Market Analysis**



## Dementia Is One Of The Greatest Health Challenges Of Our Time

Dementia is a rapidly growing public health problem that primarily affects, but not exclusively, older people, and leads to a deterioration in cognitive functionality beyond what might be considered the usual consequences of biological aging. Though dementia is the broader term for this condition, Alzheimer's disease is the most common form and constitutes up to 70% of all cases of dementia. In 2019, around 55 million people lived with some form of dementia, with the majority living in low-and middle-income countries, and due to an increasing proportion of older people in practically every country's population, this number is expected to almost triple by 2050 and reach 139 million. Today there are nearly 10 million new cases on an annual basis and dementia is not only the seventh leading cause of death among all diseases, with one in every three seniors dying with dementia in the US, but also one of the major causes of disability and dependency among older people worldwide.

Mild Cognitive Impairment (MCI) is a condition in which a person's cognitive abilities, such as memory, language, attention, or problem-solving skills, deteriorate more than would be expected for their age and education level, but do not significantly interfere with their daily activities or independence. MCI is sometimes regarded as a transitional stage between normal cognitive changes associated with aging and the more severe cognitive decline associated with dementia. According to research, 10-15% of people with MCI develop dementia each year, with around one-third developing dementia related to Alzheimer's disease within five years. However, not everyone with MCI develops dementia, in fact, some people may recover or remain stable over time. Given that MCI is an earlier stage within the Dementia disease stage, the prevalence rate is significantly greater, and it is predicted that 150-200 million individuals worldwide live with MCI (according to the Company), more than three times as many as those living with dementia.

The social and economic implications of dementia are tremendous in terms of direct medical and social care costs, as well as the costs of informal care. In 2019, the total global societal cost of dementia was estimated to be USD 1.3 trillion by WHO, and these costs are expected to more than double by 2030, exceeding USD 2.8 trillion, driven by increased care costs and the number of people living with dementia.

## 139M

People living with dementia in 2050

#### +10M

New dementia cases each year

#### **■ 150-200M**

People living with MCI today

#### Dementia At A Glance.

Prevalence rate worldwide, fatality rate in the US and global cost of dementia.



Current treatments of dementia come either as a drug/medicine or as a non-drug treatment, like for instance cognitive stimulation, music-based therapies, and psychological treatment with the overall goal to maintain or improve cognitive function, enhance quality of life, and the ability to perform daily activities. However, these treatments for dementia are not able to cure the disease itself but rather help to temporarily reduce or alleviate symptoms and provide general beneficial outcomes for the person with dementia. As a result, pharma companies have begun to address both alternatives and complementary treatments for traditional medicine/methods.

In January 2023, the FDA approved breakthrough Alzheimer's drug Lecanemab, developed by U.S. Biogen and Japanese Eisai, in a so-called *accelerated approval process*, which, in turn, increases the overall incentives from market participants and stakeholders to invest and focus on the Alzheimer's space.

Source: Alzheimer's Association & WHO

# **Market Analysis**



#### A New Fast-Growing Digital Health Care Industry Is Emerging

Digital Therapeutics ("DTx") are a relatively new fast-growing sub-group of medicine that provides evidence-based therapeutic interventions to patients that are driven by high-quality software programs to manage, treat and prevent diseases or other medical disorders, prescribed by doctors and often reimbursed by public or private funders. DTx enables much richer and more continuous data that allows personalization and adaptation of treatments to the patient's evolving needs. Some DTx treatments are even "stand-alone", meaning that it provides similar health outcomes for patients without the need for external support. Further, since DTx products are developed after the same principles as classic drug developments, meaning it goes through clinical trials, similar regulatory and safety requirements, DTx-treatments can replace and/or work as a complementary tool for existing treatments. However, the major differences between DTx and classic pharma are that the general R&D and clinical development come at a much lower cost, but at the same time enables a faster time-to-market. Risk of severe side effects are also reduced with DTx, and it also has the potential to offer a range of customized interventions in contrast to traditional medicine that comes with a "one-size-fits-all" approach. Even though DTx are associated with reduced costs and risks, the commercial potential and health benefits are comparable to those of traditional pharma.

#### The Value-Proposition And Relevance of DTx

**Challenges for DTx to Overcome** 

DTx have the potential to offer numerous benefits to various stakeholders. DTx can help **society** by improving access to evidence-based treatments, reducing healthcare costs, promoting better health outcomes, and enhancing the overall healthcare infrastructure through technology. **Patients and caregivers** can benefit from DTx as they can access healthcare services in a more convenient and flexible manner. DTx can provide personalized interventions, empower patients and caregivers through access to real-time data, and reduce the stigma associated with seeking help for certain conditions.

Further, DTx can also enhance clinical decision-making for clinicians, while offering greater efficiency, reducing administrative burden, and extending the reach of care through remote delivery. DTx can reduce healthcare costs and complications, offer cost-sharing and risk-sharing models for **payors**, and improve member satisfaction and retention. Furthermore, DTx can enable **pharma companies** to develop new therapies, collect real-world data, improve engagement and adherence, and enter new markets. Finally, **policymakers** can promote innovation and efficiency in healthcare delivery, improve access to treatments, address disparities, and develop regulatory frameworks to ensure patient safety and the effectiveness of DTx.

While DTx holds great potential, there are several key challenges that needs to be addressed. First, regulatory and reimbursement challenges can make it difficult for companies to develop and commercialize DTx, since lack of clear regulatory guidance and reimbursement frameworks can create uncertainty and limit the adoption of DTx. Secondly, DTx collects and processes sensitive health data, which can raise privacy and security concerns. Companies must ensure that they comply with applicable data protection regulations and implement robust security measures to protect patient data. Thirdly, user engagement and adoption can be a challenge for DTx. Patients may not be motivated to use the technology or may lack the necessary digital literacy skills to access and use the DTx solutions effectively. Fourthly, DTx needs to be integrated with existing healthcare systems to provide optimal care for patients. However, interoperability challenges can arise due to the lack of standardization across platforms and technologies.

Finally, in a business model for prescription DTx, the clinician is the gatekeeper who must know about the therapy's benefits and appropriate use. Barriers include lack of awareness and scepticism among healthcare providers. Hence, there is a need for robust clinical studies to generate evidence for the safety and efficacy of DTx, while also obtaining the products' certification as medical device software in order to overcome these obstacles. This requires significant investments in research and development and may pose challenges for companies seeking to commercialize their products. Addressing these challenges will be critical to the success of DTx and the realization of its potential benefits for patients, healthcare providers, payors, and society as a whole.

