

DiviTum®TKa approaching FDA approval

SEK 000s	Q1 21/22	Q1 20/21	May-April 20/21
Net sales	381	340	2,077
Operating profit (loss)	-12,238	-8,665	-40,181
Profit (loss) for the period	-12,225	-8,374	-39,482
Earnings per share, after dilution	-0.43	-0.36	-1.39

Significant events during the first 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.
- Biovica has strengthened its management team with the addition of Warren Cresswell, President Americas, with responsibility for the launch of DiviTum®TKa in the USA.

Audiocast:

When: 2 September 2021 at 10:00 AM CET

Where: <https://tv.streamfabriken.com/biovica-international-q1-2021-2022>

Phone numbers: SE: +46850558365, DK: +4578150108, UK: +443333009262, US: +16467224902

Broadcast language: in English

CEO's comments

During the first quarter, our focus has been on concluding the 510(k) process with the FDA. We had several meetings with the FDA and completed a SIR process (Submission Issue Request), which provided us with valuable feedback on how we should supplement our application with additional information.

Based on that, we were able to address all the areas where the FDA has requested additional information. We will be submitting that supplemental documentation at the beginning of September and, with normal processing time from the FDA, we should receive a response from them also during the month of September. The possible outcomes of that are, either approval (clearance), or a request to submit more information.

In preparation for our launch in the USA, we have grown the commercial part of the organization in both Sweden and the USA. Our latest recruitment is Warren Cresswell as President Americas. He has 25 years of experience in the diagnostics industry, bringing with him an extensive network and experience for building up and leading successful commercial organizations.

One of the most essential cornerstones of a successful commercialization of DiviTum®TKa in the USA is reimbursement from payers. Warren's experience in this area is an important puzzle piece for this effort. With Warren at the helm in the USA, I am convinced that we will succeed with our launch and inclusion in the reimbursement system. Please read more about Warren's background on page 3.

One of Biovica's strengths is all of the positive results from clinical trials using the assay. At the ASCO annual meeting during 4-8 June 2021, results from a new study in a new area were presented. The study was carried out by Karolinska University Hospital and it is significant to us in that it serves as Proof of Concept in a new, important area. They show the prognostic and predictive capabilities of DiviTum®TKa for metastatic cutaneous melanoma patients undergoing immunotherapy. There is a

large need in this area for better biomarkers, which is why the results are so promising, providing an additional strong indication that DiviTum®TKa has great potential beyond our first indication of metastatic breast cancer as well as immunotherapy.

Simultaneous with commercialization of DiviTum®TKa for metastatic breast cancer, Biovica will be working with additional regulatory approval for use of the assay with other indications than metastatic breast cancer, which is called intended use extension. Our belief is that, in the future, wide clinical use of DiviTum®TKa will be possible for a number of commonly occurring types of cancer.

At the company's capital market day in May, we presented our plan for the areas where we intend to expand beyond that of breast cancer. The three areas we will first focus on are metastatic cancer in the areas of malignant melanoma, prostate cancer and lung cancer. These three areas more than double the already large market potential for our product.

We are looking forward to the upcoming commercialization and soon being able to make a meaningful difference for patients with metastatic breast cancer. We are excited and optimistic about the remainder of 2021 and all it holds.



Anders Rylander, CEO

Significant events during the period

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.

Strengthening of the management group

Warren Cresswell has been appointed President Americas and will join the executive management team as of 1 August. He has worked in leading positions for the last 17 years at the Danish diagnostics company, Dako. After that, he worked for 5 years at Prometheus Laboratories, 3 of which were in the role of CEO. It is a start-up diagnostics company that was acquired by Nestlé Health Science. Warren will be able to contribute vast experience in building up and leading commercially successful organizations. Given his 25 years in the diagnostics industry, he also brings with him a comprehensive network and valuable knowledge of the US market in the area of oncology.



2021 AGM

Biovica's Annual General Meeting will be held on 31 August 2021 via postal voting.

Comments on the financial performance of the Group

Q1 - Sales and earnings

Net sales for the period amounted to SEK 381 (340) thousand. First quarter sales are attributable to customers in the research market.

Capitalized work performed by the company for its own use amounts to SEK 883 (1,659) 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 -12,238 (-8,665) thousand.

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

Net financial items amounted to SEK 12 (290) thousand. Loss after financial items was SEK -12,226 (-8,376) thousand. Loss for the period was SEK -12,225 (-8,374) thousand.

