BIOVICA

PRESS RELEASE

Thursday, 5 December 2019, 8.00 CET

Q2 Interim report: Work with the FDA application progressing as planned

"The results from two additional studies with DiviTum® will be presented at San Antonio Breast Cancer Symposium, the world's largest scientific conference on breast cancer".

- **Anders Rylander, CEO of Biovica**

Period: May-October 2019/2020

SEK 000s	Q2 19/20	Q2 18/19	May-Oct 19/20	May-Oct 18/19	May-April 18/19
Net sales	1,249	68	1,616	981	3,005
Operating profit (loss)	-5,990	-5,609	-12,087	-9,566	-21,718
Profit (loss) for the period	-5,958	-5,563	-12,026	-9,592	-21,556
Earnings per share, before dilution	-0.25	-0.32	-0.51	-0.55	-1.23

Significant events during the second quarter

- Plan for clinical validation established following feedback from FDA
- Contract signed with leading US cancer group, SWOG, for analysis of major study where the results will be an important part of the FDA submission
- Timetable for 510(k) submission - now set for mid-2020

Significant events after the end of the period

- Otti Bengtsson Gref appointed as the new R&D Director, effective January 2020
- New results where DiviTum® has been validated as a dynamic biomarker for metastatic breast cancer in a collaborative study with Institut Curie in Paris accepted for presentation at the San Antonio Breast Cancer Symposium in December 2019
- DiviTum® – New clinical data that it is a strong prognostic marker in operable breast cancer. The results will be presented at the San Antonio Breast Cancer Symposium in December 2019

Audiocast

When:	6 December 2019 at 10.00 CET
Where:	https://tv.streamfabriken.com/biovica-international-q2-2019 or SE: +46850558369 / DK: +4578150107 / UK: +443333009261 / US: +18335268384
Broadcast language:	in English

CEO's comments

Biovica is diligently working to launch DiviTum® in the US and European market for monitoring of early treatment effect of metastatic breast cancer. Events worth mentioning in Q2 include our meeting with the US Food and Drug Administration (FDA), progress with our clinical studies and more efforts with our commercial activities.

A market approval from the FDA is necessary in order to launch DiviTum® in USA as a tool for monitoring metastatic breast cancer. After having received written feedback from the FDA and meeting with them over the summer, we had a clear understanding of their requirements and are happy to report that the analytical validation is now progressing as planned and also showing good results. Furthermore, clinical validation is progressing as planned and the 1,500 samples to be analyzed have now been sent from USA. This comprehensive material that we received from the SWOG study (a study on metastatic breast cancer conducted by a US network of prominent oncologists) provides an excellent foundation that we will be able to reference in our FDA 510(k) submission. It also creates favorable conditions for clinical acceptance. Analytical and clinical validation are two important pieces of the puzzle for the submission and in summary, our work is progressing as planned for being able to submit the 510(k) towards the middle of next year.

As for our clinical studies, we obtained strong results subsequent to the end of the quarter in line with prior results, namely, that DiviTum® could be a valuable tool for ensuring that patients get the best possible results from their treatment. I would also like to highlight one of the studies that will be presented at the world's largest congress on breast cancer, SABCS, San Antonio Breast Cancer Symposium, during 10-14 December 2019. The study, which is based on more than 100 patients, was carried out in collaboration with the internationally renowned research center, Institut Curie. Results of the study show that DiviTum® can be used to monitor the treatment response of women with metastatic breast cancer. It supports the results from the TREnd study that was presented earlier in the year and it gives us much confidence in pursuing our plans for making DiviTum® a well-established biomarker for metastatic breast cancer.

Subsequent to the end of the quarter, we also announced clinical data demonstrating that DiviTum® is a strong prognostic marker in operable breast cancer. In particular, I would like to highlight a study that shows the prognostic effect of DiviTum®, making it possible to assess the risk of recurrence. That study will also be presented at SABCS in December. It was based on more than 600 patient samples. Adding that to the prior published study conducted in Israel in 2010, it means that we now have results from more than 800 patients. Our main focus area is still monitoring of metastatic breast cancer. However, these results help pave the way for expanding use of DiviTum® to other application areas, such as operable breast cancer, later on.

In total, we now have more than 10 studies encompassing more than 1,700 breast cancer patients. These studies create a unique value for DiviTum® and provide the foundation for commercialization of the product.

We appointed Otti Bengtsson Gref as our new R&D Director. She has leading expertise and extensive experience in developing diagnostic products that have obtained regulatory approval and successfully been launched on the market. She also has experience in production of this type of product, as well as an Executive MBA. We warmly welcome her to Biovica as a valuable addition to our team.

In summary, we are working diligently to achieve our goal of launching DiviTum® so that patients with metastatic breast cancer will receive the best possible treatment from day one. Our work with the FDA application is progressing as planned. We are reporting good results from

studies and pursuing our commercialization plan. We have a unique product that meets an important need in a large, attractive market. The pieces are now in place for taking Biovica to the next level. I'm very much looking forward to the journey ahead with all of you.

Contact

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In the event of contradictions or differences between the Swedish press release and this English translation of the Swedish press release, the Swedish text shall be given priority.

Biovica – Best Treatment from Day One.

Biovica develops and commercializes blood-based biomarker assays to evaluate efficacy of cancer treatments. Biovica's assay DiviTum® measure cell proliferation by detecting a biomarker in the blood stream. The assay has successfully demonstrated its capabilities to early evaluate therapy effectiveness in several clinical trials. The first application for DiviTum is monitoring of treatment for patients with metastatic breast cancer. Biovica's vision is that all cancer patients will get an optimal treatment from day one. Biovica collaborates with world-leading cancer institutes and pharmaceutical companies. DiviTum is CE-marked and registered with the Swedish Medicines Agency. Biovica's shares are traded on the Nasdaq First North Growth Market (BIOVIC B). FNCA Sweden AB is the company's Certified Adviser, info@fnca.se, +46 8 528 00 399. For more information please visit: www.biovica.com.