#### DTx vs Pharma



DTx includes significantly lower risk



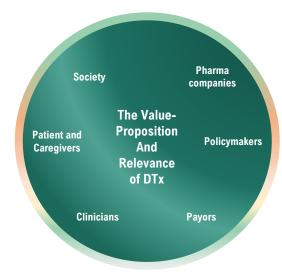
DTx is not as costly



**Shorter Time-To-Market** 



Despite lower risk and cost, DTx faces similar potential



# **Market Analysis**



#### **INITIAL ADRESSABLE MARKETS & SIZE**











**EUR** 170m

#### Digital Therapeutics Market is Set to Nearly Ten-Fold in the Coming Eight Years...

The global DTx market was valued at USD 4.2 billion in 2021 and is estimated to grow at a CAGR of 26.1% from 2022 to 2030 to reach USD 33.9 billion. The growth is estimated to be driven by increasing smarTChone penetration, the cost-effectiveness of digital health technology for providers and patients, and increased demand for not only integrated healthcare systems but also patient-centric care. For the commercial rollout of its first product, CST-Therapy Companion, Brain+ is concentrating on the Danish, German, and UK markets. According to the Company, the addressable markets in these nations are projected to be EUR 30 million, EUR 400 million, and EUR 170 million, respectively. Europe is leading the way in DTx and Germany is a key market for Digital Therapeutics given that the German healthcare system has a national reimbursement pathway. In 2019 Germany introduced a DTx-specific P&R framework for digital health applications called DiGA and has ever since its inception approved 32 products. In June 2022, Germany announced the establishment of new procedures to verify the reimburseability of digital care applications through the so-called DiPA pathway.

#### ... And Enables High-Cost Savings Within The Healthcare Sphere

There is increasing evidence suggesting that DTx can lead to significant cost savings in healthcare. For instance, a study published in the Journal of Medical Economics found that DTx for substance use disorder (SUD) had the potential to reduce healthcare costs by up to 31% over two years compared to usual care. Another study published in the Journal of Medical Internet Research found that DTx for depression and anxiety disorders resulted in an average savings of \$1,172 per patient over six months compared to usual care. Regarding dementia and Alzheimer's disease, some studies have explored the potential cost savings of DTx for these conditions. For instance, a computerized cognitive training program for individuals with mild cognitive impairment (MCI) led to significant cost savings over five years compared to usual care. The estimated cost savings were \$14,213 per patient for the computerized cognitive training program, with most of the savings coming from reduced healthcare utilization. Additionally, a web-based intervention for caregivers of individuals with dementia resulted in cost savings of \$1,046 per caregiver over six months compared to usual care. The cost savings were primarily due to a reduction in the number of caregiver visits to healthcare providers.

#### Multiple USD +100m Licensing Deals Has Already Been Made Within The DTx Space

As drugs and DTx targets different health outcomes and require different modes of action, they, can, in general, be seen as complementary rather than competitive and a combination of the treatments is likely to emerge. This has already been demonstrated through the variety of recent collaborations and licensing deals between DTx and pharma companies, which are illustrated in the graph below, as it emphasizes the commercial potential of partnerships between DTx and Pharma companies.





Revenue Forecast 2023-2027



# COMMERCIAL ROLL-OUT:











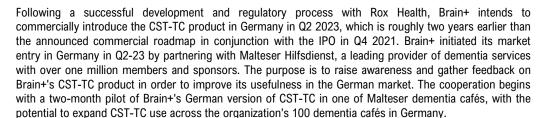
Q2-23





2024





Brain+ first product for dementia - CST-Therapist Companion ("CST-TC") - was officially introduced in

Denmark in November 2022, shortly thereafter (December 31) Brain+ closed the first commercial sales contract, worth DKK 50,000, with the municipality of Herning, Denmark. In Q1 2023, the municipality of Herning expanded existing contract, from having CST-TC in one training facility for one year to a municipal-wide license for 1.5 years, which almost doubled the initial contract value, and allows all therapists in Herning to get access to and utilize the CST-TC for people with dementia. Yet another commercial sales contract was closed in Q2 2023 with the Danish municipality of Gladsaxe, which demonstrates the strong interest that exists among the Danish municipalities, given that the usual sales cycle spans between 1-2

Based on requests, Brain+ developed the *CST-Home Companion* in Q1-23, which is an extension to the CST-TC product and is designed to provide people enrolled in CST group sessions with access to the software at home. This is a useful feature that can help ensure continuity of care and support for patients outside of clinical settings. The other CST-products includes *CST- Home Care* and *CST for MCI*, where both products rely on a caregiver to interact with the person with dementia when the CST therapy is done at home. The latter is, however, expected to combine all of Brain+'s three core technologies and target people with MCI, which significantly expands the commercial reach, given that the condition is 3-4x as prevalent as dementia. The second as well as the third CST-product are under development, were the second, *Home Care*, is expected to complete the product development phase in 2024, where the time to market is expected to be in 2025.

The CST-TC product will initially be offered directly to Danish municipalities and care homes in Germany as a B2B SaaS solution. It initially takes the form of a digital health tool to support therapists and is not required to have a regulatory certification. Since DTx are considered medical devices, they must comply with MDR, which came into effect in May 2021, or FDA requirements for the US market, and Brain+ is currently developing a second MDR-compliant (Class 1) version of the CST-TC product that is reimbursable, with a planned market introduction in 2024. The 2<sup>nd</sup> version of CST-TC will be a more advanced product version that includes additional functions and features. Because the UK is the founding country of CST and is where it is used extensively, it enables the UK market introduction as a more complex version for more sophisticated users in the UK, thereby opening this new market for sales. In the UK, Brain+ will target NHS Trust/clinics and care centers for the sale of the CST-TC product.

The MDR regulation requires that companies have a QMS in place when applying as a medical device, which Brain+ completed in Q4 2022. As Brain+ collects more clinical data as well as gather real and tangible evidence, the Company can move its products into the medical class with medical claims and with reimbursement, and then they become what is called prescription digital therapeutics which means that it is something that eventually a general practitioner would be able to prescribe. This is already something that is happening in countries like Germany and the U.S.

While the *CST-TC* (1st) product will be sold as a SaaS solution, the goal is to sell the other CST-products (*CST-TC* 2nd, *CST Home Care*, and *CST for MCI*) in accordance with a reimbursed prescription model (as a Software-as-a Medical-Device) which is the primary business model of Brain+ going forward. There have been several breakthroughs regarding the establishment of US and EU-wide DTx reimbursement and regulatory pathways during 2022, including for example the revised FDA regulations, the establishment of DiPA in Germany, and the foundation of NordDEC, which paves the way for a faster adoption of DTx going forward. The new DiPA procedure, established in Germany in June 2022, is a part of a broader European movement and other countries are following the path, such as Belgium and France.

Given the further maturity of the DTx market and Brain+'s established collaboration with Rox Health, Analyst Group forecast that Brain+ could secure reimbursement for the CST-TC 2<sup>nd</sup> product and *CST-Home Care* product in Germany and in the UK in 2025, which is estimated to unlock higher pricing in not only Germany and the UK but Denmark as well, supported by live data collection from the commercialization and subsequent in-house Proof-of-Concept and pivotal studies for medical classification.

INITIALLY SOLD AS A B2B SAAS-SOLUTION...

> ...WITH THE GOAL TO BE REIMBURSED GOING FORWARD

REIMBURSE-MENT UNLOCK HIGHER PRICING





#### **Product Revenue Forecast 2023-2027**

The financial forecast made for the period 2023-2027 are based solely on the CST-product suite, which are the products that Brain+ initially are prioritizing. To capture the additional revenue potential, beyond product revenue, in not only the CST product suite but also the other products under development, CCT and Starry Night, Analyst Group has modeled for future potential collaboration/licensing deals, in terms of deal worth, deal structure and length. Since we have made revenue assumptions for the CST for MCI product, which is expected to combine Brain+'s three core technologies, we have indirectly captured some of the potential in the other two technologies, however, not on a stand-alone basis. Lastly, the revenue forecast includes sales within the Danish, German, and UK markets during the period 2023-2027, which are the markets that Brain+ will focus on initially, hence Analyst Group is not explicitly accounting for revenues in other markets. However, Analyst Group is aware that Brain+ intends to enter one or two new markets annually beyond 2023, where the US is high-priority market. However, this should be seen as an extra option to our forecasts.

