

Preparations for the launch of DiviTum®TKa

SEK 000s	Q4 20/21	Q4 19/20	May-April 20/21	May-April 19/20
Net sales	318	0	2,077	1,671
Operating profit (loss)	-12,169	-10,296	-40,181	-29,816
Profit (loss) for the period	-11,992	-10,777	-39,482	-30,318
Earnings per share, after dilution	-0.42	-0.46	-1.39	-1.24

Significant events during the fourth quarter

- The PROMIX breast cancer study at Karolinska University Hospital has been published in the scientific journal, ESMO Open.
- The DiviTum®TKa budget impact model shows potential for savings of three times the cost of DiviTum®TKa.
- Biovica strengthens its management team by appointing a new commercial manager and a new quality and regulatory manager.

Significant events after the end of the period

- Results presented for DiviTum®TKa showing its prognostic and predictive capabilities for patients with metastatic skin cancer who are undergoing immunotherapy.

Audiocast:

When: 18 June 2021 at 10.00 CET

Where: <https://tv.streamfabriken.com/biovica-international-q4-2020-2021>

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CEO's comments

For Biovica, the fourth quarter has been focused on activities to prepare for the upcoming launch of DiviTum®TKa in the US market. We are following our schedule for being able to launch DiviTum®TKa in the USA during the third quarter 2021 and utilizing the time prior to approval in the best way possible.

As part of that, we have grown the organization in both Sweden and the USA. The management team was strengthened with the addition of Helle Fisker as the new commercial manager and Joakim Arwidson as the new quality and regulatory manager. Their contribution and extensive experience will be a key factor for ensuring the success of our upcoming launch. Besides their recruitment, the addition of our new Scientific Director, Amy Williams, working from our office in Boston, was also very important.

One of the most essential cornerstones of a successful commercialization of DiviTum®TKa in the USA is reimbursement from payers. And for that to happen, we need to ensure that both oncologists and payers are informed about its value. With that in mind, we have created economic models based on the excellent clinical results of DiviTum®TKa, thereby generating data on the social benefits through cost savings of using the assay.

Subsequent to the end of the quarter, we presented the results from one such budget impact model at the leading health economics and outcomes research conference, ISPOR. The benefits from including DiviTum®TKa when monitoring hormone receptor positive metastatic breast cancer would primarily come from a reduction in futile therapy costs and other monitoring costs. The model shows that there are potential savings of up to three times the cost of DiviTum®TKa. These are very strong results, particularly since new healthcare interventions tend to add to the total cost of care.

One of Biovica's strengths is the amount of positive results from clinical trials using the assay. At the ASCO annual meeting during 4-8 June 2021, results from a new study at Karolinska University Hospital were presented. They show the prognostic and predictive capabilities of DiviTum®TKa for metastatic cutaneous melanoma patients

undergoing immunotherapy. Metastatic skin cancer (malignant melanoma) is an aggressive form of cancer. Patients are treated with expensive immunotherapy, in the order of around USD 30,000 per patient/month, and they may experience serious side effects. For patients who respond well however, the treatment can make an enormous difference. There is a great need for better biomarkers in this area, which is why the results are so promising.

The results provide another strong indication that DiviTum®TKa has great potential beyond our initial area of metastatic breast cancer.

Our application is one of the few that the FDA resumed its review of, already back in January. Because of that, we are sticking to our goal and remain confident that we will obtain 510(k) approval for DiviTum®TKa during the third quarter of 2021, even though the FDA 510 (k) reviews for IVD products in general have been significantly delayed.

Major cancer institutes are already important partners in our study collaborations and they could later become important commercial partners to us as well. In preparation for the launch in the USA, we have been having discussions with several oncology labs. Each of them has a sales force that could offer DiviTum®TKa as a service to their customers. Our intention is to enter into an agreement with a commercial partner after we obtain 510(k) approval during the third quarter.

Fourth quarter sales of SEK 318 thousand are derived from two new customers. It is both encouraging and satisfying that we are adding new pharmaceutical companies as customers and that they are using DiviTum®TKa when developing new, promising cancer drugs.

All of this activity during the quarter brings us one step closer to realizing our vision of helping doctors arrive at treatment decisions with greater certainty. It means that we can make a difference in giving cancer patients a longer life with better life quality. We are looking forward to the upcoming commercialization and soon being able to make a meaningful difference for patients with metastatic breast cancer. A successful launch in the USA for

use of DiviTum®TKa in treating metastatic breast cancer is the first step towards realizing the product's full potential. In summary, it has been an intensive quarter and year for Biovica. I'm excited and optimistic about the remainder of 2021 and all it holds.



