BIOVICA

Q3 Interim report

DiviTum® – first study published on CDK4/6 inhibitor against clinical results

Period: May-January 2019/2020

SEK 000s	Q3 19/20	Q3 18/19	May-Jan 19/20	May-Jan 18/19	May-April 18/19
Net sales	55	288	1,671	1,269	3,005
Operating profit (loss)	-7,433	-5,780	-19,520	-15,346	-21,718
Profit (loss) for the period	-7,515	-6,045	-19,540	-15,636	-21,556
Earnings per share, after dilution	-0.31	-0.34	-0.87	-0.87	-1.18

Significant events during the third quarter

- Otti Bengtsson Gref joined the company as Biovica's new R&D Director and Henrik Winther joined as SVP Business Development in January 2020
- Additional results validating DiviTum® as a dynamic biomarker in monitoring metastatic breast cancer were presented by Institut Curie, Paris at the San Antonio Breast Cancer Symposium in December 2019
- New clinical data demonstrating that DiviTum® is a strong prognostic marker in operable breast cancer were presented at the San Antonio Breast Cancer Symposium in December 2019
- Clinical Cancer Research published data from the TREnd study on the benefits of using DiviTum®. The new results show that a change in TK levels one month after the start of treatment can be used to evaluate treatment effect.

Significant events after the end of the period

- Submission of our 510(k) application for DiviTum® to the FDA is expected to occur during the third quarter of 2020, rather than in mid-2020, as earlier announced.

Audiocast

When: 12 March 2020 at 10.00 CET

Where: https://tv.streamfabriken.com/biovica-international-q3-2019-2020 or
SE: +46850558352 / DK: +4578150110 / UK: +443333009263 /
US: +18335268398

Broadcast language: in English

CEO's comments

During the quarter, we made significant progress in our prioritized areas: regulatory preparations, clinical studies and commercial activities.

We have a clear understanding of the FDA's requirements for granting market approval for DiviTum® to be launched in USA as a tool for monitoring treatments in metastatic breast cancer patients.

I am very proud to announce that, thus far, the results from the analytical validation meet our established requirements. Simultaneous to that, all of the patient samples from SWOG have been analyzed and the results will soon be published.

Production has been delayed due to late deliveries of one of the product's components. These problems have now been solved, which means that the analytical validations will be completed during the second quarter. Our goal is to submit the 510(k) application for market approval to the FDA during the third quarter of 2020.

Clinical results confirmed and strengthened with new studies

As for our clinical studies, we presented new results during 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 was presented at the world's largest congress on breast cancer, SABCS, San Antonio Breast Cancer Symposium, during 10-14 December 2019. The study is based on more than 100 patient samples and it was carried by 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 presented early in 2019 and it gives us confidence in our plans for making DiviTum® a clinically useful cell proliferation biomarker for monitoring metastatic breast cancer.

During the quarter, clinical data was presented 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 was also presented at SABCS in December. It was based on more than 600 patients. Adding that to Nisman's earlier groundbreaking study, it means that we now have data on more than 800 patients Subsequent to the end of the quarter, results were also published from a study by researchers at Lund University in the prestigious journal, Scientific Report. The results support prior evidence showing that DiviTum® can be used to more quickly evaluate treatment effect and as a prognostic tool. The results of this study give us confidence that with time, we should be able to expand the use of DiviTum® to other application areas.

New additions to the senior management team

During the quarter, Otti Bengtsson Gref joined the company as our new R&D Director and Henrik Winther joined as SVP Business Development. They have extensive expertise and experience in development, production, regulatory approval and commercialization of diagnostic products. They will be valuable assets to Biovica and important pieces in the puzzle for our continued market expansion. At Biovica, we now possess quite a unique combination of scientific expertise and commercial experience.

We are reporting favorable results from studies and moving towards launch of the product in the US market early in 2021 and in selected European markets shortly thereafter. Wide knowledge of DiviTum® at the time when it obtains market approval will facilitate quicker progress in the test reaching its full commercial potential.

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 would like to end by taking this opportunity to thank our shareholders for the continued confidence they have in us and all our dedicated employees for the excellent work they've done. I'm very much looking forward to the journey ahead with all of you.

Anders Rylander, CEO

Significant events during the period

New R&D Director appointed

Otti Bengtsson Gref has been appointed as Biovica's new R&D Director and she will also join the senior management team. Most recently, she worked as the R&D Director at Cavidi.