As of 31 July 2021, the company had 23 (21) employees, of which 11 (8) are women.

Financial position, cash flow and investments

The closing amount for cash & cash equivalents on 31 July 2021 was SEK 130,927 (31,394) 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 two years of operation.

Capitalized expenditure for development work during the period amounts to SEK 883 (1,659) 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 31 July 2021 was SEK 130,927 (31,394) 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 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 49 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 31 July 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. No reclassification occurred on 30 June 2021.

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. The review has been ongoing since the end of January, taking more than 90 days to obtain the first feedback.

KPIs for the Group

SEK 000s	Q1 21/22	Q1 20/21	Full year 20/21	Full year 19/20	Full year 18/19	Full year 17/18
Net sales	381	340	2,077	1,671	3,005	2,723
				-	-	-
Operating profit (loss)	-12,238	-8,665	-40,181	29,816	21,718	17,956
				-	-	-
Profit (loss) for the period	-12,225	-8,374	-39,482	30,318	21,556	18,010
Capitalized R&D costs	883	1,659	3,560	7,035	6,464	6,596
Capitalized R&D exp., % of op. expenses	-7%	-15%	-8%	-18%	-22%	-26%
Earnings per share, before dilution	-0.43	-0.36	-1.39	-1.29	-1.23	-1.02
Earnings per share, after dilution	-0.43	-0.36	-1.39	-1.29	-1.23	-1.02
Cash and cash equivalents at the end of the period	130,92	31,39	145,36			
	7	4	4	40,777	16,831	42,127
				-	-	-
Cash flow from operating activities	-13,263	-7,363	-34,411	24,780	17,966	14,882
			104,69		-	-
Cash flow for the period	-14,451	-9,328	0	23,927	25,295	23,342
	170,45	69,83	182,66			
Equity	2	5	1	78,217	52,097	73,713
Equity per share	6.00	2.96	6.43	3.32	2.96	4.19
Equity ratio (%)	96%	86%	95%	87%	86%	91%
Average number of employees	23	21	20	17	16	14

Definitions are the same as those presented in the Annual Report for 2020/2021.

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

	Q1 2021/2022	Q1 2020/2021	Full year 2020/2021
Amount in SEK thousands			
Net sales	381	340	2,077
Other income	69	80	3,241
Work performed by the company and capitalized	883	1,659	3,560
Operating income	1,333	2,078	8,878
Materials cost	-96	-51	-367
Other external costs	-5,129	-3,968	-15,332
Employee benefit expenses	-6,784	-5,701	-27,218
Depreciation/amortization	-1,563	-1,023	-6,142
Operating expenses	-13,572	-10,744	-49,059
Operating profit (loss)	-12,238	-8,665	-40,181
Financial income	23	0	855
Financial expenses	-11	290	-60
Profit (loss) before tax	-12,226	-8,376	-39,386
Income tax	1	2	-96
Profit (loss) for the period	-12,225	-8,374	-39,482
Consolidated statement of comprehensive income			
Profit (loss) for the period	-12,225	-8,374	-39,482
Exchange diff. foreign net invest.	0	0	0
Other comprehensive income for the period	0	0	0
Comprehensive income for the period	-12,225	-8,374	-39,482
Earnings per share			
Earnings per share, before dilution (SEK)	-0.43	-0.36	-1.39
Average number of shares, before dilution	28,418,372	23,573,372	28,418,372
Earnings per share, after dilution (SEK)	-0.43	-0.36	-1.39
Average number of shares, after dilution	29,111,372	24,418,372	29,111,372

Consolidated statement of financial position, in summary

Amount in SEK thousands	2021-07-31	2020-07-31
ASSETS		
Intangible assets	41,626	43,756
Machinery, equipment, tools, fixtures and fittings	579	1,095
Right-of-use assets	1,867	2,997
Deferred tax asset	407	677
Total fixed assets	44,479	48,525
Inventories	452	547
Accounts receivable	479	365
Current receivables	1,616	159
Cash and cash equivalents	130,927	31,394
Total current assets	133,474	32,464
TOTAL ASSETS	177,953	80,989
EQUITY		
Share capital	1,895	1,572
Other contributed capital	338,758	195,133
Retained earnings (losses), including loss for the year	-170,201	-126,870
Total equity	170,452	69,835
LIABILITIES		
Right-of-use liabilities	687	1,716
Deferred tax liability	368	641
Total non-current liabilities	1,055	2,358
Right-of-use liabilities	1,295	1,431
Advance payments from customers	1,216	3,537
Accounts payable	929	229
Current tax liabilities	53	145
Other liabilities	692	806
Accrued expenses and deferred income	2,262	2,650
Current liabilities	6,446	8,797
TOTAL EQUITY AND LIABILITIES	177,953	80,989

