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Gabather initiates phase II with licensing in sight

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Gabather has initiated its first patient study with drug candidate GT-002 in schizophrenia, a phase II study targeting cognitive symptoms in an area with significant unmet need and no approved pharmacological treatments. With a recently completed capital raise and a clearly stated ambition to sign a licensing deal in 2026, BioStock reached out to CEO Michael-Robin Witt to learn more.

Gabather develops next-generation drugs for psychiatric and neuropsychiatric disorders, with a focus on selective modulation of the GABA-A receptor – the primary inhibitory receptor in the brain. The company's lead candidate, GT-XNUMX, works as a partial positive allosteric modulator of the GABA receptor, selectively enhancing GABAergic signaling with the aim of improving cognition without the sedative side effects that limit the use of traditional benzodiazepines. $_{A}$-receptor – the brain’s primary inhibitory receptor. The Company’s lead candidate GT-002 is a partial positive allosteric modulator of the GABA receptor that selectively enhances the GABAergic signaling system. The goal is to improve cognition without the sedating side effects that make traditional benzodiazepines difficult to use in clinical practice.

The study, called TOTEMS, is being conducted at the Center for Neuropsychiatric Schizophrenia Research at Copenhagen University Hospital. The study is financed by the Danish state, equivalent to approximately SEK 18 million, which enables its execution without additional financial burden on Gabather.

TOTEMS is a randomised, double-blind, placebo-controlled phase II study that also includes an active comparator. The objective is to capture early signals on how GT-002 affects brain function and cognitive ability. It will include both patients and healthy volunteers and will use advanced biomarkers such as EEG and EMG alongside cognitive tests to map the drug's effects.

Cognitive impairment is one of the most debilitating aspects of schizophrenia, affecting memory, attention and executive function – and it is an area where no approved pharmacological treatment exists. Gabather is targeting the underlying neurobiological mechanisms, including disruptions in brain networks linked to hypofrontality and impaired information processing.

– This is a decisive milestone for Gabather. For the first time, we are evaluating GT-002 in patients, taking us a major step closer to understanding its clinical potential, said CEO Michael-Robin Witt.

Licensing in 2026

In his year-end letter, Witt was explicit about what comes next:

– Our ambition is clear – based on the study's progress and coming clinical results, to sign a licensing agreement during 2026.

Partner dialogues are described as intensifying as the project approaches its next clinical milestone, with interest driven by GT-002's high selectivity, documented effect on cognition, and a unique neuronal signature supported by additional patent protection currently being built out.

To ensure Gabather can engage with potential partners from a position of financial stability rather than necessity, the company completed a directed share issue in March 2026, raising approximately SEK 4,2 million from a number of existing shareholders and external investors. The proceeds are expected to extend the company's financial runway into the first half of 2027 at the current cost rate.

The board was explicit about the rationale: to be able to initiate potential licensing negotiations from a relatively stronger position rather than out of necessity.

Questions for CEO Michael-Robin Witt

BioStock contacted CEO Michael-Robin Witt to learn more about the TOTEMS study and the path towards a licensing agreement.

TOTEMS is now activated and ready to recruit patients. What are the most important things to watch as the study gets underway, and when do you expect to have meaningful data to share?

- The initiation of TOTEMS is a very important milestone for Gafather because it marks the first time GT-002 is being evaluated in patients with schizophrenia. What we are particularly focused on now is the quality and consistency of the translational data we will generate through the combination of cognitive assessments and neurophysiological biomarkers such as EEG.

- The study has been designed not only to evaluate safety and tolerability, but also to deepen our understanding of how GT-002 modulates brain function in a clinically relevant setting. We believe this approach significantly strengthens the scientific value of the program.

– As the study progresses, key areas to monitor will include participant recruitment and retention, as well as the quality and consistency of the EEG and broader translational biomarker data generated throughout the study. In parallel, we will closely evaluate early indications of cognitive engagement.

- We expect the study to generate meaningful data during 2026, and we will communicate important milestones to the market as they are reached.

