Biovica Q1 Interim Report: May-July 2020/2021

Clinical validation completed, work with the FDA submission in the final phase

SEK thousands	Q1 20/21	Q1 19/20	May-April 19/20
Net sales	340	367	1,671
Operating profit (loss)	-8,665	-6,147	-29,816
Profit (loss) for the period	-8,374	-6,118	-30,318
Earnings per share, after dilution	-0.36	-0.33	-1.24

Significant events during the fourth quarter

- Biovica announced its goal to achieve 15 percent share of the total market potential in each market within three years of the launch.
- Importance of DiviTum® and TK activity acknowledged in two scientific journals.
- ASCO Educational Book 2020 highlights DiviTum® results and TK activity.

Significant events after the end of the period

- Clinical validation, which is the last step required for the FDA validation, has been completed with positive results and the stated criteria have been met.
- Directed share issue for SEK 148 million a number of Swedish and international investors, including Andra AP-fonden, Coeli Asset Management and Lancelot Asset Management.

CEO's comments

During the quarter, we took important steps towards achieving our goals. Preparations for the market launch of DiviTum® have intensified and we are working in accordance with our timetable to submit the application for market approval to the US Food and Drug Administration (FDA) during the third quarter of 2020.

After having submitted the 510(k) application to the FDA, we expect to receive market approval at the start of 2021, which will give us access to the substantial US market for patient monitoring. Efforts to document the assay prior to approval have been extensive and during the quarter, we took several important steps in this process. One important part of the application is the extensive clinical validation study on American patients, which we are carrying out in collaboration with SWOG Cancer Research Network.

The clinical validation was completed during the summer, where we analyzed more than 1,700 samples with good results. Just as with the analytical validation, we met the criteria we had defined. The clinical validation has thus been completed with positive results. What now remains is to compile and submit the application, which we are planning to do during the month of September.

Also during the summer, we submitted the results from the SWOG study for publication and presentation. We expect that they will be presented at a conference just prior to year-end, along with publication of the results during the first quarter of next year.

Our important collaboration with SWOG also lays the foundation for Biovica to, via the organization's network of more than 12,000 oncologists and 1,000 cancer hospitals, widely reach the right target group and in doing so, quickly gain clinical acceptance for DiviTum®. In addition to the clinical validation study with SWOG, we have strong clinical results from eleven studies comprising more than 1,800 breast cancer patients, which were carried out in collaboration with world-leading oncologists at some of the most prestigious institutions in the world (e.g. Johns Hopkins, Mayo Clinic and Dana Farber Cancer Institute). Furthermore, there are currently five published studies underway comprising a total of 670 breast cancer patients, in addition to the SWOG study. These collaborations with the laboratory divisions of major cancer institutes are very important, in that they could later become important commercial partners for us.

During the quarter, results from a study with DiviTum® were published in Scientific Reports, a prestigious journal from the publishers of Nature. Furthermore, the ASCO Educational Book 2020 highlighted DiviTum® and the unique, strong results achieved when using it for monitoring the treatment effect of CDK4/6 inhibitors. This type of recognition is extremely important because it gives us extensive coverage and thereby creates excellent channels for reaching future customers. Wide knowledge of DiviTum® at the time when it obtains market approval will facilitate quicker progress in the test reaching its full commercial potential.

Besides that, we have made progress in creating a plan for reimbursement. Specifically, our efforts during the quarter have resulted in a clear plan for coding, coverage and payment of DiviTum®. We also initiated studies on the social benefits via cost savings of using the DiviTum® assay to treat metastatic breast cancer and thereby convince payers in USA of its value.

The market potential in the initial markets for DiviTum® is substantial, at USD 400-700 million per year for metastatic breast cancer. It is important to keep in mind, however, that initially, we are only addressing about 1 percent of all the 43 million people who are living with cancer and could potentially benefit from DiviTum®. The first step towards realizing the enormous potential is a successful launch in the USA for use of DiviTum® in treating metastatic breast cancer.

In May, we held a Capital Market Day, where we presented our strategy and announced our goal of achieving a 15 percent market share in each market within three years of the launch of DiviTum®. Long term, our goal is to claim 50 percent of the market share in each market. We also explained our plan for companion diagnostics (CDx) at the event.

To finance the commercialization plan, we carried out a directed share issue for a total of SEK 148 million.

