# BI VICA

## Plan for 510(k) submission specified

# QI Interim Report: May-July 2019/2020

SEK thousands	Q1 19/20	Q1 18/19	May-April 18/19
Net sales	367	914	3,005
Operating profit (loss)	-6,097	-3,956	-21,718
Profit (loss) for the period	-6,068	-4,028	-21,556
Earnings per share, after dilution	-0.33	-0.23	-1.18

#### Significant events during the first quarter

- Targeted new share issue for SEK 60 million to European and Swedish institutional investors and family offices
- Positive study results from the EFECT study with DiviTum<sup>®</sup> published in the prestigious European Journal of Cancer

Significant events after the end of the period

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



# CEO's comments

**Commercialization of DiviTum® for breast cancer** During the first quarter of the new financial year, we achieved several important milestones in our efforts to launch DiviTum® in the US and European market for monitoring of treatment for metastatic breast cancer. Significant milestones during the period:

• We carried out a targeted new share issue to broaden the scope of ownership and fund our ongoing commercialization efforts

Significant events after the end of the period:

- We signed an agreement with a leading US network for cancer research aimed at analyzing the clinical value of DiviTum<sup>®</sup> based on data from their major study. It will serve as the basis for our FDA application
- Based on feedback from the FDA, Biovica set the timetable for its 510(k) application
- The timetable for submitting the application has been adjusted from end of 2019 (previously communicated) to mid-2020

### Broader ownership and equity injection of SEK 60 million

Biovica boosted its equity by SEK 60 million during the fourth quarter via a targeted new share issue. The new share issue was targeted at professional investors like European funds, institutional investors and family offices. In total, 29 professional investors subscribed for shares. The financing provides Biovica with resources for pursuing its business plan.

#### Contract signed for analysis of a major study that

will be used as the basis for the FDA application Biovica signed a contract with a US cancer research network consisting of leading oncologists who are analyzing a major study on metastatic breast cancer. The study involves several hundred patients and this comprehensive material has great potential for serving as the foundation for Biovica's FDA 510(k) application and creating the conditions for gaining clinical acceptance.

## Timetable set for Biovica's 510(k) application based on feedback from the FDA

Supplement II contained Biovica's questions to the FDA on the company's clinical validation plan. During the summer, Biovica received written feedback from the FDA and had meetings with its contacts there, which has given us a clear understanding of how to meet the FDA requirements in our clinical validation plan. This has enabled us to move forward towards



our next milestone, which is clinical validation. The feedback gives us assurance that our plan will meet the stated requirements for approval. As previously communicated, we will submit our application for approval for one area of application on monitoring treatments of metastatic breast cancer.

We decided to move the date for submitting the application until the middle of 2020 so that we can, in it, include the major US breast cancer study we now have access to and, to improve the likelihood of covering all areas we've established in consultation with the FDA.

#### Launch of DiviTum®

Other work is being done simultaneous to the 510(k) application efforts. We are striving to introduce DiviTum® for routine clinical use by getting it included in treatment guidelines, payment systems and by setting up commercial partnerships for sales in networks that will serve as a channel for reaching Biovica's market.

The product is already being sold for research purposes, primarily by major pharmaceutical companies that are using DiviTum® in clinical studies for taking new drugs to market.

I can proudly conclude that we are getting very close to the day when we will launch DiviTum® for clinical use and thereby offer patients with metastatic breast cancer a diagnostic tool ensuring that they get the best possible treatment from day one. In doing so, we will also generate value to our shareholders.

Anders Rylander CEO Significant events during the period

#### Targeted new share issue of SEK 60 million

Via a targeted new share issue that was approved at an extraordinary general meeting on 2 May 2019, Biovica obtained a capital injection of SEK 56.7 million after issue costs. The price of Biovica's Class B share amounted to SEK 10 and it was established via a book building process. The new share issue resulted in dilution of approximately 25.5 percent on the number of shares and 15.7 percent on the number of votes in Biovica (calculated on the number of outstanding shares after the new issue). The new issue increased the number of outstanding shares by 6,000,000 from 17,573,372 to 23,573,372 and the number of votes from 32.168.248 to 38.168.248 (allocated between 7,297,438 Class A shares and 16,275,934 Class B shares). Share capital increased by SEK 400,000.00 (from SEK 1,171,558.13 to SEK 1,571,558.13).