Anders Rylander, CEO

Significant events during the period

DiviTum®TKa predicts long-term outcomes

The PROMIX breast cancer study at Karolinska University Hospital has been published in the scientific journal, ESMO Open. The study showed that testing for TKa levels during early treatment is prognostic for the long-term outcome of preoperative chemotherapy.

The results demonstrate that serial measurements of TKa during the preoperative chemotherapy treatment period provides long-term prognostic information on Event Free Survival (EFS) and Overall Survival (OS). A high increase in TKa after two cycles of chemotherapy resulted in improved EFS and OS. Hence, testing for TKa levels during early treatment will predict the long-term outcome of chemotherapy provided before surgery. The study also showed a significant interaction between the prognostic value of TKa and Ki67. This supports the use of DiviTum®TKa as a blood-based alternative to the tissue-based Ki67 biomarker when assessing breast tumor cell growth.

The DiviTum®TKa budget impact model shows potential for savings in the cost of care

A DiviTum®TKa budget impact model for calculating the potential savings in the cost of care was developed and presented at ISPOR 2021 in May. It shows that there are potential savings of up to three times the cost of DiviTum®TKa.

The benefits from including DiviTum®TKa when monitoring hormone receptor positive metastatic breast cancer would primarily come from a reduction in futile therapy costs and other monitoring costs, such as imaging diagnostics.

"New healthcare interventions often add to the total cost of care. We set out to understand if adding a new blood-based test could actually translate to savings in cost of care. In this context the model indicates that inclusion of DiviTum®TKa seems to be a positive exception and should deliver savings," says Scott D. Ramsey from the Fred Hutchison Cancer Research Center.

Biovica strengthens its management team

Biovica strengthened its management team with the addition of Helle Fisker as the new commercial manager and Joakim Arwidson as the new quality and regulatory manager.

Helle Fisker has more than 25 years of experience in commercializing both diagnostics and pharmaceuticals in oncology and other areas. In total, Helle has been involved in launching over 30 treatments and vaccines, and more than 350 medical products worldwide.

Joakim Arwidson has more than 25 years of experience in life science with experience in quality and regulatory affairs from development, production, market introduction and market follow-up in North America, Europe and Asia. Joakim has completed 14 successful 510(k) processes in oncology and theranostics (combining treatment and diagnosis of tumors).

Significant events after the end of the period

DiviTum®TKa part of a study on malignant melanoma

Results reveal that DiviTum®TKa has prognostic and predictive capabilities for patients with metastatic skin cancer undergoing immunotherapy. These results from a new study at Karolinska University Hospital were presented at the ASCO annual meeting during 4-8 June 2021.

Other

2021 AGM

Biovica's Annual General Meeting will be held on 31 August 2021 at 1 p.m. at the company's office, Dag Hammarskjölds väg 38 in Uppsala, Sweden. Notice of the AGM will be 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.

Comments on the financial performance of the Group

Q4 - Sales and earnings

Net sales for the period amounted to SEK 318 (0) thousand. Fourth quarter sales are derived from two new customers. It is both encouraging and satisfying that we are adding new pharmaceutical companies as customers and that they are using DiviTum®TKa when developing new cancer drugs.

Capitalized work performed by the company for its own use amounts to SEK 636 (1,634) thousand. The capitalized amount pertains to expenditure associated with developing a new version of DiviTum®TKa for measuring thymidine kinase (TK).

The operating loss for the period was SEK -12,169 (-10,296) thousand.

The increase in costs compared to last year is attributable preparations for the commercialization of DiviTum®TKa.

Net financial items amounted to SEK 258 (-463) thousand. Loss after financial items was SEK -11,991 (-10,777) thousand. Loss for the period was SEK -11,992 (-10,777) thousand.

As of 30 April 2021, the company had 20 (17) employees, of which 9 (8) are women.

Full year - Sales and earnings

Net sales for the period amounted to SEK 2,077 (1,671) thousand. Sales are solely to customers in the research market.

Capitalized work performed by the company for its own use amounts to SEK 3,560 (7,035) thousand. The capitalized amount pertains to expenditure associated with developing DiviTum®TKa for measuring thymidine kinase (TK). Capitalized expenditure is lower this year since further development of DiviTum®TKa has been completed and we have sold the first Research Use Only (ROU) kit of the new version developed for the FDA application. Capitalization of costs now continues for our next project.

Operating expenses amount to SEK -49,059 (-39,737) thousand. During the year, several activities have been underway to prepare for the upcoming

launch of DiviTum®TKa. It is in line with what has been planned for (slightly lower, in fact).