In recent years, Biovica has attracted unique expertise and built a strong organization that is prepared for our important launch in the USA. At today's AGM, two individuals will be proposed as new Board members: Annika Carlsson Berg and Marie-Louise Fjällskog. Annika Carlsson Berg has 34 years of experience in the pharmaceutical, biotech and diagnostics industry, of which, 23 years have been in executive positions. She is currently employed as the Director of Quality and Regulatory Affairs at the ImmunoDiagnostic Division of Thermo Fisher Scientific. Marie-Louise Fjällskog is an oncologist with more than 25 years of experience in clinical oncology, transnational research and pharmaceutical development. She is currently employed as the Chief Medical Officer at Sensei Biotherapeutics in Boston, USA. Their expertise and talent will be a great asset to Biovica and I am very much looking forward to the contribution each will make by participating on the Board.

Biovica has had an intensive quarter, where we've taken further steps towards achieving our goal: that patients with metastatic breast cancer will receive the best possible treatment from day one. We have a unique product that meets an important need in a large, attractive market, which gives us a very solid foundation for our commercialization. A successful launch in the USA for use of DiviTum® in treating metastatic breast cancer is the first step towards realizing the product's full potential. I'm looking forward to what lies ahead and reporting our next successes.

Anders Rylander
CEO

Significant events during the period

Goals for market share

Biovica is approaching the market launch of DiviTum® for monitoring treatment of metastatic breast cancer. DiviTum® is currently being sold primarily to major pharmaceutical companies, which are using it for research purposes in clinical studies. Once FDA approval has been obtained, Biovica will have access to the important US market for patient monitoring.

Within three years of the launch, Biovica's goal is to have achieved a market share of 15 percent. DiviTum® will first be launched in the US market, followed by the five largest markets in Europe and the Nordic countries. After that, further geographic expansion will occur, with an initial focus on the Japanese market. Long term, Biovica's goal is to claim 50 percent of the share in the markets where we launch DiviTum®. The total market potential of these markets is estimated at USD 400-700 million per year.

DiviTum® acknowledged in prestigious scientific journals

The scientific journals, British Journal of Cancer, Scientific Reports (publishers of Nature) and Biomarkers in Medicine have each published articles on DiviTum® results and using TK activity as a biomarker for evaluating the treatment effect CDK4/6 inhibitor. They all conclude that DiviTum® has the potential to become a standard prognostic biomarker for early detection of treatment resistance in patients with metastatic breast cancer.

DiviTum® measures thymidine kinase (TK) activity, which is an established marker for the cell proliferation rate. The authors state that for many researchers thus far, identifying new predictive and prognostic biomarkers for breast cancer has been a frustratingly elusive goal. However, DiviTum® has been shown to be both prognostic for progressive disease and overall survival and with the ability to identify early resistance to treatment in patients receiving endocrine therapy with or without CDK4/6 inhibitors in metastatic breast cancer. The authors conclude that TK seems an intuitive choice of biomarker to monitor the efficacy of CDK4/6 inhibitors.

DiviTum® acknowledged in ASCO Educational Book 2020

The ASCO Educational Book 2020 highlights DiviTum® as a potential solution for addressing unmet needs as regards monitoring the treatment effect of CDK4/6 inhibitors.

The authors Erik S. Knudsen, PhD at Roswell Park Cancer Center, Geoffrey I. Shapiro, MD, PhD at Dana Farber Cancer Institute and Khandan Keyomarsi, PhD at MD Anderson conclude that: "These preliminary results highlight the potential for serum TK1 activity to act as a noninvasive biomarker for CDK4/6 inhibitor target engagement." The authors also summarize the clinical trials that demonstrate the ability of DiviTum® to identify CDK4/6 treatment resistance.

Effects of COVID-19

Thus far, the COVID-19 pandemic has only had a marginal impact on Biovica's operations. The most significant risk areas associated with COVID-19 are a delay of commercial activities, potential disruptions in supply chains, the health of our employees and financial stability of our customers and suppliers.

Significant events after the end of the period

Clinical validation completed with positive results

The clinical validation is the final part of Biovica's application for US market approval. Biovica remains on schedule to submit its regulatory filing during September 2020. DiviTum® TKa has met its predefined criteria. In the clinical validation, more than 1.700 samples from over 400 patients were analyzed. This is an important step towards finalizing our 510(k) application. It is the last major step required before finalizing our 510(k) application.