# Publication in the European Journal of Cancer

The convincing results that were previously presented from the EFECT study have now been published in the prestigious European Journal of Cancer (impact factor 7.191, which corresponds to the highest 3% in the ranking of scientific journals).

The study evaluated hormonal standard therapy for metastatic breast cancer and DiviTum<sup>®</sup> was used to evaluate the treatment effect via an ordinary blood sample. DiviTum<sup>®</sup> was used when analyzing the blood samples of 244 patients and the study documented a correlation between thymidine kinase activity (TKA), a circulating prognostic and monitoring biomarker for patients with metastatic breast cancer treated with hormonal therapy, and the efficacy of the treatment.

Significant events after the end of the period

# Clinical validation plan set and timetable for FDA application adjusted

We have signed an agreement with a leading US network for cancer research aimed at analyzing patient samples from a major study with DiviTum<sup>®</sup>. The results of the study will be an important component of our FDA application. Based on feedback from the FDA, we've established the plan for our 510(k) application. The timetable for submitting the application has been adjusted from end of 2019 (previously communicated) to mid-

2020 so that we can use the results of that study in our application.

#### Other events

#### Warrants scheme concluded

TO1 expired on 30 June 2019. No shares have been subscribed.

#### **Reclassification of shares**

At the end of each quarter, class A shareholders are offered the opportunity of reclassifying their shares to B shares. A total of 3,750 shares were reclassified on 30 June 2019.

2019-06-30	Class A shares	Class B shares	Total
Before			
reclassification	7,297,438	16,275,934	23,573,372
Reclassification	-3,750	3,750	0
After reclassification	7,293,688	16,279,684	23,573,372

#### Annual General Meeting (AGM)

The AGM for the 2018/2019 financial year will be held on 29 August 2019 at 4 p.m. The location is Hubben, Dag Hammarskjölds väg 38 in Uppsala, Sweden. Notice of the AGM has been published on Biovica's website, in Post- och Inrikes Tidningar (gazette) and in SvD (newspaper). The Board of Directors proposes that no dividends shall be distributed to shareholders.

#### Company overview

Biovica is a Swedish biotech company with its own laboratory, production facility and head office in Uppsala, Sweden. Biovica has developed DiviTum<sup>®</sup>, which is an innovative, blood-based biomarker test for measuring the cell proliferation rate of solid tumors. The company is in the early stage of the commercialization process for DiviTum<sup>®</sup>, where the first application area is evaluation of the treatment effect on metastatic breast cancer.

The vision is for every cancer patient to receive the right treatment from day I. And this will be possible by using DiviTum<sup>®</sup> for more personalized treatments. In order to ensure that the product is used in cancer clinics worldwide, Biovica is collaborating with many world-leading oncologists and research groups to prove how valuable the product is in terms of personalized treatments. Results from these collaborations are a key component of generating demand for the product, providing support for its regulatory approval, for reimbursement and for setting up commercial partnerships. Thus far, 17 scientific articles and clinical studies have been published. Biovica has also won several prestigious awards and research grants, including Horizon 2020 (phase 2).

#### Important partners

The company collaborates with leading partners in healthcare and academia, including Karolinska Institutet (Sweden), Prato Hospital (Italy), Dana Farber Cancer Institute (Boston), Washington University (St Louis), Baylor College of Medicine (Houston), Mayo Clinic (Minnesota), City of Hope Research & Treatment Center (Los Angeles), Johns Hopkins (Baltimore), The International Breast Cancer Study Group (IBCSG) and Breast International Group (BIG).

#### Technology

DiviTum® is an innovative, blood-based test for measuring the cell proliferation rate of solid tumors. With DiviTum®, the effect of cancer treatment can be measured and tailored from day one, thereby improving the treatment results for patients and generating benefits to society. DiviTum® measures the activity of thymidine kinase (TK) in serum or cells. In normal cells, TK activity is low. It rises, however, with cell division. Because the level of TK activity is closely associated with cell growth, it has been concluded in several scientific publications that it is a suitable tumor biomarker (Bagegni, 2017 and Bonechi, 2018). Measuring TK activity provides treating physicians with useful information on the tumor cell proliferation rate and aggressiveness.

In the studies it has conducted, Biovica has shown that an assessment of the treatment's effect can be made within 2-4 weeks, while the average time for medical imaging diagnostics is approximately 3-4 months. (Bagegni, 2017 and Bonechi, 2018). And, all that's required for analysis with DiviTum<sup>®</sup> is a simple blood sample. By quickly and reliably being able to determine if a drug is having any effect, treatment can thereby be tailored and optimized.