**Product** Revenue **Drivers** 



To derive future product revenues for Brain+ during the forecast period, Analyst Group has based the revenue model for the CST-Home Care and CST for MCI products upon the following key drivers:

Prescriptions Written - Number of prescription written by a clinician or doctor of the company's commercial products.

Fulfillment rate - The percentage of prescription written by a clinician for one of the company's commercial products that result in patients downloading and accessing therapeutic software content.

Payment rate - In a given period, this is the number of prescriptions for which the company receives payment divided by Fulfilled Prescriptions, (Fulfilled Prescriptions times Payment Rate equals Paid Prescriptions).

Average Selling Price (ASP) - In a given period, this is the average price received by the company per script for which the company receives payment.

The actual price levels in different countries can vary depending on factors such as if the DTx product is reimbursed or not, conditions negotiated in a contract, discounts/rebates, annual or monthly payments, and many more. Therefore, Analyst Group has derived an average annual selling price in each country based on available data, to capture the fluctuations in future selling prices. To weigh in the potential that Brain+ could claim for higher prices along with more data from clinical trials being collected, general market traction and awareness after commercialization and that a higher share of the product revenues comes from reimbursement, Analyst Group has modeled for a general price increase, on an annual basis, during the forecast period. To showcase how the revenues for Brain+ are derived in accordance with the abovementioned key drivers, Analyst Group gives an illustrative example below on an annual basis:

# Illustrative example (On annual basis)

Even though a doctor or clinician prescribes a DTx product to a patient...

... it is reasonable to assume that not all patients goes through with the prescription...

... and even if they do, i.e. downloading the prescribed app, not all will sign up and actually pay for it.

The prices depends on various factors, which is why an average selling price is used.

# 1,000

WRITTEN PRESRIPTIONS

50% **FULFILLMENT RATE** 

**EUR 100** 

50% PAYMENT RATE

AVERAGE SELLING PRICE (ASP)

**EUR 25.000** 

PRODUCT REVENUE

The CST-TC product is initially priced in Denmark either as a fee per therapist usage or as a full municipal license for unlimited therapist users. The product was first sold to the municipality of Herning as a basic package for one training facility, which was later expanded to cover the entire municipality. This demonstrates the potential for contract expansion after an initial agreement has been established.

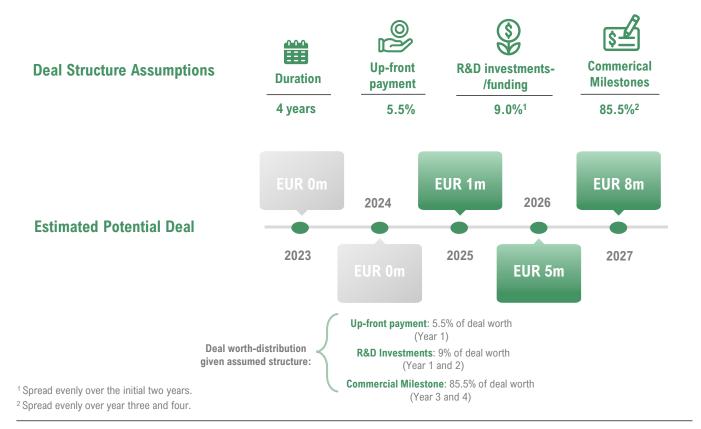
For the sake of the model, Analyst Group has derived the revenue for the CST-TC product by estimating the number of municipalities sold to and an average selling price (ASP). The same approach has been used for the upcoming commercial introduction in Germany in Q2 2023, and estimated introduction in UK in 2024, though Brain+ here rather addresses care homes/centers. Analyst Group has utilized the three-year duration of Brain+'s second commercial sales contract as a benchmark for future contracts with municipalities or care homes.



#### Licensing/Collaboration Deals Forecast 2023-2027

A common phenomenon within the Pharmaceutical/Life science space is that smaller market players engage with strategic partners such as Big Pharma companies who are offered the opportunity to finance and engage with the pivotal trial or regulatory process in exchange for licensing deals or partial commercialization rights. The same pattern has already been seen in the DTx market with several USD +100m deals being made, as illustrated in the market section earlier. Brain+ signed a partnership agreement with RoX Health in late 2021, who supports Brain+ with expertise and funding for the development and regulatory processes in order for Brain+ to commercially introduce its CST-product suite in Germany. In return, RoX Health will receive a share of the initial years of net revenues, covering the first two product versions of the planned CST-products (*Therapist Companion* and *Home Care*).

Given the overall market trends within DTx and the validation for Brain+ offering that comes with the partnership with RoX Health, Analyst Group projects that further collaboration/ licensing deals are to come during the forecast period. In a licensing/collaboration deal, it is common that the licensor (in this case Brain+) collects royalties from the licensee's (a potential Big Pharma company) revenues when selling the licensed products. However, due to the difficulties that come with estimating these potential revenues going forward, Analyst Group has not included these in the model explicitly, hence it should rather be seen as a lucrative option on the potential valuation going forward. The assumed structure of the estimated potential deals in terms of deal worth, up-front payments, investments in R&D/funding, and commercial milestones are illustrated below and are based upon deal structures from other licensing/collaboration deals within DTx and Pharma.



Regarding the commercial milestones, which are based upon the success within agreed project milestones, Analyst Group has used a risk-adjusted approach to factor in the possibility of them not being met and therefore paid to Brain+. A risk-adjusted rate of 50% has been used for this purpose, which could be seen as an aggressive/conservative approach with regards to the generally lower risk of failure within the DTx space compared to Pharma.

Previously, Analyst Group estimated that a licensing/collaboration deal could take place in 2024. However, due to a slight delay in the expected time to market for the *CST-Home Care* product, our estimates have been revised. It is now expected that the first licensing/collaboration deal will occur in 2025.





# Perspective on Revenue Assumptions



## Denmark

98

(Number of municipalities)



+30

(of which currently using the non-digital version of CST)



## Germany

~2,275

(Nursing homes specialized in dementia)

+3,800

(Out-Patient Services specialized in dementia)



# UK

~7,590

(Care homes with dementia specialism, England)

~8,690

(Care homes for older people and those living with dementia)

#### Summary Of Revenue Forecast 2023-2027

Given the outlaid methodology and assumptions regarding the key revenue drivers described in previous pages, Analyst Group has derived a revenue forecast for Brain+ for the period 2023-2027 as illustrated in the table below. However, since Brain+ is not explicitly reporting net revenues as of today, but rather the gross profit, Analyst Group has made assumptions regarding the capitalized development costs (more on this on next page) and other operating income, as well as the other external expenses that are included in the gross profit as of today. Estimations on not only RoX Health's, but also existing and future sales partners' claims on future generated net revenue has also been made, which are recognized as gross expenses.