The operating loss for the period was SEK -40,181 (-29,816) thousand.

Net financial items amounted to SEK 795 (-443) thousand. Loss after financial items was SEK -39,386 (-30,259) thousand. Loss for the period was SEK -39,483 (-30,318) thousand.

As of 30 April 2021, the company had 20 (17) employees, of which 9 (8) are women.

Financial position, cash flow and investments

The closing amount for cash & cash equivalents on 30 April 2021 was SEK 145,364 (40,777) thousand. During the year, SEK 148 million in capital was raised, prior to issues costs. Investments will need to be made over the next few years in order to ensure successful commercialization in the USA and Europe. The current amount of capital secured is sufficient for more than two years of operation.

Capitalized expenditure for development work during the period amounts to SEK 3,560 (7,035) thousand.

Net investments in property, plant and equipment in the form of equipment for the year amounted to SEK 0 (0) thousand.

Funding

The closing amount for cash & cash equivalents on 30 April 2021 was SEK 145,364 (40,777) thousand. Biovica has secured an ample amount of capital for commercialization in the USA and Europe. It is estimated that the current level of capital is sufficient for more than two years of operations, without factoring in the expected increase in sales.

Related party transactions

During the period, 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 198 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
TO4	Board of Directors	150,000	19.50	0.94	25 March 2022 - 25 August 2023	10,000.00	150,000
TO5	employees	170,000	17.16	1.23	25 March 2021 - 25 August 2022	11,333.33	170,000
TO6	employees	173,000	45.14	3.31	25 March 2022 - 25 August 2023	11,533.33	173,000
TO7	Board of Directors	200,000	45.14	3.31	25 March 2022 - 25 August 2023	13,333.33	200,000
						46,200.00	693,000

Shares

As of 30 April 2021, the number of outstanding shares in Biovica was 28,418,372, of which 6,542,860 shares are Class A and 21,875,512 shares are Class B. The total number of votes amounts to 41,504,092.

Reclassification of shares

At the end of each quarter, class A shareholders are offered the opportunity of reclassifying their shares to B shares. Reclassification from Class A to Class B shares lowers the voting power, in that Class A shares carry three votes each and Class B shares carry one vote each. The Class A shares are unlisted, while Biovica's Class B shares are traded on Nasdaq First North Premier Growth Market, Stockholm. A total of 80,310 shares were reclassified on 31 March 2021.

2021-03-31	Class A shares	Class B shares	Total
Before reclassification	6,623,170	21,795,202	28,418,372
Reclassification	-80,310	80,310	0
After reclassification	6,542,860	21,875,512	28,418,372

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 2019/2020.

New standards and interpretations that enter into force in 2020 and later

As of the date when these financial statements were approved for release, no new standards, revisions or interpretations of existing standards that have not yet entered into force or been published by IASB have been early-adopted by the Group.

Significant risks and uncertainties

There are a number of risks and uncertainties associated with the company's operations, including market, regulatory and financial risks. For a more detailed description of the risks (in Swedish), please see the Annual Report for 2019/2020. There was one COVID-19 risk that materialized during the period, more information on that is provided below. Other risks have not changed compared to what is described in the Annual Report.

COVID-19

There was one COVID-19 risk that materialized during the period. Review of the company's FDA application was delayed by one quarter due to the FDA having reallocated resources to Emergency Use Authorization (EUA) requests for in vitro diagnostics (IVDs) to address COVID-19. Although the FDA has once again resumed its review, there is still a risk that the process could take longer than the customary 90 days.

KPIs for the Group

SEK 000s	Full year 20/21	Full year 19/20	Full year 18/19	Full year 17/18
Net sales	2,077	1,671	3,005	2,723
Operating profit (loss)	-40,181	-29,816	-21,718	-17,956
Profit (loss) for the period	-39,483	-30,318	-21,556	-18,010
Capitalized R&D costs	3,560	7,035	6,464	6,596
Capitalized R&D exp., % of op. expenses	-8%	-18%	-22%	-26%
Earnings per share, before dilution	-1.39	-1.29	-1.23	-1.02
Earnings per share, after dilution	-1.36	-1.29	-1.23	-1.02
Cash and cash equivalents at the end of the period	145,364	40,777	16,831	42,127
Cash flow from operating activities	-34,409	-24,780	-17,966	-14,882
Cash flow for the period	104,692	23,927	-25,295	-23,342
Equity	182,661	78,217	52,097	73,713
Equity per share	6.43	3.32	2.96	4.19
Equity ratio (%)	95%	87%	86%	91%
Average number of employees	20	17	16	14

Definitions are the same as those presented in the Annual Report for 2019/2020.