#### Breast cancer

Each year, approximately 8,000 Swedish women are diagnosed with breast cancer. Approximately I out of every 10 women will develop breast cancer and prevalence of the disease has increased over the last twenty years. Four out of five women diagnosed with breast cancer are over 50 years old. There are various stages of cancer. For example, Stage I means that cancer is small and only in one area. Stage IV, however, means that the cancer has spread to other parts of the body. When breast cancer is discovered early, the prognosis is good. In such cases, four out of every five women are still alive five years after having been diagnosed with cancer. In the EU and USA, there are approximately 450,000 women with metastatic breast cancer. Recently, research has made advancements in the area of recurrent/metastatic breast cancer. Women with metastatic breast cancer can be offered a variety of new treatments to slow progression of the disease and reduce the size of tumors. But, some patients respond well to certain treatments, others less so. This is why it is important to have tools for selecting the right treatment for each person and quickly evaluate whether it is having any effect. With medical imaging diagnostics, 3-4 months is typically required to analyze volume changes. DiviTum<sup>®</sup> has been developed to provide information on treatment within 2-4 weeks. All that is required is a simple blood sample. It can also help doctors determine whether the patient is on the right treatment, and, if not, switch to a more effective one.

For metastatic breast cancer, the market potential for DiviTum<sup>®</sup> in USA and the EU is estimated at approximately SEK 6 billion.

#### Patent protection

Biovica owns two patent families. Patent protection on the company's ELISA assay technique expires in 2026. Patent protection on the company's real-time method of measuring TK activity expires in 2031. It was added to Biovica's product portfolio in conjunction with its acquisition of cSens in 2016. The acquisition increased the scope of Biovica's patent portfolio. It also extended patent protection for Biovica's portfolio by 5 years in the company's main markets. Besides patent protection, Biovica safeguards its product from being copied by not revealing its composition in patent applications and agreements with partners. It provides protection from copying beyond what can be obtained from patents.

Screening High risk		reast cancer age I-II	Locally advanced Stage III	Metastasized breast cancer Stage IV
Nisman, 2013	Nismar	n, 2010	Bjöhle	, 2013
			Bagegni, 2017	Bonechi, 2018
			FELINE	McCartney, 2019
			PREDIX	Lund, SABCS 2017
				TREnd, AACR 2019
				Johns Hopkins
Published stuc	lies			ΡΥΤΗΙΑ
Presented stud	dies			U-Penn
Ongoing stud	ies			City of Hope

#### Overview of concluded and ongoing studies on breast cancer.

#### **Ongoing studies**

#### Breast cancer

DiviTum<sup>®</sup> is repeatedly mentioned and documented in many international and national studies on metastatic breast cancer, which is Biovica's first commercial application. Biovica has 8 ongoing clinical breast cancer studies. The company is also involved in an ongoing study on lung and gastrointestinal cancer.

At SABCS 2017, a study by Lund University was presented. It involved 142 patients with metastatic breast cancer and its purpose was to measure the treatment effect of 3 types of standard treatment. Efforts to get a full-length article on this published are currently underway.

At AACR 2019, the results of DiviTum<sup>®</sup> from the TREnd study were presented. The study shows that DiviTum<sup>®</sup> is able to evaluate the effect of palbociclib treatment for 45 patients with metastatic breast cancer. A full-length article on this is currently being compiled.

Together with Johns Hopkins, Biovica is conducting a prospective study involving 100 patients to measure drug resistance development, including CDK 4/6 inhibitor. Patients are currently being signed up.

PYTHIA is a prospective study that is being conducted by BIG and IBCSG involving 120 stage IV patients to measure the treatment effect of targeted therapy. The study is underway, all of the patients have been signed up and analysis of the samples is being planned. Together with University of Pennsylvania, Biovica is conducting a pilot study involving 28 stage IV patients to measure the effect of combination treatment with chemotherapy and targeted therapy. All patients have been recruited and collection of samples is underway.

FELINE is a study that is being conducted by University of Kansas involving 120 stage III patients aimed at measuring the effect of targeted therapy and correlation with other biomarkers. The study is underway.

Together with City of Hope, Biovica has conducted a pilot study involving 18 patients to measure the effect of two new cancer drugs. No additional samples will be analyzed from this experimental study with DiviTum<sup>®</sup>.