Revenue Assumptions and Derived Revenue Forecast: Base scenario	2022	2023E	2024E	2025E	2026E	2027E
B2B SaaS (CST-Therapist Companion) Denmark						
Number of municipalities sold to	1	4	10	9	6	6
Acc. Municipalities sold to	1	5	15	24	30	36
Average Selling Price (net), EUR	6 500	9 500	13 500	22 500	26 500	29 500
Germany						
Number of care homes sold to	0	3	20	22	25	27
Acc. care homes sold to	0	3	23	45	70	97
Average Selling Price (net), EUR		3 167	4 500	7 500	8 833	9 833
UK	0	0	0	10	20	20
Number of care homes sold to	0	0	2	10	20	20
Acc. care homes sold to Average Selling Price (net), EUR	0	0 3 167	2 4 500	12 7 500	32 8 833	52 9 833
Prescriptions Written (Annually)	U	3 107	4 300	1 300	0 000	ə 033
Denmark						
CST-Home Care	0	0	0	1 700	2 500	3 500
CST for MCI	0	0	0	0	800	2 800
Germany						
CST-Home Care	0	0	0	2 800	4 500	6 700
CST for MCI	0	0	0	0	1 800	5 500
UK						
CST-Home Care	0	0	0	1 000	3 000	5 000
CST for MCI	0	0	0	0	1 000	3 000
Fulfillment rate  Denmark						
CST-Home Care	0%	0%	0%	55%	65%	70%
CST for MCI	0%	0%	0%	0%	50%	60%
Germany	0 /0	U /0	0 /0	U /0	JU /0	0070
CST-Home Care	0%	0%	0%	60%	65%	70%
CST for MCI	0%	0%	0%	0%	50%	60%
UK						
CST-Home Care	0%	0%	0%	60%	65%	65%
CST for MCI	0%	0%	0%	0%	50%	55%
Payment Rate						
Denmark	000					
CST-Home Care	0%	0%	0%	60%	60%	65%
CST for MCI	0%	0%	0%	0%	50%	60%
Germany	00/	00/	0%	7E0/	900/	000/
CST-Home Care	0%	0%		75%	80% 65%	80% 70%
CST for MCI UK	0%	0%	0%	0%	65%	70%
CST-Home Care	0%	0%	0%	65%	70%	70%
CST for MCI	0%	0%	0%	0%	60%	65%
Average Selling Price, EUR (Annually)	<b>5</b> / 0	J /0	<b>0</b> / 0	570	0370	5570
Denmark						
CST-Home Care/CST for MCI	100	120	130	145	155	165
Germany						
CST-Home Care/CST for MCI	914	989	1 064	1 114	1 164	1 214
UK						
CST-Home Care/CST for MCI	825	900	975	1 025	1 075	1 125
Product Revenue, (EURm)	0.04	0.05	0.00	0.00	0.00	1.40
Denmark	0,01	0,05	0,20	0,62	0,98	1,49
Germany UK	0,00	0,01 0,00	0,10 0,01	1,74 0,49	4,02 2,07	8,31 4,28
Total Product Revenue, (EURm)	0,00	0,00	0,32	2,85	7,07	14,08
Licensing revenue, EURm	0,00	0,00	0,00	0,10	0,55	1,24
Other Operating Income, (EURm)	0,19	0,15	0,15	0,15	0,15	0,15
Capitalized development costs	0,15	0,13	0,13	0,13	0,13	0,13
	0,00					
	0.85	1.04	1.30	3.94	8.60	16.30
Total revenue (EURm) Total Net Revenue (EURm)	0,85 0,01	1,04 0,06	1,30 0,32	3,94 2,95	8,60 7,62	16,30 15,32



#### **Operating Expenses 2023-2027**

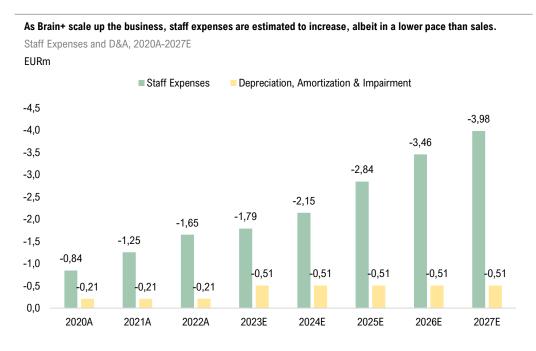
Due to Brain+'s accounting standard and decision to aggregate several cost items directly into gross expenses, staff expenses are, together with D&A, the only expenses reported on an operational level. Staff expenses have historically been the largest cost driver for Brain+. Considering the early stage in the business cycle that Brain+ currently operates within and the characteristics of the business and industry itself, staff expenses will continue to constitute a large chunk of the overall costs of the business for the foreseeable future as Brain+ progresses with its clinical trials, R&D and technology developments and general in-house sales/support efforts in conjunction with market introductions. However, Brain+ is anticipated to rely on external partners for sales to a large extent, and expenses associated with that will be recorded as gross expenses in accordance with Brain+'s accounting standard/methodology. Analyst Group has estimated a steady increase in staff expenses to reflect the upcoming business scale-up which requires a larger organization, albeit at a slower pace than the projected revenues.

#### **Depreciation & Amortization and Capital Expenditure 2023-2027**

Brain+'s depreciation and amortization (D&A) mainly consists of amortization on completed development projects, which amounted to approximately EUR 0.2m in 2022. The completed development projects are amortized on a straight-line basis over a 10-year period, while the capital expenditures (Capex) for development projects in progress are capitalized on the profit and loss statement as capitalized development costs, also known as "Own Work Capitalized". These capitalized development costs are included in the gross profit along with other revenue and cost items, as mentioned earlier.

In 2022, Brain+ completed several clinical projects, which increased the value of completed development projects on the balance sheet and correspondingly decreased the value of development projects in progress by the same amount. Therefore, we have modeled for higher amortizations going forward.

Regarding capital expenditures, we expect investments made in intangible and tangible assets to be consistent with the historical average of approximately EUR 0.83m during the forecast period, based on Brain+'s current project pipeline and what Brain+ estimated to use in clinical programs with the proceeds from the rights issue and accompanied warrants of series TO2 and TO3. Ultimately, we then project that the capitalized development costs will amount to ~ EUR 0.83m during the forecast period, boosting the gross profit.



