Gentian Diagnostics: product and market developments update

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Gentian Diagnostics ASA, a fast-growing developer and manufacturer of innovative and efficient diagnostics for better treatment decisions, is targeting several large and growing disease areas such as infections and inflammation, kidney failure and congestive heart failure.

The company today provides an update on project milestones, which includes GCAL in market development, and SARS-CoV-2 Ab and NT-proBNP in product development. SARS-CoV-2 Ab is on track for launch in Q4 2021, whereas for GCAL the company is in final negotiations with the first global partner with an ambition for commercial roll-out during 1H 2022. The development of NT-proBNP will however be delayed due to the complexity of the assay optimisation phase.

NT-proBNP: reference method achieved – launch date to be rescheduled
The development of a platform independent NT-proBNP turbidimetric assay is expected to represent ground-breaking advances in the field of high throughput diagnostics. Gentian Diagnostics aims to push the boundaries regarding measurement of low concentrations and a successful development of NT-proBNP will represent a significant advance for the PETIA technology.

The development of an independent reference method has been achieved and preliminary results provides for the possibility of calibrating the Gentian NT-proBNP assay to existing measurement ranges. However, to fully qualify the reference method, more tests are required, and the company has therefore initiated further trials to substantiate the method.

The optimisation of the NT-proBNP assay has proven to be more complex than assumed. Although several milestones have been achieved, it is now apparent that the technical development will have to continue further before the assay optimisation phase can be concluded. The remaining challenges are related to particle aggregation, differences in measurement of NT-proBNP in plasma and serum samples, and reaching an even lower level of quantification to ensure a competitive product. The earlier set launch date in Q1 2022 will hence not be met, and the company will revert with more information regarding a new launch date once a timeline for the remaining optimisation issues have been established. The company will host an R&D presentation in connection with the Q3 results scheduled for release on 21 October.

GCAL: in final negotiations with first global partner
The commercial development of GCAL is progressing well. The company advises that it is in the final stage of negotiating a commercial collaboration contract regarding GCAL with a leading global diagnostics provider. The goal is to start the commercial roll-out during 1H 2022. In addition, Gentian has entered into promising commercial collaboration agreements with specialised distributors in several countries so far this year, most recently in South Korea.

SARS-CoV-2 Ab: on track for launch in Q4 2021
The SARS-CoV-2 Ab project is in the final development phase. The project is on track for launch towards the end of Q4 2021, and the company is encouraged by the increasing interest for antibody testing as a tool to manage immunisation status.

Other pipeline projects and funding
Gentian advises that other ongoing pipeline development projects are developing according to plans. Going forward, the company may decide to reallocate resources to bolster some of the more

promising key projects that hold a commercial potential outside of the existing products. Regardless of such reallocations, the company's current business plan is fully funded.

Invitation to Q3 2021 and R&D presentation
Gentian will provide more information on its projects as new information becomes available. On 21 October 10.00-12.00 CET, the company will present its results for Q3 2021 followed by an R&D presentation. For participation, please register using the following link:

https://attendee.gotowebinar.com/register/1577263042320634384

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About Gentian Diagnostics
Gentian Diagnostics (OSE: GENT), founded in 2001, develops and manufactures high-quality, in vitro diagnostic reagents. Gentian's expertise and focus lies within immunochemistry, specifically infections, inflammations, kidney failures and congestive heart failures. By converting existing and clinically relevant biomarkers to the most efficient automated, high-throughput analysers, the company contributes to saving costs and protecting life. Gentian is based in Moss, Norway, serving the global human and veterinary diagnostics markets through sales and representative offices in Sweden, USA and China. For more information, please visit www.gentian.com.