PREDIX is a prospective study that is being conducted by Karolinska Institutet involving 200 stage III patients to measure the effect of targeted therapy and the survival rate. Patients are currently being enrolled and that process is taking longer than expected.

#### Other studies

A lung, stomach and intestinal study with Dana-Farber Cancer Institute is underway. Interim results on 39 patients were presented at AACR 2017.

Biovica has also started collaborating with WntResearch to identify patients with colon cancer who could benefit from Foxy-5 treatment. A Phase II study will be conducted with these patients to investigate the potential of using DiviTum<sup>®</sup> to supplement Foxy-5 and potentially become a Companion Diagnostic (CDx) to the drug.

# Summary of published studies on breast cancer

Thus far, six studies have been published in scientific journals where DiviTum® was used for evaluation of breast cancer treatment.

Biovica collaborates globally with leading cancer researchers, medical institutes and pharmaceutical companies to provide strong pre-clinical and clinical evidence of the effectiveness of DiviTum<sup>®</sup>. Studies have been conducted with more than 1,000 patients (early-stage to metastatic breast cancer) where DiviTum<sup>®</sup> has successfully been used to assess TK activity as a suitable biomarker for measuring tumor growth and as a monitoring tool for treatment response. The studies have shown that DiviTum<sup>®</sup> is a successful prognostic tool for patient survival, as well as a monitoring tool for obtaining early evidence of treatment response with endocrine therapy, and cyclin-dependent kinase (CDK) inhibitors.

The use of DiviTum<sup>®</sup> as a quick and precise monitoring and prognostic tool has been substantiated by a vast amount of evidence that has been collected from carefully designed, randomized, controlled trials. Thus far, DiviTum<sup>®</sup> has been used in 8 studies involving more than 1,000 patients with early stage cancer (n = 211) and metastatic breast cancer (n = 845) in collaboration with world-leading oncologists and medical institutes in several countries including Israel, Sweden, Italy, USA and China. DiviTum<sup>®</sup> has been studied:

- prospectively in two major studies as a prognostic factor for PFS (progression-free survival) and OS (overall survival) of more than 400 patients with metastatic breast cancer;
- as a monitoring tool for obtaining early evidence of treatment response with endocrine therapy in two studies involving more than 270 patients with metastatic breast cancer;
- to evaluate the effects on patients with early stage breast cancer (in a study involving more than 50 patients) who have been treated with CDK inhibitors; and
- in two studies involving 140 patients with metastatic breast cancer.

In addition to the positive results from studies using DiviTum<sup>®</sup> to treat breast cancer, many

studies have been conducted where DiviTum<sup>®</sup> has been used in the treatment of lung, liver, pancreatic and colorectal cancer substantiating the effectiveness of DiviTum<sup>®</sup> as a prognostic tool for measuring and monitoring the effect of treatment over time.

Clinical studies have shown that DiviTum<sup>®</sup> is particularly useful as a prognostic tool for tumor cell proliferation rate and aggressiveness, as well as the overall survival in patients with stage III-IV breast cancer. Its potential has also been substantiated as a monitoring tool for obtaining early evidence of treatment response and resistance to chemotherapy, endocrine therapy and CDK inhibitors such as palbociclib.

DiviTum<sup>®</sup> has been used to evaluate the treatment effect of standard hormonal therapies on patients with metastatic breast cancer via an ordinary blood sample. (McCartney, 2019)

DiviTum<sup>®</sup> both predicts and shows the effect of endocrine treatment for metastatic breast cancer. (Bonechi, 2018)

The effect of CDK4/6 inhibitor treatment is reflected in changes in TK activity for stage II/III patients with breast cancer. (Bagegni, 2017)

DiviTum<sup>®</sup> predicts PFS (progression free survival) and OS (overall survival) for patients with metastatic breast cancer. (Bjöhle, 2013)

DiviTum<sup>®</sup> is able to predict the risk of recurrence within five years of surgery for patients with breast cancer. (Nisman, 2010)

DiviTum<sup>®</sup> predicts the risk of developing breast cancer in women with BRCA1/2 and BRCA2 mutations. (Nisman, 2013)

#### Glossary and explanations

AACR American Association for Cancer Research - the world's largest conference focused on cancer research. It is held each year, in April.

ASCO American Society of Clinical Oncology – the world's largest cancer congress with clinical focus. It is held each year in June.

CDx Companion Diagnostics is a test that provides information that is critical for safe and effective use of a corresponding drug.