Source: Analyst Group (estimates)



#### A Summary of Analyst Group's Financial Forecasts for Brain+.

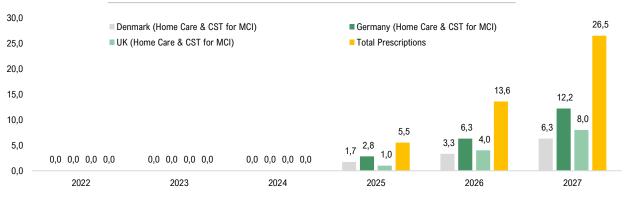
Financial Forecasts, 2020A-2027E, Base Scenario

Base Scenario: Income Statement, (EURm)	2020A	2021A	2022A	2023E	2024E	2025E	2026E	2027E
Gross Profit	0,87	0,52	0,42	0,65	0,89	2,50	5,31	9,90
Staff Expenses	-0.84	-1,25	-1,65	-1.79	-2,15	-2,84	-3,46	-3,98
Depreciation, Amortization & Impairment	-0,21	-0,21	-0,21	-0,51	-0,51	-0,51	-0,51	-0,51
EBIT	-0,18	-0,94	-1,44	-1,65	-1,76	-0,85	1,34	5,41
Other Finance Income	0.00	0,01	0,00	0,00	0,00	0.00	0,00	0,00
Finance Expenses	-0,03	-0,25	-0,01	0,00	0,00	0,00	0,00	0,00
EBT	-0,21	-1,18	-1,44	-1,65	-1,76	-0,85	1,34	5,41
Tax Expense	0,05	0,26	0,19	0,00	0,00	0,00	0,00	0,00
Net income	-0.17	-0.92	-1 26	-1 65	-1 76	-0.85	1 34	5 41





#### **Prescriptions Written (in thousands)**



#### **Total Number of Municipalities/ Care Homes/Care Centers sold to**



Source: Analyst Group (estimates)

## **Valuation**



To derive a company valuation for Brain+, Analyst Group has studied three listed DTx-companies with different level of maturity, which are Akili Inc, Better Therapeutics and DarioHealth. Although different digital therapeutics solutions are addressed, Analyst Group sees similarities with Brain+ with regards to the business model, growth prospects, profitability potential, capital structure, and that all operates within an, to date, immature market. Given the relatively small sample of public DTx companies, Analyst Group decided to broaden the peer group to also include innovative healthcare companies. This decision, taken combined, forms the basis for the valuation of Brain+.

# **DTx Companies**



Akili Inc. is a digital medicine company engaged in the development of cognitive treatments through technologies. The Company develops digital therapeutics that combine science and technology to address cognitive impairments in patients. The Company's software-based medicine is designed to directly target brain function and is delivered through engaging consumer entertainment. Akili's platform is powered by proprietary therapeutic engines designed to target cognitive impairment at its source in the brain. The Company's products include EndeavorRx, Selective Stimulus Management Engine (SSME), Body Brain Trainer (BBT) and Spatial Navigation (SNAV) Engine. EndeavorRx product is measured by computer-based testing in children ages 8-12 years old with primarily inattentive or combined-type ADHD, who have a demonstrated attention issue. Akili's products are delivered through captivating action video game experiences.



**Better Therapeutics, Inc.** is a prescription digital therapeutics (PDT) company. The Company is engaged in developing a novel form of cognitive-behavioral therapy to address the root causes of cardiometabolic diseases. The Company's Nutritional Cognitive Behavioral Therapy (Nutritional CBT) is a novel form of behavioral therapy for patients with type 2 diabetes and other cardiometabolic diseases. It targets the cognitive structures, behavioral routines, emotional patterns, and coping skills that underlie culturally specific eating behaviors. Its clinical development pipeline includes BT-001, BT-002, BT-003, and BT-004. The Company's platform consists of three integrated components, behavioral therapy, treatment plans, and personalization. Its behavioral therapy consists of lessons, skill-building modules, and a mechanism for goal setting.



**DarioHealth Corp.** is a Digital Therapeutics (DTx) company. DarioHealth operates at the intersection of life sciences, behavioral science, and software technology to deliver integrated and engaging digital therapeutics interventions. DarioHealth offers digital therapeutics solutions covering multiple chronic conditions including diabetes, hypertension, weight management, musculoskeletal and behavioral health within one integrated technology platform. Its products include Dario Blood Glucose Monitoring Starter Kit and Dario Blood Pressure Monitoring System.

# **Disruptive Healthcare Companies**

**Disruptive Healthcare Companies:** As DTx technology shapes the way how therapies are administered, and with that introduces a new level of scalability, so do selected peers in this category, who instead target other parts of the broader healthcare industry. Selected peers consists of Novocure Limited, Guardant Health, Adaptive Biotechnologies, Shockwave Medical, Inspire Medical Systems, Shrodinger Inc, Dexcom, Outset Medical, Teladoc Health, Orexo, and ResMed Inc.



SHOCKWAVE MEDICAL INC









DTx-Peers At a Glance

Company	Total Adressable Market (TAM)	Commercial-stage	Product Clearence
Akili	USD 10b	Yes	One FDA-cleared product
Better Therapeutics	USD 490b	No	No
DarioHealth Corp.	USD 108b	Yes	One FDA-cleared app
Brain+	USD 5b	Yes	No



# **Valuation**



	Equity Value	Enterprise Value		EV			EV/Gross		Revenue CAGR	Gross Profit	Gross	Gross	EBITDA-	EBITDA-
Company	(EURm)	(EURm)	2023E	/Sales	2025E	20225	Profit 2024E	2025E	2023-2025E	2023-2025E	margin 2024E	margin 2025R	margin 2024E	margin 2025E
DTx Companies (DTx)	(EUKIII)	(EUKIII)	2023E	2024E	ZUZ3E	ZUZ3E	ZUZ4E	ZUZ3E	2023-2025E	2023-2025E	ZUZ4E	2023K	2024E	ZUZ3E
Akili Inc	- 96	-12	-5,5x	-1,3x	-0,4x	-40,1x	-2,9x	-0,7x	253%	333%	44%	65%	-568%	-172%
Better Therapeutics	33	28	30,8x	1,4x	0,2x	-7,5x	2,7x	0,2x	1281%	1127%	53%	74%	-573%	-89%
DarioHealth	80	60	2,0x	1,4x	0,9x	4,5x	2,5x	1,5x	36%	157%	57%	63%	-40%	-15%
Disruptive Healthcare Companies (DHC)	_													
Novocure Limited	6 369	5 998	12,3x	11,7x	10,7x	15,6x	14,7x	13,6x	4%	4%	79%	79%	-6%	-9%
Guardant Health Adaptive Biotechnology	2 043	2 158	4,4x	3,6x	2,9x	6,7x	5,6x	4,6x	21%	20%	64%	64%	-50%	-32%
Corp.	971	612	3,2x	2,6x	2,1x	4,5x	3,5x	2,8x	19%	24%	74%	76%	-33%	5%
Shockwave Medical	9 526	9 301	15,1x	12,3x	10,0x	17,4x	14,5x	11,7x	30%	28%	85%	85%	30%	32%
Inspire Medical Systems	7 268	6 860	13,1x	10,2x	8,5x	15,6x	12,1x	10,1x	29%	29%	85%	84%	0%	6%
Schrodinger Inc	1 883	1 576	7,1x	5,3x	4,1x	11,0x	7,4x	4,5x	33%	56%	72%	91%	-39%	-31%
Dexcom	41 688	41 296	13,0x	10,8x	9,1x	20,6x	16,8x	14,0x	19%	19%	64%	65%	26%	27%
Outset Medical	910	734	5,5x	4,0x	2,2x	26,3x	12,5x	4,4x	46%	117%	32%	51%	-51%	-16%
Teladoc Health	3 897	4 483	1,9x	1,7x	1,6x	2,7x	2,5x	2,3x	9%	9%	69%	69%	12%	12%
Orexo	34	50	0,9x	0,7x	0,6x	1,0x	0,8x	0,6x	16%	20%	92%	93%	0%	7%
ResMed Inc	31 893	33 318	8,8x	8,1x	7,6x	15,4x	13,8x	12,8x	10%	12%	59%	59%	34%	34%
Maximum	41 688	41 296	30,8x	12,3x	10,7x	26,3x	16,8x	14,0x	1281,2%	1127,4%	91,7%	92,5%	33,8%	34,4%
75th Percentile	7 043	6 644	12,8x	9,7x	8,3x	15,6x	13,5x	11,3x	34,8%	101,9%	78,1%	82,9%	9,0%	10,9%
Median	1 963	1 867	6,3x	3,8x	2,6x	8,8x	6,5x	4,4x	25,2%	26,1%	66,8%	71,8%	-19,6%	-1,9%
Mean	7 621	7 604	8,0x	5,2x	4,3x	6,7x	7,6x	5,9x	129,0%	139,8%	66,3%	72,7%	-89,8%	-17,1%
25th Percentile	300	198	2,3x	1,5x	1,1x	3,1x	2,5x	1,7x	16,8%	19,5%	57,2%	64,0%	-47,4%	-27,1%
Minimum	33	-12	-5,5x	-1,3x	-0,4x	-40,1x	-2,9x	-0,7x	4,1%	4,1%	31,8%	50,9%	-572,7%	-172,0%
Median, DTx	80	28	2,0x	1,4x	0,2x	-7,5x	2,5x	0,2x	252,6%	332,8%	52,8%	65,2%	-567,5%	-88,7%
Mean, DTx	70	25	9,1x	0,5x	0,2x	-14,4x	0,7x	0,3x	523,1%	539,2%	51,3%	67,4%	-393,5%	-91,8%
Median, DHC	3 897	4 483	7,1x	5,3x	4,1x	15,4x	12,1x	4,6x	19,5%	20,3%	71,6%	75,8%	0,2%	6,1%
Mean, DHC	9 680	9 671	7,7x	6,4x	5,4x	12,4x	9,5x	7,4x	21,5%	30,9%	70,4%	74,1%	-6,9%	3,3%
Brain+1	3	1	19.5x	3.5x	0.4x	1.7x	1.2x	0.4x	668.7%	81.3%	-29.2%	51.5%	-397.9%	-11.6%