Targeted new share issue of SEK 148 million

Via a directed share issue that was approved by the Board of Directors based on authorization granted by the annual general meeting held on August 29, 2019, Biovica raised SEK 148 million in capital, before transaction costs. The subscription price in the Directed Issue has been determined to SEK 31.5 per share through an accelerated book building procedure The Directed Issue entails a dilution of approximately 16.6 percent of the number of shares and 11.2 percent of the number of votes in the Company. Through the Directed Issue, the number of outstanding shares increases by 4,700,000 from 23,573,372 to 28,273,372 and the number of votes increases from 37,299,640 to

41,999,640 (distributed between 6,863,134 Class A shares and 21,410,238 Class B shares). The share capital increases by approximately SEK 313,333.33, from approximately SEK 1,571,558.13 to approximately SEK 1,884,891.46.

Other

Annual General Meeting (AGM)

The AGM for the 2019/2020 financial year will be held today, 27 August 2020 at 4 p.m. The location is Hubben, Dag Hammarskjölds väg 38 in Uppsala, Sweden.

Comments on the financial performance of the Group

Q1 - Sales and earnings

Net sales for the period amounted to SEK 340 (367) thousand. Sales during the period were to customers in the research market and one repeat customer that purchases the kit to conduct clinical studies.

Capitalized work performed by the company for its own use amounts to SEK 1,659 (1,358) thousand. The capitalized amount pertains to expenditure associated with developing DiviTum® for measuring thymidine kinase (TK).

Operating expenses amount to SEK -10,893 (-8,110) thousand. The increase in operating expenses compared to last year is partly attributable to a nonrecurring cost of SEK 1 million in the US subsidiary, along with high activity in the DiviTum® project associated with the upcoming submission of the 510(k) application to the FDA prior to commercialization.

The operating loss for the period was SEK -8,665 (-6,147) thousand.

Net financial items amounted to SEK 290 (29) thousand. Loss after financial items was SEK -8,376 (-6,118) thousand. Loss for the period was SEK -10,777 (-6,118) thousand.

As of 31 July 2020, the company had 21 (17) employees, of which 8 (8) are women.

Financial position, cash flow and investments

The closing amount for cash & cash equivalents on 31 July 2020 was SEK 31,394 (68,207) thousand.

The year's capitalized expenditure for development work is SEK 1,659 (1,358) thousand.

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

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.

Warrants

Program	To	Class B shares	Subscription price	Warrant price	Subscription period	Share capital increase	Number of class B shares
TO3	employees	200,000	21.90	0.44	30 March 2020 - 25 August 2021	13,333.33	200,000
TO4	Board of Directors	175,000	19.50	0.94	25 March 2022 - 25 August 2023	11,666.67	175,000
TO5	employees	270,000	17.16	1.23	25 March 2021 - 25 August 2022	18,000.00	270,000
						43,000.00	**645,000**

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 144,390 shares were reclassified on 30 June 2020.

2020-06-30	Class A shares	Class B shares	Total
Before reclassification	7,007,524	16,565,848	23,573,372
Reclassification	-144,390	144,390	0
After reclassification	**6,863,134**	**16,710,238**	**23,573,372**

Policies for preparing the interim report

Accounting policies

This interim report was prepared in accordance with IAS 34, Interim Financial Reporting. The Group applies the Annual Accounts Act, International Financial Reporting Standards (IFRS) that have been adopted by the EU and RFR 1 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 2018/2019.

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.

KPIs for the Group

SEK thousands	Q1 20/21	Q1 19/20	Full year 19/20	Full year 18/19	Full year 17/18	Full year 16/17
Net sales	340	367	1,671	3,005	2,723	632
Operating profit (loss)	-8,665	-6,147	-29,816	-21,718	-17,956	-14,690
Profit (loss) for the period	-8,374	-6,118	-30,318	-21,556	-18,010	-14,715
Capitalized R&D costs	1,659	1,358	7,035	6,464	6,596	5,075
Capitalized R&D exp., % of op. expenses	0	-19	-18	-22	-26	-27
Earnings per share, before dilution	-0.36	-0.26	-1.29	-1.23	-1.02	-0.84
Earnings per share, after dilution	-0.36	-0.33	-1.29	-1.23	-1.02	-0.84
Cash and cash equivalents at the end of the period	31,394	68,207	40,777	16,831	42,127	65,469
Cash flow from operating activities	-7,363	-3,509	-24,780	-17,966	-14,882	-10,746
Cash flow for the period	-9,328	-5,230	23,927	-25,295	-23,342	64,541
Equity	69,835	102,712	78,217	52,097	73,713	91,664
Equity per share	2.96	4.36	3.32	2.96	4.19	5.22
Equity ratio (%)	1	92	87	86	91	94
Average number of employees	21	17	17	16	14	8

