



# Summary from H1 2022 report: Brain+ (BRAINP) on track for accelerated first dementia product launches in Denmark and Germany in 2022 and 2023

Copenhagen, Denmark, September 29, 2022 – Brain+ A/S (Nasdaq First North: BRAINP)

***“We are dedicated to helping people with dementia and Alzheimer’s disease as well as their families and caregivers, through the use of our suite of unique and clinically validated Digital Therapeutics. The net financial result in H1 2022 reflects the addition of organizational competencies as well as a higher activity level and was fully in line with expectations. Since the start of the year, our partnership with RoX (part of Roche) has helped identify a faster route to market and fueled accelerated product development of Cognitive Stimulation Therapy – Therapist Companion. Consequently, we have been able to advance commercial launch of the product in Denmark to Q4 this year and in Germany to Q2 2023”,*** said Kim Baden-Kristensen, CEO of Brain+

The following is a summary of the Brain+ H1 2022 report that was announced today.

## **Business milestones and achievements during H1 2022 and to date:**

- Finalized the Danish version of Cognitive Stimulation Therapy (“CST”) – Therapist Companion for commercialization faster than expected and advanced launch plans to Q4-22 (from previously expected Q2-23)
- Identified faster regulatory route to market for the German version of CST – Therapist Companion via our RoX partnership, and accelerated product development, which has advanced our planned product launch in the largest European dementia market to Q2 2023 (~2 years earlier than projected when Brain+ went public in October 2021)
- Board expanded with three international profiles with competencies within Life Science, Digital Therapeutics, and Dementia and Alzheimer’s disease: Anders Härfstrand (named new Chairman), Johan Luthman, and Betül Unaran
- Expanded operational team with new key competencies added in finance, quality and compliance management, research, and software engineering
- Positive results from 3 clinical trials providing early proof of concept for our three core technologies
- New strategic collaborations as part of Danish-German Care Alliance, FORTE project, and with Coopmed, a specialized German medtech sales distributor

## **Financial Highlights for H1 2022 (unaudited)**

- Gross profit was DKK 1.9 million in H1 2022 compared to DKK 2.7 million in H1 2021. Gross profit in H1 2022 was driven primarily by income from innovation-grant funded projects, ongoing development, and a milestone payment from our partner, RoX
- Staff expenses were DKK 6.6 million in H1 2022 compared to DKK 4.1 million in H1 2021. The increase versus H1 2021 primarily reflects the onboarding of new talent to support accelerated business activities including the preparation of CST-Therapist Companion for commercialization and advancement of the clinical development of other pipeline products to fulfill our objective to

achieve large-scale reimbursement in major European markets and the US

- Profit/loss was DKK -4.1 million in H1 2022 compared to DKK -2.8 million in H1 2021
- Operations during H1 2022 were financed predominantly by the proceeds from Brain+' IPO in October 2021
- Net change in cash and cash equivalents in H1 2022 was DKK -7.5m million compared to DKK 4.5 million in H1 2021, which included the issuance of DKK 12.2m in long-term convertible debt. On 30 June 2022, the company's cash and cash equivalents amounted to DKK 2.5 million (30 June 2021: DKK 5.9 million)

## **Funding events**

In H2 2022, Brain+ expects to, and has already received, grant payments related to ongoing projects. Furthermore, a material funding event will take place in October (17th - 31st), when 4.8m publicly traded Brain+ warrants can be exercised for new shares at a 30% discount to the market price. In addition to the warrant proceeds, we expect an external funding round will be needed during 2023.

## **Strong forces drive the market for dementia DTx**

Dementia represents a vast and growing challenge to healthcare systems, patients and caregivers. With an annual treatment cost of ~1% of global GDP, it is among the most expensive diseases today. The combination of aging demographics, and scarcity of effective treatments today, signify a material and accelerating unmet clinical need.

For Digital Dementia Therapeutics, the estimated current global addressable market is \$ ~5B, or 0,5% of the total \$ 1.000B Dementia treatment cost. However, as Digital Therapeutics have established their relevance and value as a new medical class, particularly for diseases with strong behavioral and mental indications, we anticipate the addressable market will expand to \$ ~15-20B by 2035.

## **Comments from the CEO, Kim Baden-Kristensen**

*"2022 is the year I have been waiting for – with our first dementia product now ready for launch!"*

*Our partnership with RoX has enabled an accelerated product development and helped identify a faster route to market for Cognitive Stimulation Therapy – Therapist Companion. Consequently, we have been able to advance commercial launch of the product in Denmark to Q4 this year and in Germany to Q2 2023.*

*Everywhere I talk to people about Brain+, they tell me how important what we are doing is, and being able to offer our first digital product to the dementia community is a meaningful first step towards fulfilling our mission: To make effective dementia treatments available to everyone, everywhere, as Digital Therapeutics. Building on the upcoming launches in Denmark and Germany, we plan to scale our sales efforts and expect to enter 1-2 new markets every year from 2023.*

*In 2022, we also received results from 3 clinical trials and now have positive early evidence for the therapeutic effects of our three core technologies. The results have fueled strategic partnership dialogues and informed the next steps of clinical development. The rest of 2022 will yield additional readouts from several ongoing studies. The next major clinical value inflection point is a pivotal trial with our Cognitive Stimulation Therapy, which pending results, may support regulatory certification in EU and reimbursement in Germany and other markets.*

*During 2022, we've also succeeded in adding core competences to our team and strengthened finance, quality and compliance management, research, and software engineering. We have also expanded our Board of Directors with heavy hitters within Life Science, Digital Therapeutics, and dementia and Alzheimer's disease. These competencies fortify our ability to leverage our position as a pioneer in DTx for dementia, enabling us to commercialize our unique suite of products, expand our technology platform and build clinical data, secure IP, and strengthen our dementia stakeholder network.*

*To deliver on our promises against the current market backdrop of heightened volatility, we diligently prioritize costs to strike a firm balance between value creation and financial runway, while we work to secure additional funding. One material funding event will take place in October, when 4.8m publicly traded Brain+ warrants can be exercised for new shares at a 30% discount to the market price. We also expect to receive grant funding from ongoing projects (Brain+ has a strong track-record with soft funding and has to date raised more than €8 million via this non-dilutive path), pursue additional grants and generate initial sales. We also explore other funding avenues, incl. potential investments from new equity investors, via loans and partner deals.*

*Importantly, 2022 has so far brought a surge in DTx interest from the pharma industry and we are in talks with several of the big players in the dementia field. Concurrently, we see great advances in DTx reimbursement schemes both in the EU and the US, including the German DiPA reimbursement pathway which can cover our products, global harmonization of digital health quality and regulatory standards, while healthcare providers display a growing appetite to prescribe DTx solutions. We see these market forces drive the value of the estimated addressable market for our products from \$ ~5 billion today to \$ ~15-20 billion by 2035.*

*I thank our shareholders and network of stakeholders for their support on our journey and very much look forward to sharing our continued progress in the months to come.”*

The H1 2022 report can be found here: [https://www.brain-plus.com/investor/announcements\\_and\\_financial\\_documents/](https://www.brain-plus.com/investor/announcements_and_financial_documents/).

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