OS overall survival

PFS progression free survival – the length of time during and after the treatment that a patient lives with the disease but it does not get worse

SABCS San Antonio Breast Cancer Symposium is held each year in December. It is the world's largest breast cancer symposium.

#### Scientific articles

#### **Breast cancer**

McCartney A, et al. Prognostic role of serum thymidine kinase I activity in patients with hormone receptor positive metastatic breast cancer: Analysis of the randomised phase III Evaluation of Faslodex versus Exemestane Clinical Trial (EFECT). European Journal of Cancer 2019; 114: 55-66

Bonechi M et al. Plasma thymidine kinase-1 activity predicts outcome in patients with hormone receptor positive and HER2 negative metastatic breast cancer treated with endocrine therapy. Oncotarget 2018; Mar; 9 (23): 16389-16399.

Bagegni N, et al. Serum thymidine kinase I activity as a pharmacodynamic marker of cyclin-dependent kinase 4/6 inhibition in patients with early-stage breast cancer receiving neoadjuvant palbociclib. Breast Cancer Res and Treat. 2017; Nov 21;19(1):123.

Bjöhle J, et al. Serum thymidine kinase activity compared with CA 15-3 in locally advanced and metastatic breast cancer within a randomized trial. Breast Cancer Res and Treat 2013; 139(3):751-8.

Nisman B, et al. Increased proliferative background in healthy women with BRCA1/2 haploinsufficiency is associated with high risk for breast cancer. Cancer Epidemiol Biomarkers Prev. 2013; Nov; 22(11):2110-5.

Nisman B, et al. Serum thymidine kinase I activity in breast cancer. Cancer Biomark. 2010; 7(2):65-72.

#### Lung cancer

Nisman B, et al. Serum Thymidine Kinase I Activity in the Prognosis and Monitoring of Chemotherapy in Lung Cancer Patients. J Thorac Oncol 2014; Oct; 9(10):1568-1572.

Korkmaz T, et al. Serum thymidine kinase I levels correlates with FDG uptake and prognosis in patients with non small cell lung cancer. Biomarkers 2013; Feb;18(1):88-94.

#### Pancreatic cancer

Felix K, et al. Preoperative Serum Thymidine Kinase Activity as Novel Monitoring, Prognostic, and Predictive Biomarker in Pancreatic Cancer. Pancreas. 2017; Nov 16.

#### Breast cancer and colorectal cancer

Bolayirli M, et al. Serum thymidine kinase I activity in solid tumor (breast and colorectal cancer) patients treated with adjuvant chemotherapy. J Clin Lab Anal. 2013; May;27(3):220-6.

#### **Kidney cancer**

Nisman B, et al. Serum Thymidine Kinase I Activity Following Nephrectomy for Renal Cell Carcinoma and Radiofrequency Ablation of Metastases to Lung and Liver. Anticancer Res. 2016; Apr;36(4):1791-7.

Nisman B, et al. Circulating Tumor M2 pyruvate kinase and thymidine kinase I are potential predictors for disease recurrence in renal cell carcinoma after nefrectomy. Urology; 76 (2), 513. e1-e6, 2010.

#### **Blood cancer**

Stelmach P, et al. Prognostic value of thymidine kinase activity in patients with chronic lymphocytic leukemia. Postepy Hig Med Dosw. 2016; 70(0):1321-1330.

Bacovsky J, et al. Analysis of thymidine kinase serum levels by novel method DiviTum<sup>™</sup> in multiple myeloma and monoclonal gammopathy of undetermined significance – comparison with imaging methods 99mTc-MIBI scintigraphy and 18F-FDG PET/CT. Biomed Pap Med Fac Univ Palacky Olomouc Czech Repub. 2015; Mar;159(1):135-8.

Procházka V, et al. High baseline serum thymidine kinase I level predicts unfavorable outcome in patients with follicular lymphoma. Leuk Lymphoma 2012; Jul;53(7):1306-10.

Rivkina A, et al. Identifying the stage of new CLL patients using TK, ZAP-70, CD38 levels. Exp. Oncology 2011; 33(2), 99-103.

#### Method

Nisman B, et al. Comparison of diagnostic and prognostic performance of two assays measuring thymidine kinase I activity in serum of breast cancer patients. Clin Chem Lab Med. 2013; 51(2):439-47.

### Comments on the financial performance of the Group

#### QI - Sales and earnings

Net sales for the period amounted to SEK 367 (914) thousand. Sales during the period were to repeat customers in the research market who conduct clinical studies.