Otti Bengtsson Gref has extensive experience in leading positions in the area of R&D and in the commercial diagnostics industry. During the period 2010-2018, she had various managerial roles in R&D at IDD and Thermo Fisher Scientific. Prior to that, between 2003 and 2010, she worked as a specialist, product manager and was later was appointed Head of Product Management at Phadia. Bengtsson Gref has a Licentiate degree in Medicine, specialized in Immunology. She also has an Executive MBA degree. She is the R&D Director as of 7 January 2020.

New SVP Business Development joins the company

Henrik Winther joined the company as SVP Business Development) and he will also be a member of the senior management team. He was most recently employed as SVP Precision Diagnostics at Immunovia.

Henrik Winther has previously held the positions of Global VP of Business Development at the Danish diagnostics company Dako and later as General Manager of the Companion Diagnostic (CDx) Division at Agilent Technologies based in California. Earlier in his career, Winther headed the R&D diagnostic reagents development at Dako. Prior to that he was associate professor in anatomy, physiology and cell biology at the University of Copenhagen.

DiviTum® – Prognostic marker for treatment with CDK4/6 inhibitor

DiviTum® can be used as a dynamic, non-invasive biomarker for patients with metastatic breast cancer who are being treated with endocrine therapy and palbociclib. Data was presented at the San Antonio Breast Cancer Symposium between 10-14 December 2019. It is the world's largest scientific conference with a focus on breast cancer.

The prognostic value of DiviTum® was evaluated in a prospective study of 103 patients with metastatic breast cancer who, between May 2016 and August 2018, received endocrine treatment and CDK 4/6 inhibitor palbociclib at Institut Curie in Paris. Plasma samples were collected prior to the start of treatment and again after four weeks of treatment. DiviTum® was used to measure thymidine kinase activity in the samples (pTKa).

Low DiviTum® values after four weeks of treatment were associated with lower progression-free (PFS) survival and total survival compared to high values (10.4 versus 4.7 months, and not reached PFS versus 20 months, respectively). Patients with a progression-free survival of less than 6 months had a significantly higher pTKa level after 4 weeks of treatment (median 256 Du/L versus 100 Du/L).

"We have shown the clinical validity of DiviTum® in an adequately designed prospective trial of combined targeted and endocrine therapies. We are encouraged by these promising results showing the potential of DiviTum® to become a clinically useful dynamic biomarker for monitoring efficacy of palbociclib and endocrine therapy in patients with metastatic breast cancer", said lead investigator Luc Cabel, MD, Institut Curie, Paris.

DiviTum® – Strong prognostic marker in operable breast cancer

DiviTum® is a strong prognostic marker in operable breast cancer. The results were presented at the San Antonio Breast Cancer Symposium, SABCS, 10-14 December,2019.

The study is a retrospective analysis of serum samples from a random clinical study of 644 women with operable breast cancer (before menopause with HR+ breast cancer in stage II-IIIB). Serum samples were collected pre-operatively on the day of surgery. After five years, patients with low pre-operative DiviTum® values (the lowest quartile, <25 percent) showed a disease-free survival rate of 81 percent versus 58 percent in the group with the highest DiviTum values (>75 percent).

"We are thrilled to see these new, interesting results. It demonstrates that pre-operative DiviTum® values measured in serum is a strong prognostic marker in operable breast cancer with a potential to identify patients with the most aggressive tumors in order to personalize their therapy," said lead investigator Dr. Luca Malorni, Prato Hospital, Italy.

Significant events after the end of the period

Update on the FDA application

Thus far, results from the analytical validation meet the requirements established by Biovica. Production has been delayed due to late deliveries of one of the DiviTum® components. These problems have now been solved. However, it means that the completion of the analytical validations will occur during the second quarter.

Our goal is to submit the 510(k) application for market approval to the U.S. Food and Drug Administration (FDA) during the third quarter of 2020.

Comments on the financial performance of the Group

Q3 - Sales and earnings

Net sales for the period amounted to SEK 55 (288) thousand.

Capitalized work performed by the company for its own use amounts to SEK 2,032 (1,713) thousand. The capitalized expenditure pertains to development efforts with DiviTum® for measuring thymidine kinase (TK).

Operating expenses amount to SEK -10,165 (-8,275) thousand. The higher level of expense compared to last year is attributable to having set up operations in USA. There was also a high level of activity in the DiviTum® project.