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

Consolidated income statement and summary statement of comprehensive income

SEK thousands	Q1 20/21	Q1 19/20	May-April 19/20
Net sales	340	367	1,671
Other income	80	205	1,215
Work performed by the company and capitalized	1,659	1,358	7,035
Change in WIP inventory	0	13	–
	2,078	**1,943**	**9,921**
Materials cost	-51	-210	-220
Other external costs	-4,019	-2,900	-15,386
Employee benefit expenses	-5,701	-4,200	-19,874
Depreciation/amortization	-454	-780	-4,170
Other expenses	-569	0	-86
Operating profit (loss)	**-8,665**	**-6,147**	**-29,816**
Other interest income and similar profit or loss items	0	58	–
Interest expenses and similar items	290	-29	-443
Profit (loss) before tax	**-8,376**	**-6,118**	**-30,259**
Tax expense	2		-59
Profit (loss) for the period	**-8,374**	**-6,116**	**-30,318**
Consolidated statement of comprehensive income			
Profit (loss) for the period	-8,374	-6,116	-30,318
Exchange diff. foreign net invest.	–	–	–
Other comprehensive income for the period	–	–	–
Comprehensive income for the period	**-8,374**	**-6,116**	**-30,318**
Earnings per share			
Earnings per share, before dilution (SEK)	-0.36	-0.26	-1.29
Average number of shares, before dilution	23,573,372	23,573,372	23,573,372
Earnings per share, after dilution (SEK)	-0.36	-0.34	-1.29
Average number of shares, after dilution	24,218,372	18,148,372	24,218,372

Consolidated statement of financial position, in summary

SEK thousands	2020-07-31	2019-07-31	2020-04-30
ASSETS			
Intangible assets	43,756	38,696	42,666
Machinery, equipment, tools, fixtures and fittings	2,997	0	1,234
Right-of-use assets	1,095	2,586	3,312
Deferred tax asset	677	0	743
Total fixed assets	**48,525**	**41,282**	**47,955**
Inventories	547	529	397
Accounts receivable	365	320	0
Current receivables	159	1,295	1,129
Cash and cash equivalents	31,394	68,207	40,777
Total current assets	**32,464**	**70,351**	**42,303**
TOTAL ASSETS	**80,989**	**111,633**	**90,259**
EQUITY			
Share capital	1,572	1,572	1,572
Other contributed capital	195,133	190,058	195,133
Retained earnings (losses), including loss for the year	-126,870	-88,918	-118,487
Total equity	**69,835**	**102,712**	**78,217**
LIABILITIES			
Deferred tax liability	641	0	709
Lease liability	1,716	0	2,272
Other non-current liabilities	0	757	0
Total non-current liabilities	**2,358**	**757**	**2,981**
Advance payments from customers	3,537	3,384	3,521
Accounts payable	229	2,492	1,007
Current tax liabilities	145	443	500
Lease liability	1,431	0	1,182
Other liabilities	806	-298	624
Accrued expenses and deferred income	2,650	2,143	2,228
Current liabilities	**8,797**	**8,163**	**9,061**
TOTAL EQUITY AND LIABILITIES	**80,989**	**111,633**	**90,259**

Consolidated statement of changes in equity, in summary

Amounts in SEK	Share capital	Other contributed capital	Reserves	Retained earnings	Profit (loss) for the year	Total equity
Opening balance, 1 May 2019	**1,172**	**133,776**	**0**	**-61,294**	**-21,556**	**52,097**
Appropriation in accordance AGM decision				-21,556	21,556	0
Reclassification		5,075		-5,075		0
Adjustment due to change in accounting policy				-246		0 -246
Translation difference			2	-2		0
New share issue	400	56,282				56,682
Profit (loss) for the period					-30,318	-30,318
Closing balance, 30 April 2020	**1,572**	**195,132**	**2**	**-88,172**	**-30,318**	**78,216**
Appropriation in accordance AGM decision				-30,318	30,318	0
Translation difference			-8			-8
Profit (loss) for the year					-8,374	-8,374
Closing balance, 31 July 2020	**1,572**	**195,133**	**-6**	**-118,491**	**-8,374**	**69,835**

