Q1 Interim report May-July 2022/2023

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DiviTum®TKa approved for launch in the US

SEK t	Q1 22/23	Q1 21/22	May-April 21/22
Net sales	545	381	2,045
Operating profit (loss)	-20,662	-12,238	-60,101
Profit (loss) for the period	-21,004	-12,225	-60,003
Earnings per share, after dilution	-0.74	-0.43	-2.11

Significant events during the first quarter

• Results with DiviTum®TKa at ASCO

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- DiviTum®TKa highlighted at ASCO in an oral presentation
- Biovica's CFO will terminate employment in December 2022
- FDA clearance for DiviTum®TKa

Significant events after the end of the period

• No events after the end of the period

CEO's comments

During the quarter, we reached one of the most important milestones in Biovica's history when the US Food and Drug Administration (FDA) granted market approval for our assay, DiviTum®TKa, as a tool for monitoring disease progression in post-menopausal women with hormone receptor positive metastatic breast cancer.

DiviTum®TKa is the first FDA approved biomarker in this area. The approval allows us to market the assay in the USA and it is thus crucial to realizing its commercial potential. Our focus now is on making the assay available to breast cancer patients in the USA before the end of the year, which will be hugely beneficial to both patients and caregivers.

Clearance was based on a number of factors, such as data showing that DiviTum®TKa has excellent capabilities to identify non progressors with high negative predictive values, NPV. For progression within 30 days, the NPV is 96.7%. This means that 96.7% of patients with DiviTum®TKa measurements below the assay clinical cutoff, did not experience disease progression within the next 30 days.

It is certainly valuable for both patients and the treating physicians to obtain this information on a monthly basis and be able to then act upon it appropriately. This has also been confirmed by the advisory boards of patient groups and oncologists that we have interacted with.

We are preparing for the upcoming launch in many ways, part of which is the comprehensive effort of obtaining CLIA certification for our wholly owned laboratory in San Diego. It will serve all of the USA and our aim is to obtain the certification for the lab sometime during this quarter. Having our own laboratory offers us greater opportunities for being able to establish a price for DiviTum®TKa that reflects the significant benefits it can offer to both payers and patients.

It also means that we can have direct contact with both customers and payers, which will provide us with valuable feedback and facilitate a smoother commercialization of the assay. Additionally, with our own CLIA lab, we will be able to efficiently manage the reimbursement process, which is a significant advantage. We will be actively working with payers to ensure that the test gets included in guidelines.

We are also building up our organization and processes in preparation for the launch so that we can get sales up and running as soon as possible. We have set up several important commercial functions and will be hiring sales staff who are specialized in oncology diagnostics. They will both train and inform healthcare professionals so that they understand the substantial benefits associated with DiviTum®TKa, which will then generate sales of the product.

Biovica has several collaboration agreements in place with pharmaceutical companies that use DiviTum®TKa in the development of new drugs. Our goal is to develop these collaborations further and the 510(k) clearance will help pave the way for achieving that goal.

FDA approval is an extremely important milestone for making the assay available to the US market. I would like to extend a huge thanks to our competent team that has worked so hard to reach this milestone.

I am very much looking forward to the launch of DiviTum®TKa so that it can benefit patients, caregivers and also create value for our shareholders!



Anders Rylander, CEO

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Significant events during the period

Biovica's DiviTum®TKa presented at ASCO

Results from the BioltaLEE study, an Italian multicenter study of metastatic breast cancer, CDK4/6inhibitors, in 287 patients, DiviTum®TKa and ctDNA. The presentation was held on 6 June at the main hall, Clinical Science Symposium at 6.18 PM local time (which was at 12.18 AM on 7 June, CET). The title of the oral presentation was: "Circulating tumor DNA (ctDNA) and serum thymidine kinase 1 activity (TKa) matched dynamics in patients (pts) with hormone receptor–positive (HR+), human epidermal growth factor 2–negative (HER2-) advanced breast cancer (ABC) treated in first-line (1L) with ribociclib (RIB) and letrozole (LET) in the BioltaLEE trial."