Alternative key performance indicators

Of the KPIs presented above, the only one that is obligatory to report, and which is defined in accordance with IFRS is: Earnings per share, before and after dilution. For the other KPIs, the following are in accordance with IFRS presentation requirements: Profit (loss) for the year, Cash & cash equivalents at the end of the period, Cash flow for the period and Equity.

KPIs	Definition	Reason for using alternative KPIs, which are not defined in accordance with IFRS.
Net sales	Income from goods sold	Shows the demand for the product.
Operating profit (loss)	Profit (loss) before financial items and tax.	Operating profit (loss) is an indication of the company's earnings generated from ordinary operations.
Earnings per share, before and after dilution	Profit (loss) divided by the weighted average number of shares during the period, before and after dilution.	
Cash & cash equivalents and short-term investments	Bank balances and short-term investments	
Cash flow from operating activities	Cash flow before the cash flow from investing activities and financing activities	
Cash flow for the period	Change in cash & cash equivalents for the period not including the effect from unrealized exchange gains and losses.	
Equity per share	Equity divided by the number of shares at the end of the period.	Management uses this KPI to monitor the value of equity per share.
Equity ratio	Equity as a percentage of total assets.	Management uses this KPI because it provides an indication of the company's financial stability.
Average number of employees	The average number of employees is calculated as the average of worked hours during the period divided by normal working hours for the period.	

Consolidated income statement and summary statement of comprehensive income

	Q4 2020/2021	Q4 2019/2020	May-April 2020/2021	May-April 2019/2020
Amount in SEK thousands				
Net sales	318	0	2,077	1,671
Other income	187	200	3,241	1,215
Work performed by the company and capitalized	636	1,634	3,560	7,035
Change in WIP inventory	0	0		0
Operating income	1,141	1,834	8,878	9,921
Materials cost	-133	0	-367	-220
Other external costs	-4,278	-4,953	-15,332	-15,386
Employee benefit expenses	-7,189	-6,021	-27,218	-19,874
Depreciation/amortization	-1,709	-1,070	-6,142	-4,170
Other operating expenses	-1	-86	0	-86
Operating expenses				
Operating profit (loss)	-12,169	-10,296	-40,181	-29,816
Financial income	271	0	855	0
Financial expenses	-13	-463	-60	-443
Profit (loss) before tax	-11,911	-10,760	-39,386	-30,259
Income tax	-80	-17	-96	-59
Profit (loss) for the period	-11,992	-10,777	-39,482	-30,318
Consolidated statement of comprehensive income				
Profit (loss) for the period	-11,992	-10,777	-39,482	-30,318
Exchange diff. foreign net invest.	0	0	0	0
Other comprehensive income for the period	0	0	0	0
Comprehensive income for the period	-11,992	-10,777	-39,482	-30,318
Earnings per share				
Earnings per share, before dilution (SEK)	-0.42	-0.46	-1.39	-1.29
	28,418,37	23,573,37	28,418,37	23,573,37
Average number of shares, before dilution	2	2	2	2
Earnings per share, after dilution (SEK)	-0.42	-0.46	-1.39	-1.29
	29,111,37	24,418,37	29,111,37	24,218,37
Average number of shares, after dilution	2	2	2	2

Consolidated statement of financial position, in summary

Amount in SEK thousands	2021-04-30	2020-04-30
ASSETS		
Intangible assets	41,869	42,666
Machinery, equipment, tools, fixtures and fittings	704	1,234
Right-of-use assets	2,312	3,313
Deferred tax asset	499	743
Total fixed assets	45,384	47,955
Inventories	527	397
Accounts receivable	222	0
Current receivables	1,153	1,129
Cash and cash equivalents	145,364	40,777
Total current assets	147,266	42,303
TOTAL ASSETS	192,650	90,259
EQUITY		
Share capital	1,895	1,572
Other contributed capital	338,758	195,133
Retained earnings (losses), including loss for the year	-157,992	-118,487
Total equity	182,661	78,217
LIABILITIES		
Right-of-use liabilities	934	2,272
Deferred tax liability	460	709
Other non-current liabilities	0	0
Total non-current liabilities	1,394	2,981
Right-of-use liabilities	1,486	1,182
Advance payments from customers	1,213	3,521
Accounts payable	1,085	1,007
Current tax liabilities	154	500
Other liabilities	634	624
Accrued expenses and deferred income	4,023	2,228
Current liabilities	8,595	9,061
TOTAL EQUITY AND LIABILITIES	192,650	90,259