Analyst Group is projecting strong revenue growth for Brain+ during the forecast period as a result of the commercial roll-out of the CST-suite but also that Brain+ can land a couple of licensing/collaboration deals. The valuation is therefore based on forecasted revenues. Generally, revenue multiples for companies within Life Science and Tech in an early phase are high as the sales are initially low or zero. Over time, however, as sales increase, the multiple tend to normalize as an effect of the company reaching a higher market share and a higher degree of maturity.

In the selected DTx peer-group, Akili and DarioHealth has reached a commercial stage with at least one of its products and therefore generate actual product revenues as of today, while Better Therapeutics is set for a potential commercial launch in mid-2023. Akili and DarioHealth both has one FDA-cleared product, which together with actual product revenues generated today, lowers the risk somewhat that is tied to the business model and product offering. Meanwhile, in October 2022, Better Therapeutics sent a *de novo* classification request seeking marketing authorization of their BT-001 product, for the treatment of adults with type 2 diabetes, which resulted in Better Therapeutics receiving a request for additional information from the FDA in February 2023. If Better Therapeutics' product becomes authorized by the FDA, it would be the first prescription solution intended to deliver highly scalable cognitive behavioral therapy ("CBT") to adults with type 2 diabetes from a digital device.

In comparison to the other DTx companies, Brain+ does not currently have product clearance. However, the company anticipates achieving Class 1 MDR certification with the 2<sup>nd</sup> version of CST-TC in 2024, followed by the CST-Home Care product in 2025. Brain+ secured its first commercial sale with a Danish municipality institution on December 31, albeit at a low contract value of EUR 6,500. Due to being behind Akili and DarioHealth in the commercialization phase and product clearance, and behind Better Therapeutics in terms of product clearance, Analyst Group argues that Brain+, who also has a significantly lower market cap, is warranted a valuation discount when compared to the other DTx companies.

However, Analyst Group argues that Brain+ has a unique position on the DTx market by being the first with digital therapeutics for dementia, particularly cognitive stimulation therapy, where Brain+ is working closely with global KOL's to leverage and facilitate the adoption wave towards digitalized CST-therapy. This, in turn, gives Brain+ a valuable *First Mover Advantage* to address one of the most expensive disease burdens of all (Dementia and Alzheimer's). Analyst Group forecasts that Brain+ sales are on the trajectory to really take off in 2025 given increased market awareness and matureness, but also as an effect of increased commercial sales efforts and advancements in trials. Even though commercial sales are expected to accelerate successively during 2023-2024 as Brain+ continues to gain market traction and *Proof of Business* in Denmark and via the projected commercial introduction in Germany in Q2 2023, Analyst Group argues that valuing Brain+ on 2025 financial figures is more appropriate because by that time, its product would potentially have been on the market for at least two years.

<sup>&</sup>lt;sup>1</sup> A subscription rate of 95% has been accounted for in announced rights issue in a Base scenario. Given that, net proceeds from the rights issue has been estimated as well as the burn rate during January to May 2023, in order to derive the net cash position and Enterprise Value.



# **Valuation**



DKK 1.12 PER SHARE IN A BASE SCENARIO Analyst Group argues that, given that there are few public DTx companies for comparison, as shown by the selected peers in the field, incorporating disruptive health care companies in the peer group would provide a stronger perspective and context for valuing Brain+. On 2025 financial revenue estimates, the mean and median EV/S-multiples are 4.3x and 2.6x, respectively, and in comparison, corresponding multiples on 2023 financial revenue estimates are 8.0x and 6.3x, reflecting strong projected revenue growth within the peer-group. Given an EV/S 2.9x target multiple on net revenues of EUR 3.0m in 2025, an Enterprise Value of approx. EUR 8.5m or DKK 65.4m is derived. To factor not only the time risk but also the fact that the DTx market faces some risks and challenges going forward, as it is still immature and in need of wider acceptance as well as adoption, Analyst Group has assumed a conservative discount rate of 16% for Brain+ to derive the present value. Based on an Enterprise Value of EUR 8.5m (DKK 65.4m) in 2025 and the applied discount rate it gives, after taking the net cash as of Q4 2022 into account, together with assumed net proceeds from the rights issue1 and estimated burn rate during January to May 2023, a potential net present value per share today of DKK 1.12 DKK. Note that Analyst Group has not accounted for the potential capital injection in October 2023, when approx. 30-31m publicly traded Brain+ warrants of series TO2 can be exercised, due to the difficulties to estimate the potential dilution and received funds from the warrants, as the proceeds to Brain+ will depend on e.g., the market price of existing share and number of warrants exercised.

#### **Bull Scenario**

The following is a selection of potential value drivers in a Bull scenario:

- The commercial introduction in Denmark, Germany, and UK becomes successful and Brain+ gains wide market traction and acceptance for its product offering.
- Brain+ ongoing clinical trials present highly positive outcomes which, together with successfully initial commercial introductions in Denmark and Germany, paves the way for reaching reimbursement faster and to a wider extent.
- Brain+ secures additional collaborations and commercial partnerships which gives a springboard to new markets and enables a larger market share.
- More valuable licensing deals than estimated in a Base Scenario are reached, which translates into higher revenues and stronger cash flows.