The operating loss for the period was SEK -7,433 (-5,780) thousand.

Net financial items amounted to SEK 27 (-265) thousand. Loss after financial items was SEK -7,406 (-6,045) thousand. Loss for the period was SEK -7,515 (-6,045) thousand.

As of 31 January 2020, the company had 16 (17) employees, of which 7 (8) are women.

Nine months - Sales and earnings

Net sales for the period amounted to SEK 1,671 (1,269) 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 5,401 (4,565) thousand. The capitalized expenditure pertains to development efforts with DiviTum® for measuring thymidine kinase (TK).

Operating expenses amount to SEK -27,607 (-21,946) thousand. The higher level of expense compared to last year is attributable to having set up operations in USA. There was also a high level of activity in the DiviTum® project.

The operating loss for the period was SEK -19,520 (-15,346) thousand.

Net financial items amounted to SEK 20 (-291) thousand. Loss after financial items was SEK -19,499 (-15,636) thousand. Loss for the period was SEK -19,540 (-15,346) thousand.

As of 31 January 2020, the company had 16 (17) employees, of which 7 (8) are women.

Financial position, cash flow and investments

The closing amount for cash & cash equivalents on 31 January 2020 was SEK 51,623 (24,203) thousand.

The year's capitalized expenditure for development work is SEK 2,032 (1,713) thousand.

Investments in property, plant and equipment in the form of equipment for the year is SEK 3,524 (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 149 thousand. Transactions were in accordance with market-based terms and conditions.

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.

New and revised standards and interpretations applied by the Group as of 1 May 2019

IFRS 16 has been implemented as of 1 January 2019. IFRS 16 replaces IAS 17 and the new standard involves new reporting requirements for the lessee. It requires a lessee to recognize assets and liabilities for all leases with a term of more than 12 months, unless the underlying asset is of low value. A lessee is required to recognize a right-of-use asset representing its right to use the underlying leased asset and a lease liability representing its obligation to make lease payments. With the new standard, leases that were reported as operating leases in the 2018/2019 financial year are, as of 1 May 2019, reported in accordance with IFRS 16. The cost of such leases will be divided between interest expense and depreciation of the right-of-use asset. Biovica applies the simplified approach, which means that the comparative figures have not been restated. Leases for low-value assets will, as before, be treated as operating leases and reported in the income statement. The company's lease portfolio consists of six agreements, which pertain to office space, office equipment and vehicles. For one lease agreement on office equipment, the underlying assets were of lesser value and as such, recognition in accordance with IFRS 16 is not required.

SEK thousand	
Opening balance on 1 May, PPE right-of-use	
Depreciation	-803
PPE, right-of-use	2,815

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.

Warrants

Program	To	Class B shares	Subscription price	Warrant price	Subscription period	Share capital increase	Number of class B shares
TO2	employees	200,000	25.00	0.54	29 March 2017 - 30 March 2020	13,333.33	200,000
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	250,000	17.16	1.23	25 March 2021 - 25 August 2022	18,000.00	270,000
						56,333	**845,000**

Reclassification of shares

At the end of each quarter, class A shareholders are offered the opportunity of reclassifying their shares to B shares. No reclassification occurred on 31 December 2019. The company has registered share capital of SEK 1,571,558.13 allocated across 23,573,372 shares of which 7,251,200 are Class A shares and 16,322,172 are Class B shares. The quotient value is SEK 0.07 per share.

KPIs for the Group

SEK 000s	Q3 19/20	Q3 18/19	May-Jan 19/20	May-Jan 18/19	Full year 18/19
Net sales	55	288	1,671	1,269	3,005
Operating profit (loss)	-7,433	-5,780	-19,520	-15,346	-21,718
Profit (loss) for the period	-7,515	-6,045	-19,540	-15,636	-21,556
Capitalized R&D expenditure	2,032	1,713	5,401	4,565	6,464
Capitalized R&D exp., % of op. expenses	-20	-21	-20	-21	-22
Earnings per share, before and after dilution	-0.32	-0.34	-0.83	-0.89	-1.23
Cash and cash equivalents at the end of the period	51,623	24,203	51,623	24,203	16,831
Cash flow from operating activities	-8,131	-5,227	-15,271	-13,025	-17,967
Cash flow for the period	44,119	-7,065	-15,271	-17,924	-25,295
Equity	89,024	58,018	89,024	58,018	52,097
Equity per share	3.78	3.30	3.78	3.30	2.96
Equity ratio (%)	88	89	88	89	86
Average number of employees	16	17	17	17	16