The PREDIX study at Karolinska Institute on 202 patients with locally advanced breast cancer was presented as an abstract. The heading was: "Serum thymidine kinase 1 and its kinetics in HER2-positive breast cancer: Results from the Swedish phase II PREDIX HER2 trial."

A study carried out by Imperial Collage and Royal Marsden Hospital, London, on 21 patients with Non-Small Cell Lung Cancer (NSCLC) who were being treated with pemetrexed was presented in a poster session. The heading was:

"[18F]fluorothymidine(FLT)-PET Imaging of thymidine kinase 1 pharmacodynamics in Non-Small Cell Lung Cancer treated with pemetrexed."

Biovica's DiviTum®TKa was highlighted in an oral presentation at ASCO

The study's conclusions were that these finds indicate that the combination of the prior dynamic assessment of both ctDNA and TKa can improve prediction of results for patients treated with RIB and LET. Patients with high values of ctDNA+/TKa did not respond to the treatment. TKa and ctDNA capture different characteristics of the tumor's biological activity and their combination motivates further evaluation in relation to other treatments, environments and diseases.

Biovica's CFO will terminate employment in December 2022

Cecilia Driving, Biovica's CFO and EVP has submitted her notice of termination. The process for recruiting

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a replacement is underway and Cecilia Driving, who has been the CFO of Biovica since 2016, will remain in her current role until 31 December 2022.

FDA clearance for DiviTum®TKa

The FDA granted 510(k) clearance for DiviTum®TKa as a tool for monitoring disease progression in postmenopausal women with hormone receptor positive metastatic breast cancer. DiviTum®TKa is the first FDA approved biomarker in this area.

Clearance for DiviTum®TKa was granted on the basis of clinical data from the SWOG study (S0226), along with a clinical validation study that was based on the SWOG study. In the clinical validation study, the assay demonstrated excellent capabilities to identify non progressors with high negative predictive values, NPV, of 96.7% for progression within 30 days and 93.5% for progression within 60 days. This means that 96.7% of patients with DiviTum®TKa measurements below the assay clinical cut-off, did not experience disease progression within the next 30 days.

Significant events after the end of the period

No significant events after the end of the period

Other

2021 AGM

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

New notified body

During the quarter, Biovica's Quality Management System (QMS) was granted ISO13485:2016 by a new notified body, TÜV Süd. Biovica was granted ISO 13485 certification some time ago. However, as a first step towards compliance with the new EU In Vitro Diagnostic Medical Device Regulation (IVDR) 2017/746, Biovica switched during the quarter to a new notified body, TÜV Süd, which can test and certify to nearly any product safety certification requirement, including IVDR. This will also be essential to the effort of obtaining CE marking for future products. IVDR 2017/746 entered into force on 26 May 2022 and it applies to all new IVD products that are introduced in the EU. Based on the IVDR transitions rules, CE marking for DiviTum®TKa is valid until 2026.

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Comments on the financial performance of the Group

Q1 - Sales and earnings

Net sales for the period amounted to SEK 545 (381) thousand. First quarter sales are attributable to repeat customers in the research market. They use DiviTum®TKa when developing new cancer drugs.

Capitalized work performed by the company for its own use amounts to SEK 446 (381) 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 -20,662 (- 12,238) thousand.

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

Net financial items amounted to SEK -392 (12) thousand. Loss after financial items was SEK - 21,054 (-12,226) thousand. Loss for the period was SEK -21,004 (-12,225) thousand.

As of 31 July 2022, the company had 26 (17) employees, of which 12 (8) are women.

Financial position, cash flow and investments

The closing amount for cash & cash equivalents on 31 July 2022 was SEK 71,705 (130,927) thousand.

Capitalized expenditure for development work during the period amounts to SEK 446 (883) thousand.

Net investments in property, plant and equipment in the form of equipment for the year amounted to SEK 603 (0) thousand.

Funding

The closing amount for cash & cash equivalents on 31 July 2022 was SEK 71,705 (130,927) thousand. At the current cost level and signed agreements with customers, it is estimated that the company's capital is sufficient for more than one year of operations.