Capitalized work performed by the company for its own use amounts to SEK 1,358 (1,196) thousand. The capitalized amount pertains to expenditure associated with developing DiviTum<sup>®</sup> for measuring thymidine kinase (TK).

Operating expenses amount to SEK -8,110 (-6,239) thousand. The higher level of expense compared to last year is attributable to having set up operations in USA. We also wrapped up a market analysis and reimbursement project with external consultants during the period.

The operating loss for the period was SEK -6,097 (-3,956) thousand.

Net financial items amounted to SEK 29 (-72) thousand. Loss after financial items was SEK -6,068 (-4,028) thousand. Profit or loss for the period was SEK -6,068 (-4,028) thousand.

As of 31 July 2019, the company had 17 (17) employees, of which 8 (9) are women.

# Financial position, cash flow and investments

The closing amount for cash & cash equivalents on 31 July 2019 was SEK 68,207 (16,831) thousand. The cash balance increased from the new share issue of SEK 60 million that occurred in May. After issue costs, the cash balance increased by SEK 56.7 million.

The year's capitalized expenditure for development work is SEK 1,358 (1,196) thousand.

Investments in property, plant and equipment in the form of equipment for the year is SEK 0 (254) thousand.

#### Warrants

On 30 June 2019, the TO1 warrant scheme expired, after which, Biovica still had 3 active warrant schemes. No shares were subscribed for in TO1. For the warrant scheme decided at the extraordinary general meeting on 24 January 2017 (TO2), warrants were offered to all Biovica employees for SEK 0.54/warrant based the Black-Scholes pricing model for determining the fair market value. Each warrant entitles the holder to subscribe for one new class B share at SEK 25 per share during the period 29 March 2017 through 30 March 2020. With full subscription of the issued warrants, Biovica can increase its share capital by, at most, approximately SEK 13,333.33 and the number of shares by, at most, 200,000.

At the AGM on 30 August 2018, it was decided to set up an additional warrant scheme for employees (TO3). The warrants have been valued at SEK 0.44. Each warrant entitles the holder to subscribe for one new class B share at SEK 21.9 per share during the period 30 August 2020 through 25 August 2021. With full subscription of the issued warrants, Biovica can increase its share capital by, at most, approximately SEK 13,333.33 and the number of shares by, at most, 200,000.

At the extraordinary general meeting on 20 March 2019, it was decided to set up a warrant scheme for members of the Board of Directors (TO4). The warrants will be valued in accordance with the Black-Scholes pricing model. Each warrant entitles the holder to subscribe for one new class B share at a per share price corresponding to 200 percent of the volume-weighted average price for class B shares on traded on Nasdaq First North during the ten (10) trading days prior to the extraordinary general meeting that was held on 20 March 2019. Holders may subscribe during the period 25 August 2022 through 25 August 2023. With full subscription of the issued warrants, Biovica can increase its share capital by, at most, approximately SEK 11,666.67 and the number of shares by, at most, 175,000.

#### Related party transactions

During the year, the company, represented by parties related to the main owner and board member, Anders Rylander, leased office facilities to the Parent Company. The total fee for rent paid was SEK 50 thousand. Transactions were in accordance with market-based terms and conditions.

#### Policies for preparing the interim report

#### **Accounting** policies

The Group applies the Annual Accounts Act, International Financial Reporting Standards (IFRS) that have been adopted by the EU and RFR I Additional Accounting Regulations for Groups when preparing the financial statements. The Parent Company applies RFR 2 Accounting for Legal Entities when preparing the financial statements. The applied accounting policies otherwise correspond with those described in the Annual Report for 2017/2018. This interim report was prepared in accordance with IAS 34, Interim Financial Reporting.

#### Significant risks and uncertainties

There are several risks and uncertainties associated with the company's operations. For a more detailed description of the risks (in Swedish), please see the Annual Report for 2018/2019. The risks have not changed compared to what is described in the Annual Report.