Consolidated statement of cash flows, in summary

SEK thousands	Q1 20/21	Q1 19/20	May-April 19/20	May-April 18/19
Cash flow from operating activities before changes in working capital	-7,587	-5,518	-26,587	-17,788
Changes in working capital	224	1,569	1,807	-179
Cash flow from operating activities	**-7,363**	**-3,949**	**-24,780**	**-17,967**
Cash flow from investing activities	-1,659	-1,358	-7,035	-7,329
Cash flow from financing activities	-306	56,682	55,742	0
Cash flow for the period	**-9,328**	**51,376**	**23,927**	**-25,296**
Cash and cash equivalents at the beginning of the period	40,777	16,831	16,831	42,127
Translation difference, cash and cash equivalents	-54	0	19	0
Cash and cash equivalents at the end of the period	31,394	68,207	40,777	16,831

Parent Company income statement, in summary

SEK thousands	Q1 20/21	Q1 19/20	Full year 19/20
Net sales	340	367	1,671
Other operating income	80	205	-
Work performed by the company and capitalized	1,659	1,358	7,035
Change in WIP inventory	149	83	972
Sales	*2,227*	*2,013*	*9,677*
Goods for resale	-43	-280	-220
Other external costs	-6,504	-3,461	-18,991
Employee benefit expenses	-3,738	-3,733	-17,849
Depreciation/amortization of property, plant and equipment and intangible assets	-707	-712	-2,843
Other operating expenses	0	0	-86
Operating expenses	*-10,844*	*-8,186*	*-39,990*
Operating profit (loss)	**-8,435**	**-6,173**	**-30,312**
Net financial income/expense	-0	64	-259
Profit (loss) before tax	**-8,435**	**-6,109**	**-30,571**
Income tax			
Profit (loss) for the period	**-8,435**	**-6,109**	**-30,571**
Earnings per share			
Earnings per share, before and after dilution (SEK)	-0.36	-0.26	-1.30
Average number of shares, before and after dilution	23,573,372	23,573,372	23,573,372
Earnings per share, after dilution (SEK)	-0.36	-0.26	-1.30
Average number of shares, after dilution	24,218,372	23,948,372	24,218,372

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

Parent Company balance sheet, in summary

SEK thousands	2020-07-31	2019-07-31	2020-04-30
ASSETS			
Intangible assets	43,756	38,696	42,666
Machinery and equipment	1,095	1658	1,234
Financial assets	1,139	296	1,248
TOTAL FIXED ASSETS	*45,990*	*40,650*	*45,148*
Inventories	547	529	397
Current receivables	1,306	2,541	1,105
Cash and bank	30,617	67,649	39,642
TOTAL CURRENT ASSETS	*32,470*	*70,720*	*41,144*
TOTAL ASSETS	**78,460**	**111,369**	**86,292**
EQUITY			
Total restricted equity	26,741	21,064	26,741
Total non-restricted equity	51,375	81,515	51,375
TOTAL EQUITY	*78,117*	*102,579*	*78,117*
LIABILITIES			
Total non-current liabilities	0	0	0
Total current liabilities	8,778	8,790	8,176
TOTAL LIABILITIES	*8,778*	*8,790*	*8,176*
TOTAL EQUITY AND LIABILITIES	**78,460**	**111,369**	**86,292**

Board of Directors' assurance

The Board of Directors and CEO hereby certify that this interim report provides a true and fair summary of the Parent Company's and the Group's operations, earnings and financial position as well as describing any significant risks or uncertainties faced by the Parent Company or any of the companies belonging to the Group.

Uppsala, 27 August 2020

Board of Directors

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

Calendar

AGM	27 August 2020
Interim Report for Q2: August-October 2020	3 December 2020
Interim Report for Q3: November - January 2021	18 March 2021
Interim Report for Q4: February – April 2021	17 June 2019

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Biovica – Treatment decisions with greater certainty

Biovica develops and commercializes blood-based biomarker assays for evaluating the effect of cancer treatments. Biovica's assay DiviTum® measures 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® has CE marking and it is registered with the Swedish Medical Products 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 (0)8-528 00 399. For more information, please visit www.biovica.com.