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 57 thousand. Transactions were in accordance with market-based terms and conditions. Intragroup transactions with the subsidiary amounted to SEK 8,147 thousand.

Warrants

Program	То	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
T05	employees	60,000	17.16	1.23	25 March 2021 - 25 August 2022	4,000.00	60,000
T06	employees	173,000	45.14	3.31	25 March 2022 - 25 August 2023	11,533.33	173,000
Т07	Board of Directors	200,000	45.14	3.31	25 March 2022 - 25 August 2023	13,333.33	200,000
TO8	employees	233,000	70.35	2.61	25 March 2023 - 25 August 2024	15,533.33	233,000
ТО9	employees	130,000	70.35	-	25 March 2023 - 25 August 2024	8,666.67	130,000
TO10	Board of Directors	120,000	70.35	3.94	1 August 2025 - 30 September 2025	8,000.00	120,000
		1,066,000				71,066.67	1,066,000

Shares

As of 31 July 2021, the number of outstanding shares in Biovica was 28,528,372, of which 6,276,293 shares are Class A and 22,232,079 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 2022.

During the first quarter, 40,000 Class B shares were issued in conjunction with the T05 warrants scheme, which generated SEK 686 thousand for the company. Subsequent to the end of the period, the remaining 60,000 Class B shares of the T05 warrants scheme were issued, which generated another SEK 1,029 thousand for the company.

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 2021/2022.

New standards and interpretations that enter into force in 2022 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 2021/2022.

COVID-19

At present, management's assessment is that COVID-19 does not have any impact on the company's delivery capability. Management is monitoring the situation and prepared to take action if the situation should change.

Russia's invasion of Ukraine

Management has assessed that the war in Ukraine, and the associated sanctions against Russia, do not

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currently have any impact on the company's operating activities. Management is continuing to monitor the situation and prepared to take action if the situation should change.

Significant assessments

Assessments and estimates in the financial statements

In preparing the financial statements, the executive management team must make assessments and estimates that affect both the application of accounting policies and the reported amounts of assets, liabilities, income and expenses. The actual outcome may deviate from these estimates and assessments.

Estimates and assessments are regularly reviewed. A change in estimates and assumptions is reported in the period when the change is made if it only impacts that period. Otherwise, it is reported in the period when the change is made *and* in future periods if it impact both the current period and future periods.

The most significant uncertainty is associated with intangible assets. Impairment testing is based on a review of the recoverable amount, which is assessed based on the value-in-use of the asset concerned. The company's senior executives calculate future cash flows based on internal business plans and forecasts.

Internal development expenditure for research and development

After capitalization occurs, management monitors that the accounting requirements for development costs are still being met, along with whether there is any indication of impairment to the capitalized expenditure. Should the situation arise whereby the company's financing is not secured, it could result in a write-down requirement on the intangible assets.

Growth and gross margin

The recoverable amount is based on a calculation of the value-in-use by using cash flow forecasts based on budgets that have been approved by the Board of Directors, along with forecasts that stretch over the life of the company's patents. The forecasts are based on the business plan for 2021/2022. Gross margin is calculated based on the product calculation.

Impairment of non-financial assets

In order to assess impairment, management calculates the recoverable amount for each cashgenerating unit based on expected future cash flows. It then uses a suitable rate to discount those cash flows to present value. There is uncertainty in assumptions about future operating profit and establishing a suitable discount rate.

Useful life of depreciable assets

At each closing date, management reviews its assessments of the useful life that has been established for each category of depreciable assets, taking into consideration how long the Group expects to use those assets. There is uncertainty in these assessments because of the demand and market acceptance.

Note 1 Financial assets measured at fair value

Of the total cash and cash equivalents, SEK 12,067 (12,567) thousand is measured at fair value as of 31 July 2022, corresponding to a value change of SEK 10 (91) thousand. The financial assets stated above consist of investments in funds. For financial instruments that are listed, the quoted prices are used for measurement at fair value (Level 1).