You have been explicit about the goal of signing a licensing agreement in 2026. How far along are those partner dialogues, and what does a potential partner typically want to see before they commit?

– Interest in cognition-related CNS programs remains strong, particularly when supported by differentiated biology and translational evidence. Over the past year, we have intensified our dialogue with potential partners, and we see increasing interest in GT-002 due to its selective mechanism of action and its potential to address an area with very high unmet medical need.

- In general, potential partners are looking for three things:

- A strong safety and tolerability profile
- Convincing evidence of target engagement and mechanistic differentiation
- Early signs of clinically meaningful cognitive effects in patients

- We believe the first two areas are already supported by a substantial body of preclinical and translational data generated to date. The third area — demonstrating clinically relevant effects in patients — is precisely what the TOTEMS study is designed to evaluate and represents the next important stage of development for the program.

– Our ambition is to create a partnership structure that maximizes the long-term value of GT-002 while ensuring the program has the resources and strategic support needed to advance efficiently into later-stage development.

GT-002 targets cognitive impairment in schizophrenia – an area with no approved treatments. How do you position GT-002 relative to what is currently being developed in that space?

- Cognitive impairment remains one of the most disabling aspects of schizophrenia, yet there are currently no approved pharmacological treatments specifically targeting these symptoms. At the same time, this has become an increasingly active field of CNS drug development, reflecting the significant unmet medical need and the growing recognition that cognitive dysfunction is a major determinant of long-term functional outcome in patients.

– Recent clinical programmes, including the CONNEX study with Iclepertin, have further highlighted both the strong interest in this area and the continued opportunity for new therapeutic approaches when important efficacy or mechanistic gaps remain to be addressed. We believe this creates a meaningful opportunity for differentiated programs with novel biology and strong translational support.

– Many existing approaches in development either address cognition indirectly or are associated with limitations related to tolerability, receptor specificity, or insufficient functional benefit.

- We believe GT-002 has the potential to offer a differentiated profile through its selective modulation of the $GABA_A$ receptor system. Our objective is to enhance cognitive processing and neuronal network function without the sedative effects often associated with traditional GABAergic compounds.

- In addition, we believe our EEG-based biomarker strategy and translational approach provide an important advantage in understanding how the compound affects brain function, which is becoming increasingly important in CNS partnering.

The TOTEMS study is financed by the Danish state. How did that funding come about, and what does it signal about the scientific credibility of the program?

– The collaboration originated through long-standing academic exchange with leading academic researchers at the Center for Neuropsychiatric Schizophrenia Research at Copenhagen University Hospital, who recognized the scientific rationale and translational potential of GT-002.

- More broadly, the scientific groundwork behind Gabather's R&D has been built through a strong Danish-Swedish academic collaboration over many years. It has taken time to reach this stage, which is natural in CNS drug development, but that process has also allowed us to build a solid translational and scientific foundation around the program.

- The fact that the TOTEMS study is supported through Danish state funding is, in our view, a strong external validation of both the scientific quality of the program and the importance of addressing cognition in schizophrenia. These types of grants are highly competitive, and securing this support represents an important quality stamp not only for the academic partners involved, but also for Gabather and the underlying science behind GT-002.

- It also reflects the high caliber of the academic environment surrounding the study and the increasing interest in innovative approaches targeting cognitive dysfunction in schizophrenia.

- From a corporate perspective, this structure is highly valuable because it allows us to advance an important clinical program in a capital-efficient manner while maintaining strategic flexibility.

The directed issue in March was framed explicitly as a way to negotiate from strength rather than necessity. How has the capital changed your strategic position in the partnering process?

- Maintaining financial flexibility is extremely important in any partnering discussion. The directed issue strengthened our balance sheet and extended our operational runway, which allows us to continue executing according to plan while advancing discussions with potential partners from a more stable position.

- Our objective has never been to pursue a transaction out of short-term necessity. Instead, we want to ensure that any future partnership appropriately reflects the long-term potential of GT-002 and the value we are building through the clinical program.

– Having the ability to focus on generating quality data while simultaneously progressing discussions allows us to engage with potential partners from a more relaxed and strategically balanced position.