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

Consolidated income statement and summary statement of comprehensive income

SEK 000s	Q3 19/20	Q3 18/19	May-Jan 19/20	May-Jan 18/19	May-April 18/19
Net sales	55	288	1,671	1,269	3,005
Other income	645	320	1,016	666	932
Work performed by the company and capitalized	2,032	1,713	5,401	4,565	6,464
Change in WIP inventory	–	174	–	101	43
	2,732	**2,495**	**8,087**	**6,600**	**10,444**
Materials cost	86	-122	-220	-637	-875
Other external costs	-4,564	-3,247	-10,433	-7,484	-11,962
Employee benefit expenses	-4,654	-4,051	-13,853	-11,554	-16,245
Depreciation/amortization	-1,033	-834	-3,101	-2,249	-3,020
Other expenses	–	-20	–	-22	-60
Operating profit (loss)	**-7,433**	**-5,780**	**-19,520**	**-15,346**	**-21,718**
Other interest income and similar profit or loss items	–	–	–	–	229
Interest expenses and similar items	27	-265	20	-291	-35
Profit (loss) before tax	**-7,406**	**-6,045**	**-19,499**	**-15,636**	**-21,524**
Tax expense	-109	–	-41		-32
Profit (loss) for the period	**-7,515**	**-6,045**	**-19,540**	**-15,636**	**-21,556**

Consolidated statement of comprehensive income					
Profit (loss) for the period	-7,515	-6,045	-19,540	-15,636	-21,556
Items that may be subsequently reclassified to profit and loss					
Exchange diff. foreign net invest.	–	–	–	–	–
Other comprehensive income for the period	–	–	–	–	–
Comprehensive income for the period	**-7,515**	**-6,045**	**-19,540**	**-15,636**	**-21,556**

Earnings per share					
Earnings per share, before dilution (SEK)	-0.32	-0.34	-0.83	-0.89	-1.23
Average number of shares, before dilution	23,573,372	17,573,370	23,573,372	17,573,372	17,573,372
Earnings per share, after dilution (SEK)	-0.32	-0.34	-0.83	-0.89	-1.23
Average number of shares, after dilution	24,418,372	17,968,332	24,418,372	17,968,332	18,343,372

Consolidated statement of financial position, in summary

SEK 000s	2020-01-31	2019-01-31	2019-04-30
ASSETS			
Intangible assets	41,601	36,577	37,907
Property, plant and equipment	5,047	2,542	2,917
Deferred tax asset	814	-13	0
Total fixed assets	**47,462**	**39,106**	**40,825**
Inventories	472	519	446
Accounts receivable	285	303	1,732
Current receivables	–	923	1,026
Cash and cash equivalents	51,623	24,203	16,831
Total current assets	**53,600**	**25,949**	**20,035**
TOTAL ASSETS	**101,062**	**65,055**	**60,859**
EQUITY			
Share capital	1,572	1,172	1,172
Other contributed capital	176,662	133,776	133,776
Retained earnings (losses), including loss for the year	-89,209	-76,930	-82,850
Total equity	**89,024**	**58,018**	**52,097**
LIABILITIES			
Deferred tax liability	786	–	–
Lease liability	2,250	–	–
Other non-current liabilities	357	571	940
Total non-current liabilities	**3,393**	**571**	**940**
Current liabilities	2,468	1,679	7,822
TOTAL EQUITY AND LIABILITIES	**101,062**	**65,055**	**60,859**

Consolidated statement of changes in equity, in summary

SEK 000s	Share capital	Other contributed capital	Retained earnings	Profit (loss) for the year	Total equity
Opening balance, 1 May 2018	**1,172**	**133,776**	**-43,225**	**-18,010**	**73,713**
Appropriation in accordance AGM decision			-18,010	18,010	–
Adjustment			-59		-59
Translation difference					–
Profit (loss) for the period				-21,556	-21,556
Closing balance, 30 April 2019	**1,172**	**133,776**	**-61,294**	**-21,556**	**52,097**
Appropriation in accordance AGM decision			-21,556	21,556	–
Adjustment			-215		-215
New share issue	400	56,282			56,682
Translation difference					0
Profit (loss) for the period				-19,541	-19,541
Closing balance, 31 January 2020	**1,572**	**190,057**	**-83,065**	**-19,541**	**89,025**