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 2020	1,572	195,132	2	-88,171	-30,318	78,217
Appropriation in accordance AGM decision				-30,318	30,318	0
Adjustment due to change in accounting policy						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
Opening balance, 1 May 2021	1,895	338,758	-20	-118,489	-39,482	182,661
Appropriation in accordance AGM decision				-39,483	39,483	0
Translation difference			25	-10		16
Profit (loss) for the period					-12,225	-12,225
Closing balance, 31 July 2021	1,895	338,758	5	-157,981	-12,224	170,452

Consolidated statement of cash flows, in summary

Amount in SEK thousands	Q1 21/22	Q1 20/21	May-April 20/21	May-April 19/20
Cash flow from operating activities before changes in working capital	-10,777	-7,587	-33,545	-26,587
Changes in working capital	-2,486	224	-866	1,807
Cash flow from operating activities	-13,263	-7,363	-34,411	-24,780
Cash flow from investing activities	-883	-1,659	-3,560	-7,035
Cash flow from financing activities	-304	-306	142,661	55,742
Cash flow for the period	-14,451	-9,328	104,690	23,927
Cash and cash equivalents at the beginning of the period	145,364	40,777	40,777	16,831

Translation difference, cash and cash equivalents	14	-54	-105	19
Cash and cash equivalents at the end of the period	130,927	31,394	145,362	40,777

Parent Company income statement, in summary

	Q1 2021/2022	Q1 2020/2021	Full year 2020/2021
Amount in SEK thousands			
Net sales	381	340	2,077
Work performed by the company and capitalized	883	1,659	3,560
Other operating income	69	80	2,071
<i>Sales</i>	1,333	2,078	7,708
Goods for resale	-96	106	-367
Other external costs	-6,873	-6,504	-22,119
Employee benefit expenses	-5,457	-3,738	-22,243
Depreciation/amortization	-1,251	-707	-4,887
Other expenses	0	0	0
<i>Operating expenses</i>	-13,677	-10,844	-49,615
Operating profit (loss)	-12,344	-8,765	-41,907
Net financial income/expense	44	330	758
Profit (loss) before tax	-12,300	-8,435	-41,150
Appropriations	0	0	1,146
Tax on profit for the year	0	0	0
Profit (loss) for the period	-12,300	-8,435	-40,004
Earnings per share			
Earnings per share, before dilution (SEK)	-0.43	-0.36	-1.41
Average number of shares, before dilution	28,418,372	23,573,372	28,418,372
Earnings per share, after dilution (SEK)	-0.43	-0.36	-1.41
Average number of shares, after dilution	29,111,372	24,418,372	29,111,372

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

Parent Company balance sheet, in summary

Amount in SEK thousands	2021-07-31	2020-07-31	2021-04-30
ASSETS			
Intangible assets	41,626	43,756	41,869
Machinery, equipment, tools, fixtures and fittings	579	1,095	704
Financial assets	2,235	1,139	2,217
Total fixed assets	44,440	45,990	44,790
Inventories	452	547	527
Current receivables	1,984	1,306	1,511
Cash and cash equivalents	128,823	30,617	142,920
Total current assets	131,259	32,470	144,958
TOTAL ASSETS	175,700	78,460	189,748
EQUITY			
Total restricted equity	29,105	196,704	29,105
Total non-restricted equity	140,657	-127,023	152,956
Total EQUITY	169,762	69,682	182,061
LIABILITIES			
Total non-current liabilities	0	0	0
Total current liabilities	5,938	8,778	7,686
Total LIABILITIES	5,938	8,778	7,686
TOTAL EQUITY AND LIABILITIES	175,700	78,460	189,748

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, 31 August 2021

Board of Directors

Calendar

AGM	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

For more information, please contact:

Anders Rylander, CEO

Phone: +46 (0)18- 44 44 835

E-mail: anders.rylander@biovica.com

Cecilia Driving, EVP CFO

Phone +46 (0)73 125 92 47

E-mail: cecilia.driving@biovica.com

Biovica International AB (publ), 556774-6150

Dag Hammarskjölds väg 54B

752 37 Uppsala

+46 (0)18- 44 44 830

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.