	Q1	Q1	Full year	Full year	Full year	Full year
SEK thousands	19/20	18/19	18/19	17/18	16/17	15/16
Net sales	367	914	3,005	2,723	632	2,432
Operating profit (loss)	-6,097	-3,956	-21,718	-17,956	-14,690	-4,617
Profit (loss) for the period	-6,068	-4,028	-21,556	-18,010	-14,715	-5,049
Capitalized R&D expenditure	1,358	1,196	6,464	6,596	5,075	4,700
Capitalized R&D exp., % of op. expenses	-19	-22	-22	-26	-27	-37
Earnings per share, basic	-0.26	-0.23	-1.23	-1.02	-0.84	-0.54
Earnings per share, after dilution Cash and cash equivalents at the end of the	-0.33	-0.23	-1.18	-1.00	-0.82	-0.53
period	68,207	37,642	16,831	42,127	65,469	928
Cash flow from operating activities	-3,509	-17,967	-11,374	-14,882	-10,746	-9,385
Cash flow for the period	-5,230	-25,296	-18,112	-23,342	64,541	-179
Equity	102,712	69,626	52,097	73,713	91,664	24,881
Equity per share	4.36	3.96	2.96	4.19	5.22	44.51
Equity ratio (%)	92	92	86	91	94	88
Average number of employees	17	17	16	14	8	5

### KPIs for the Group

Definitions are the same as those presented in the Annual Report for 2018/2019.



## Financial information

# Consolidated income statement and summary statement of comprehensive income

SEK thousands	Q1 19/20	Q1 18/19	May-April 18/19
Net sales	367	914	3,005
Other income	205	238	932
Work performed by the company and capitalized	1,358	1,196	6,464
Change in WIP inventory	13	-65	43
	1,943	2,283	10,444
Materials cost	-210	-160	-875
Other external costs	-2,900	-2,106	-11,962
Employee benefit expenses	-4,200	-3,231	-16,245
Depreciation/amortization	-780	-740	-3,020
Other expenses	0	-2	-60
Operating profit (loss)	-6,147	-3,956	-21,718
Other interest income and similar profit or loss			
items	58	1	229
Interest expenses and similar items	-29	-73	-35
Profit (loss) after financial items	-6,118	-4,028	-21,524
Tax expense	0	0	-32
Profit (loss) for the year	-6,118	-4,028	-21,556
Consolidated statement of comprehensive income			
Profit (loss) for the year	-6,116	-4,028	-21,556
Exchange diff. foreign net invest.	0	0	0
Other comprehensive income for the year	0	0	0
Comprehensive income for the year (loss)	-6,116	-4,028	-21,556
Earnings per share			
Earnings per share, before dilution (SEK)	-0.26	-0.23	-1.23
Average number of shares, before dilution	23,573,372	17,573,372	17,573,372
Earnings per share, after dilution (SEK)	-0.34	-0.23	-1.18
Average number of shares, after dilution	18,148,372	17,773,332	18,343,372

Consolidated statement of financial position, in summary
--

SEK thousands	2019-07-31	2019-04-30
ASSETS		
Intangible assets	38,696	37,907
Property, plant and equipment	2,586	2,917
Financial assets	, 0	, 0
Total fixed assets	41,282	40,825
Inventories	529	446
Accounts receivable	320	1,732
Current receivables	1,295	1,026
Cash and bank	68,207	16,831
Total current assets	70,351	20,035
TOTAL ASSETS	111,633	60,859
EQUITY		
Share capital	1,572	1,172
Other contributed capital	190,058	133,776
Retained earnings (losses), including loss for the year	-88,918	-82,850
Total equity	102,712	52,097
Other non-current liabilities	757	940
Advance payments from customers	3,384	3,571
Accounts payable	2,492	860
Current tax liabilities	443	557
Other liabilities	-298	545
Accrued expenses and deferred income	2,143	2,289
Current liabilities	8,163	7,822
TOTAL EQUITY AND LIABILITIES	111,633	60,859

### Consolidated statement of changes in equity, in summary

SEK thousands	Share	Other contributed	Retained earnings (losses)	Net profit (loss) for	Total
Opening balance on 1 May 2018	capital 1,172	capital 133,776	-43,225	the year -18.010	equity 73,713
Appropriation in accordance with	1,1/2	155,770	-43,223	-18,010	/3,/15
AGM decision			-18,010	18,010	_
Adjustment			-59		-59
Translation difference					_
Net profit (loss) for the year				-21,556	-21,556
Closing balance on 30 April 2019	1,172	133,776	-61 ,294	-21,556	52,097
New share issue		56 282			56,682
Net profit (loss) for the year				-6,068	-6068
Closing balance on 31 July 2019	1,572	190,058	-61,294	-27,624	102,712