Given a discount rate of 16% and a target multiple of EV/S 3.1x on estimated sales of EUR 4.4m in 2025 in a Bull scenario, a potential present value per share of DKK 1.64 is derived<sup>1</sup>.

#### DKK 1.64 PER SHARE IN A BULL SCENARIO

#### **Bear Scenario**

The following is a selection of potential factors to consider in a Bear scenario:

- DTx is still in the early stages and the outlook for the industry relies on behavioral changes across stakeholders and overall market acceptance. In a Bear Scenario, Analyst Group anticipates a slower grade of acceptance and usage adoption of DTx products, which hampers the growth outlook for
- Brain+ is not expected to land any additional licensing/collaboration deals in a Bear scenario as the competitive landscape becomes more crowded and/or Brain+ faces unfavorable outcomes in ongoing clinical trials.
- The payment systems for DTx are not yet mature and while many DTx have gone through the regulatory processes and achieved product clearances, they have not necessarily been reimbursed. As the DTx regulations and pathways are still being defined by most countries, stricter requirements and higher evidence required from trials pose a real risk going forward. Therefore, any reimbursement for Brain+ has not been accounted for in a Bear scenario.

In a Bear scenario, a lower valuation of the share is justified, as potential headwinds mentioned above are expected to have a material adverse effect on the business and result in additional capital injections going forward. Based on estimated sales of EUR 1.1m, a target multiple of EV/S 2.4x and a discount rate of 16%, a potential present value per share of DKK 0.46 is derived in a Bear scenario<sup>1</sup>.

DKK 0.46 PER SHARE IN A BEAR SCENARIO

<sup>&</sup>lt;sup>1</sup> A subscription rate of 95% has been accounted for.

<sup>&</sup>lt;sup>2</sup> A subscription rate of 100% has been accounted for.

<sup>&</sup>lt;sup>3</sup> A subscription rate of 85% has been accounted for, i.e, in line with what the rights issue is secured to.

# **Management & Board**





#### Kim Baden-Kristensen, Co-founder and CEO

Kim began his career in high-tier strategic management consulting with The Boston Consulting Group before he moved into the industry as part of the business unit leadership, as Vice President of Marketing and Strategy, at Vestas Wind Systems A/S, Northern Europe. His passion for psychology and neuroscience led him to found Brain+ in 2012, with the purpose of bridging the gap between emerging scientific insights and the commercial space. Areas of expertise include leadership, organization & change management, marketing & sales excellence, business intelligence, competitive analysis, strategy planning, and execution.

Shareholding in the Company: Kim Baden-Kristensen owns a total of 2,630,416 shares in the Company, of which 2,056,530<sup>1</sup> shares via the wholly owned company Baden-K Holding ApS and 573,886 shares privately.



#### Bertil Stengaard Jessen, Chief Financial Officer

With an M.Sc. in Economics and Business Administration at CBS, Bertil has held roles in Strategy and M&A in Maersk and J.P Morgan's investment banking division. Further, Bertil has had roles including Head of a global strategic business program in GN Store Nord, which has now led him to the role of CFO.

Shareholding in the Company: Bertil Stengaard Jessen owns no shares in the Company.



#### Simon Nielsen, Chief Science & Innovation Officer

Simon has 12 years of experience as a biomedical engineer and joined Brain+ in 2019 as Director of Research & Innovation. Before joining Brain+ Simon spent four years at Coloplast A/S, latterly as a team manager and Senior Scientist, where his roles included managing a pre-clinical R&D team, and developing a core science area for technology maturation and development for the new innovative product portfolio. Previously, he has worked in smaller MedTech start-ups and also in research, recently as a Postdoc at Copenhagen University focussing on theoretical and applied science within the attention and short-term memory, the key cognitive functions targeted with Brain+ technologies.

Shareholding in the Company: Simon Nielsen owns 44,848 shares privately in the Company.



#### Paula Petcu, Chief Technology Officer

With over ten years of experience in Software Development and seven years of experience in Pharma, Paula has climbed her way up to one of Berlingske's Top 100 talents in Denmark. With an M.Sc. in Computer Science from the University of Copenhagen, Paula has had roles including Head of Digital Technologies at Lundbeck. Further, Paula has co-founded the health tech companies FindZebra and Healthy Mind Tech.

Shareholding in the Company: Paula Petcu owns no shares in the Company.



#### Brian Østergaard, Business Development Manager

Originally educated as a graphic designer, Brian has more than 20 years of experience in designing SaaS solutions and more than 15 years of experience in selling and innovating such solutions in the Scandinavian healthcare market. A platform that he developed to assist in structuring the workday of caregivers and also help to structure the daily life of people with cognitive challenges was implemented by 39 Danish municipalities as well as in care homes in Norway and Sweden.

Shareholding in the Company: Brian Østergaard owns 47,955 shares privately in the Company.

# **Management & Board**





#### Anders Härfstrand, Chairman of the Board

Anders Härfstrand has a solid background from business development and product commercialization from multiple large pharmaceutical corporations, most notably former Executive Vice President at Pfizer and currently Chairman of the Board at Diurnal. Anders was announced as Chairman of the Board in September 2022.

Shareholding in the Company: Anders owns no shares in the Company.



#### Lars Terney, Vice Chairman of the Board

Having worked with the Boston Consulting Group from 1994 – 2008, where he became a managing director and head of the Group's Copenhagen office, Lars joined Nordic Capital in 2008. He is, since April 2020, the senior partner of Nordic Capital, which is the second largest Nordic-based private equity fund. Lars was Chairman of the Board until the election of Anders Härfstrand.

Shareholding in the Company: Lars owns a total of 1,055,402 shares in the Company, of which 866,854 shares via the wholly owned company 4T Impact ApS and 188,548 shares privately.



#### Hanne Leth Hillman, Chairman of the Audit Comittee & Member of the Board

15 years of experience in senior executive positions in both public and private life science companies, with a focus on financing, leadership, investor relations, and corporate governance. Since 2017 she has been CFO of Nanovi A/S and prior to that she was Head of IR and Corporate Communications at Zealand Pharma A/S. From 2013 – 2019 she served as a board member and Co-Chairman of the Danish Investor Relations Association.

Shareholding in the Company: Hanne Leth Hillman owns 87,000 shares privately in the Company.



#### Johan Luthman, Member of the Board

With positions as Executive Vice President and Head of R&D at Lundbeck, former Senior Program Leader of Neuroscience R&D at Merck, and former CEO at GoNeuro, Luthman brings strong expertise within neuroscience and dementia.

Shareholding in the Company: Johan Luthman owns no shares in the Company.



#### Betül Susamis Unaran, Member of the Board

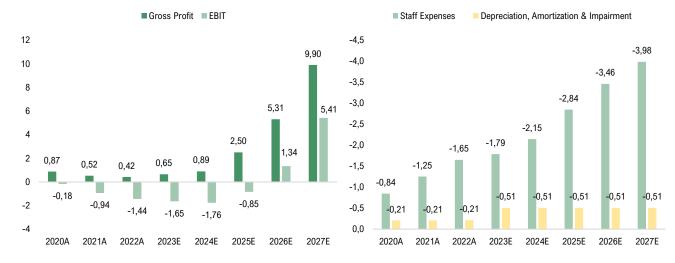
As a Chief Strategy and Digital Officier at Zur Rose Group, the largest pharmacy run as an e-commerce in Europe, Board of Directors of Ypsomed, and former Global Head of Digital Medicines at Novartis Pharmaceuticals, Susamis contributes with important experience within the field of Digital Therapeutics and Pharma

Shareholding in the Company: Betül Susamis Unaran owns no shares in the Company.