Consolidated statement of cash flows, in summary

SEK 000s	Q3 19/20	Q3 18/19	May-Jan 19/20	May-Jan 18/19	May-April 18/19
Cash flow from operating activities before changes in working capital	-5,674	-5,329	-16,313	-13,267	-17,788
Changes in working capital	1,492	102	1,041	242	-179
Cash flow from operating activities	**-4,181**	**-5,227**	**-15,271**	**-13,025**	**-17,967**
Cash flow from investing activities	**-2,503**	**-1,838**	**-5,401**	**-4,899**	**-7,329**
Cash flow from financing activities	-572	0	55,453	0	0
Cash flow for the period	**-7,257**	**-7,065**	**34,781**	**-17,924**	**-25,296**
Cash and cash equivalents at the beginning of the period	58,876	31,268	16,831	42,127	42,127
Translation difference, cash and cash equivalents	4	0	11	0	0
Cash and cash equivalents at the end of the period	51,623	24,203	51,623	24,203	16,831

Parent Company income statement, in summary

SEK 000s	Q3 19/20	Q3 18/19	May-Jan 19/20	May-Jan 18/19	May-April 18/19
Net sales	422	2,656	1,671	288	3,005
Change in WIP inventory	83	139	0	675	751
Work performed by the company and capitalized	3,390	4,941	5,401	1,713	6,464
Other operating income	641	387	772	-245	43
Sales	*4,535*	*8,123*	*7,844*	*2,431*	*10,263*
Goods for resale	-194	-793	-220	-122	-875
Other external costs	-8,829	-7,515	-12,888	-3,517	-12,638
Employee benefit expenses	-8,176	-10,224	-12,563	-3,916	-15,736
Depreciation/amortization	-1,422	-1,877	-2,132	-714	-2,840
Other operating expenses	0	-17	0	-20	-60
Operating expenses	*-18,621*	*-20,426*	*-27,804*	*-8,289*	*-32,149*
Operating profit (loss)	**-14,085**	**-12,303**	**-19,961**	**-5,858**	**-21,886**
Net financial income/expense	355	-87	162	-202	280
Profit (loss) before tax	**-13,731**	**-12,389**	**-19,798**	**-6,060**	**-21,606**
Income tax	0	0	0	0	0
Profit (loss) for the period	**-13,731**	**-12,389**	**-19,798**	**-6,060**	**-21,606**
Earnings per share					
Earnings per share, before dilution (SEK)	-0.26	-0.32	-0.83	-0.89	-1.23
Average number of shares, before dilution	23,573,372	17,573,372	23,573,372	17,573,372	17,573,372
Earnings per share, after dilution (SEK)	-0.26	-0.32	-0.83	-0.89	-1.23
Average number of shares, after dilution	24,418,372	17,968,372	24,418,372	17,968,372	18,143,372

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

Parent Company balance sheet, in summary

SEK 000s	2020-01-31	2019-01-31	2019-04-30
ASSETS			
Intangible assets	41,601	36,577	37,907
Machinery and equipment	1,375	1,906	1,801
Financial assets	1,235	160ss	300
TOTAL FIXED ASSETS	*44,211*	*38,643*	*40,008*
Inventories	472	519	446
Current receivables	1,556	2,148	3,738
Cash and bank	50,247	23,421	15,779
TOTAL CURRENT ASSETS	*52,275*	*26,088*	*19,963*
TOTAL ASSETS	**96,486**	**36,577**	**59,972**
EQUITY			
Total restricted equity	178,234	17,407	19,307
Total non-restricted equity	-89,344	40,552	32,699
TOTAL EQUITY	*88,890*	*57,959*	*52,005*
LIABILITIES			
Total non-current liabilities	0	100	–
Total current liabilities	7,596	6,672	7,966
TOTAL LIABILITIES	*7,596*	*6,772*	*7,966*
TOTAL EQUITY AND LIABILITIES	**96,486**	**64,731**	**59,972**

Uppsala, 12 March 2020

Board of Directors

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

Calendar

Interim Report for Q4: February – April 2020	12 June 2020
Annual Report	24-30 June 2020
Interim Report for Q1: May-July 2020	27 August 2020
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 2021

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Biovica – Best possible treatment from day one

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.