Consolidated statement of changes in equity, in summary

Amount in SEK thousands	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		5,074		-5,074		0
Adjustment due to change in accounting policy				-246		-246
Translation difference			2			2
New share issue	400	53,249				53,649
Issue costs		-3,033				-3,033
Profit (loss) for the period					-30,318	-30,318
Closing balance, 30 April 2020	1,572	195,132	2	-88,171	-30,318	78,217
Opening balance, 1 May 2020	1,572	195,132	2	-88,171	-30,318	78,217
Appropriation in accordance AGM decision				-30,318	30,318	0
New share issue	313	147,737				148,050
Issue costs		-7,151				-7,151
Warrants scheme	10	3,040				3,050
Translation difference			-22			-22
Profit (loss) for the period					-39,482	-39,482
Closing balance, 30 April 2021	1,895	338,758	-20	-118,489	-39,482	182,661

Consolidated statement of cash flows, in summary

Amount in SEK thousands	Q4 20/21	Q4 19/20	May-April 20/21	May-April 19/20
Cash flow from operating activities before changes in working capital	-10,261	-10,060	-33,545	-26,587
Changes in working capital	1,278	765	-866	1,807
Cash flow from operating activities	-8,984	-9,295	-34,409	-24,780
<i>Investing activities</i>				
Cash flow from investing activities	-636	-1,634	-3,560	-7,035
Cash flow from financing activities	-291	74	142,661	55,742
Cash flow for the period	-9,910	-10,855	104,692	23,927
Cash and cash equivalents at the beginning of the period	155,266	51,623	40,777	16,831

Translation difference, cash and cash equivalents	9	9	-105	19
Cash and cash equivalents at the end of the period	145,364	40,777	145,364	40,777

Parent Company income statement, in summary

	Q4 2020/2021	Q4 2019/2020	May-April 2020/2021	May-April 2019/2020
Amount in SEK thousands				
Net sales	318	0	2,077	1,671
Change in WIP inventory	0	200	0	972
Work performed by the company and capitalized	636	1,634	3,560	7,035
Other operating income	121	0	2,071	0
Sales	1,074	1,834	7,708	9,677
Goods for resale	-133	0	-367	-220
Other external costs	-6,531	-6,103	-22,119	-18,991
Employee benefit expenses	-5,471	-5,286	-22,243	-17,849
Depreciation/amortization	-1,388	-710	-4,887	-2,843
Other expenses	0	-86	0	-86
Operating expenses	-13,523	-12,185	-49,615	-39,990
Operating profit (loss)	-12,449	-10,351	-41,907	-30,312
Net financial income/expense	106	-422	758	-259
Profit (loss) before tax	-12,343	-10,773	-41,150	-30,571
Appropriations	0	0	1,146	0
Tax on profit for the year	0	0	0	0
Profit (loss) for the period	-12,343	-10,773	-40,004	-30,571
Earnings per share				
Earnings per share, before dilution (SEK)	-0.43	-0.44	-1.41	-1.30
Average number of shares, before dilution	28,418,372	23,573,372	28,418,372	23,573,372
Earnings per share, after dilution (SEK)	-0.43	-0.44	-1.41	-1.30
Average number of shares, after dilution	29,111,372	24,418,372	29,111,372	24,418,372

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

Parent Company balance sheet, in summary

Amount in SEK thousands	2021-04-30	2020-04-30
ASSETS		
Intangible assets	41,869	42,666
Machinery, equipment, tools, fixtures and fittings	704	1,234
Financial assets	2,217	1,248
Total fixed assets	44,790	45,148
Inventories	527	397
Current receivables	1,511	1,105
Cash and cash equivalents	142,920	39,642
Total current assets	144,958	41,144
TOTAL ASSETS	189,748	86,292
EQUITY		
Total restricted equity	28,543	26,741
Total non-restricted equity	153,519	51,375
Total EQUITY	182,061	78,117
LIABILITIES		
Total current liabilities	7,686	8,176
Total LIABILITIES	7,686	8,176
TOTAL EQUITY AND LIABILITIES	189,748	86,292

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

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, 17 June 2021

Board of Directors

Calendar

Annual report	30 June 2021
AGM	31 August 2021
Interim Report for Q1: May-July 2021/ 2022	31 August 2021
Interim Report for Q2: August-October 2021/ 2022	1 December 2021
Interim Report for Q3: November-January 2021/ 2022	15 March 2022
Interim Report for Q4: May-July 2021/ 2022	16 June 2022

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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®TKa 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®TKa is evaluation of the treatment effect on 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®TKa 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.