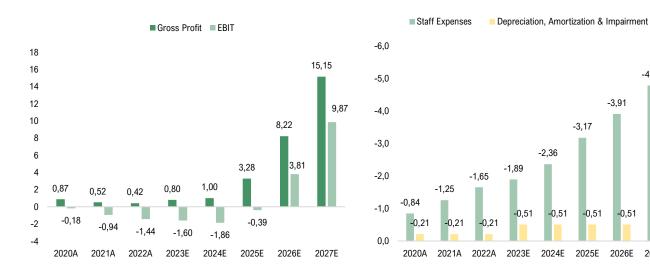
# **Appendix**



Base Scenario: Income Statement, (EURm)	2020A	2021A	2022A	2023E	2024E	2025E	2026E	2027E
Gross Profit	0.87	0.52	0.42	0.65	0.89	2.50	5.31	9.90
Staff Expenses	-0.84	-1.25	-1.65	-1.79	-2.15	-2.84	-3.46	-3.98
Depreciation, Amortization & Impairment	-0.21	-0.21	-0.21	-0.51	-0.51	-0.51	-0.51	-0.51
EBIT	-0.18	-0.94	-1.44	-1.65	-1.76	-0.85	1.34	5.41
Other Finance Income	0.00	0.01	0.00	0.00	0.00	0.00	0.00	0.00
Finance Expenses	-0.03	-0.25	-0.01	0.00	0.00	0.00	0.00	0.00
EBT	-0.21	-1.18	-1.44	-1.65	-1.76	-0.85	1.34	5.41
Tax Expense	0.05	0.26	0.19	0.00	0.00	0.00	0.00	0.00
Net income	-0.17	-0.92	-1.26	-1.65	-1.76	-0.85	1.34	5.41



Bull Scenario: Income Statement, (EURm)	2020A	2021A	2022A	2023E	2024E	2025E	2026E	2027E
Gross Profit	0.87	0.52	0.42	0.80	1.00	3.28	8.22	15.15
Staff Expenses	-0.84	-1.25	-1.65	-1.89	-2.36	-3.17	-3.91	-4.78
Depreciation, Amortization & Impairment	-0.21	-0.21	-0.21	-0.51	-0.51	-0.51	-0.51	-0.51
EBIT	-0.18	-0.94	-1.44	-1.60	-1.86	-0.39	3.81	9.87
Other Finance Income	0.00	0.01	0.00	0.00	0.00	0.00	0.00	0.00
Finance Expenses	-0.03	-0.25	-0.01	0.00	0.00	0.00	0.00	0.00
EBT	-0.21	-1.18	-1.44	-1.60	-1.86	-0.39	3.81	9.87
Tax Expense	0.05	0.26	0.19	0.00	0.00	0.00	0.00	0.00
Net income	-0.17	-0.92	-1.26	-1.60	-1.86	-0.39	3.81	9.87



-4,78

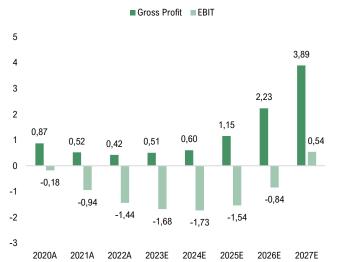
-0,51

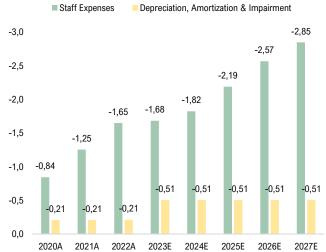
2027E





Bear Scenario: Income Statement, (EURm)	2020A	2021A	2022A	2023E	2024E	2025E	2026E	2027E
Gross Profit	0.87	0.52	0.42	0.51	0.60	1.15	2.23	3.89
Staff Expenses	-0.84	-1.25	-1.65	-1.68	-1.82	-2.19	-2.57	-2.85
Depreciation, Amortization & Impairment	-0.21	-0.21	-0.21	-0.51	-0.51	-0.51	-0.51	-0.51
EBIT	-0.18	-0.94	-1.44	-1.68	-1.73	-1.54	-0.84	0.54
Other Finance Income	0.00	0.01	0.00	0.00	0.00	0.00	0.00	0.00
Finance Expenses	-0.03	-0.25	-0.01	0.00	0.00	0.00	0.00	0.00
EBT	-0.21	-1.18	-1.44	-1.68	-1.73	-1.54	-0.84	0.54
Tax Expense	0.05	0.26	0.19	0.00	0.00	0.00	0.00	0.00
Net income	-0.17	-0.92	-1.26	-1.68	-1.73	-1.54	-0.84	0.54





## **Disclaimer**

These analyses, documents and any other information originating from AG Equity Research AB (Henceforth "AG) are created for information purposes only, for general dissipation and are not intended to be advisory. The information in the analysis is based on sources, data and persons which AG believes to be reliable. AG can never guarantee the accuracy of the information. The forward-looking information found in this analysis are based on assumptions about the future, and are therefore uncertain by nature and using information found in the analysis should therefore be done with care. Furthermore, AG can never guarantee that the projections and forward-looking statements will be fulfilled to any extent. This means that any investment decisions based on information from AG, any employee or person related to AG are to be regarded to be made independently by the investor. These analyses, documents and any other information derived from AG is intended to be one of several tools involved in investment decisions regarding all forms of investments regardless of the type of investment involved. Investors are urged to supplement with additional relevant data and information, as well as consulting a financial adviser prior to any investment decision. AG disclaims all liability for any loss or damage of any kind that may be based on the use of analyzes, documents and any other information derived from AG.

#### **Conflicts of Interest and impartiality**

To ensure AG's independence, AG has established compliance rules for analysts. In addition, all analysts have signed an agreement in which they are required to report any and all conflicts of interest. These terms have been designed to ensure that COMMISSION DELEGATED REGULATION (EU) 2016/958 of 9 March 2016, supplementing Regulation (EU) No 596/2014 of the European Parliament and of the Council with regard to regulatory technical standards for the technical arrangements for objective presentation of investment recommendations or other information recommending or suggesting an investment strategy and for disclosure of particular interests or indications of conflicts of interest. Compliance policy: htTCs://analystgroup.se/interna-regler-ansvarsbegransning/ (Swedish)

#### Other

This analysis is a task analysis. This means Analyst Group has received payment for doing the analysis. The Principal, **Brain+ A/S** (furthermore" the Company") has had no opportunity to influence the parts where Analyst Group has had opinions about the Company's future valuation or anything that could constitute an objective assessment.

The parts that the Company has been able to influence are the parts that are purely factual and objective.

The analyst does not own shares in the Company.

This analysis is copyright protected by law © AG Equity Research AB (2014-2023). Sharing, dissemination or equivalent action to a third party is permitted provided that the analysis is shared unchanged.