# Consolidated statement of cash flows, in summary

	Q1	Q1	May-April	May-April
SEK thousands	19/20	18/19	18/19	17/18
Cash flow from operating activities before				
changes in working capital	-5,518	-3,037	-17,788	-15,009
Changes in working capital	1,569	2	-179	127
Cash flow from operating activities	-3,949	-3,035	-17,967	-14,882
Cash flow from investing activities	-1,358	-1,450	-7,329	-8,459
Cash flow from financing activities	56 <i>,</i> 682	0	0	0
Cash flow for the period	51,376	-4,485	-25,296	-23,342
Cash and cash equivalents at the beginning of				
the period	16,831	42,127	42,127	65,469
Cash and cash equivalents at the end of the period	68,207	37,642	16,831	42,127

### Parent Company income statement, in summary

SEK thousands	Q1 19/20	Q1 18/19	May-April 18/19
Net color	267	014	2.005
Net sales	367	914	3,005
Change in WIP inventory	83	-65	751
Work performed by the company and capitalized	1,358	1,196	6,464
Other operating income	205	238	43
Sales	2,013	2,283	10,263
Goods for resale	-280	-160	-875
Other external costs	-3,461	-2,157	-12,638
Employee benefit expenses	-3,733	-3,231	-15,736
Depreciation/amortization	-712	-707	-2,840
Other operating expenses	0	-2	-60
Operating expenses	-8,186	-6,258	-32,149
Operating profit (loss)	-6,173	-3,975	-21,886
Net financial income/expense	64	-71	280
Profit (loss) after financial items	-6,109	-4,046	-21,606
Income tax	0	0	0
Profit (loss) for the period	-6,109	-4,046	-21,606
Earnings per share			
Earnings per share, before dilution (SEK)	-0.26	-0.23	-1.23
Average number of shares, before dilution	23,573,372	17,573,372	17,573,372
Earnings per share, after dilution (SEK)	-0.26	-0.23	-1.19
Average number of shares, after dilution	23,948,372	17,968,372	18,143,372
	20,0 .0,072	1,000,072	10,1 .0,0,2

Comprehensive income (loss) equals the loss for the period.

### Parent Company balance sheet, in summary

SEK thousands	2019-07-31	2018-07-31	2019-04-30
ASSETS			
Intangible assets	38,696	34,346	37,907
Machinery and equipment	1,658	2,053	1,801
Financial assets	296	173	300
TOTAL FIXED ASSETS	40,650	36,571	40,008
Inventories	529	338	446
Current receivables	2,541	1,574	3,738
Cash and bank	67,649	36,685	15,779
TOTAL CURRENT ASSETS	70,720	38,597	19,963
TOTAL ASSETS	111,369	75,168	59,972
EQUITY			
Total restricted equity	21,064	14,038	19,307
Total non-restricted equity	81,515	55,527	32,699
TOTAL EQUITY	102,579	69,565	52,005
LIABILITIES			
Total non-current liabilities	0	100	0
Total current liabilities	8,790	5,503	7,966
TOTAL LIABILITIES	8,790	5,603	7,966
TOTAL EQUITY AND LIABILITIES	111,369	75,168	59,972

Uppsala, 29 August 2019

Board of Directors

This report has not been reviewed by the company's auditor.

Calendar

Interim Report for Q2: August-October 2019 Interim Report for Q3: November - January 2020 Interim Report for Q4: February – April 2020 5 December 2019 12 March 2020 12 June 2020

For more information, please contact: Anders Rylander, CEO Phone: +46 (0)18-44 44 835 Email: <u>anders.rylander@biovica.com</u>

Biovica International AB (publ), 556774-6150 Dag Hammarskjölds väg 54B 752 37 Uppsala +46 (0)18-44 44 830 Cecilia Driving, CFO Phone +46 (0)73 125 92 47 Email: cecilia.driving@biovica.com

#### About Biovica

Biovica develops and commercializes blood-based biomarker assays for evaluating the effect of cancer treatments. Biovica's DiviTum® technology measures cell proliferation rate and clinical studies have shown that it can quickly reveal whether treatment is effective. Biovica's vision is a future where every patient receives the best possible therapy from the very first day of treatment. Biovica collaborates with world-leading cancer institutes and pharmaceutical companies to develop next-generation cancer therapies. Biovica has obtained ISO 13485 certification DiviTum® has CE marking and it is registered with the Swedish Medical Products Agency. Biovica's class B shares are listed on Nasdaq First North. FNCA Sweden AB is the appointed Certified Adviser.

For more information, please visit the company's website: www.biovica.com