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KPIs for the Group

				Full	Full	
	Q1	Q1	Full year	year	year	Full year
SEK 000s	22/23	21/22	21/22	20/21	19/20	18/19
Net sales	545	381	2,045	2,077	1,671	3,005
Operating profit (loss)	-20,662	-12,238	-60,101	-40,181	-29,816	-21,718
Profit (loss) for the period	-21,004	-12,225	-60,003	-39,482	-30,318	-21,556
Capitalized R&D costs	446	883	2,992	3,560	7,035	6,464
Capitalized R&D exp., % of op. expenses	-2%	-7%	-5%	-8%	-18%	-22%
Earnings per share, before dilution	-0.74	-0.43	-2.11	-1.39	-1.29	-1.23
Earnings per share, after dilution	-0.74	-0.43	-2.11	-1.39	-1.29	-1.23
Cash and cash equivalents at the end of the period	71,705	130,927	89,792	145,364	40,777	16,831
Cash flow from operating activities	-16,974	-13,263	-52,126	-34,409	-24,780	-17,966
Cash flow for the period	-18,104	-14,451	-55,659	104,690	23,927	-25,295
Equity	103,841	170,452	124,088	182,661	78,217	52,097
Equity per share	3.64	6.00	4.36	6.43	3.32	2.96
Equity ratio (%)	79%	96%	82%	95%	87%	86%
Average number of employees	26	25	25	20	17	16

Definitions are the same as those presented in the Annual Report for 2021/2022.

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	
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 of comprehensive income

	Q1 2022/2023	Q1 2021/2022	Full year 2021/2022	Full year 2020/2021
Amount in SEK thousands				
Net sales	545	381	2,045	2,077
Other income	100	69	1,259	3,241
Work performed by the company and				
capitalized	446	883	2,992	3,560
Change in WIP inventory		0		
Operating income	1,091	1,333	6,296	8,878
Materials cost	-123	-96	-371	-367
Other external costs	-9,079	-5,129	-17,290	-15,332
Employee benefit expenses	-10,316	-6,784	-42,058	-27,218
Depreciation/amortization	-2,062	-1,563	-6,439	-6,142
Other operating expenses	-174	0	-239	0
Operating expenses	-21,753	-13,572	-66,397	-49,059
Operating profit (loss)	-20,662	-12,238	-60,101	-40,181
Financial income	0	23	188	855
Financial expenses	-392	-11	-79	-60
Profit (loss) before tax	-21,054	-12,226	-59,991	-39,386
Income tax	50	1	-12	-96
Profit (loss) for the period	-21,004	-12,225	-60,003	-39,483
Consolidated statement of comprehensive income				
Profit (loss) for the period	-21,004	-12,225	-60,003	-39,483
Exchange diff. foreign net invest.	0	0	135	-12
Other comprehensive income for the period	0	0	0	0
Comprehensive income for the period	-21,004	-12,225	-59,868	-39,496
Earnings per share				
Earnings per share, before dilution (SEK)	-0.74	-0.43	-2.11	-1.39
Average number of shares, before dilution	28,508,372	28,418,372	28,488,372	28,418,372
Earnings per share, after dilution (SEK)	-0.74	-0.43	-2.11	-1.39
Average number of shares, after dilution	29,574,372	29,111,372	29,736,372	29,111,372

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Consolidated statement of financial position, in summary

Amount in SEK thousands	2022-07-31	2021-07-31	2021-04-30
ASSETS			
Intangible assets	39,672	41,626	41,869
Machinery, equipment, tools, fixtures and fittings	1,106	579	704
Right-of-use assets	12,403	1,867	2,312
Deferred tax asset	2,612	407	499
Total fixed assets	55,794	44,479	45,384
Inventories	1,614	452	527
Accounts receivable	505	479	222
Current receivables	2,489	1,616	1,153
Cash and cash equivalents	71,705	130,927	145,364
Total current assets	76,312	133,474	147,266
TOTAL ASSETS	132,106	177,953	192,650
EQUITY			
Share capital	1,902	1,895	1,895
Other contributed capital	340,764	338,758	338,758
Reserves	155	0	-20
Retained earnings (losses), including loss			
for the year	-238,980	-170,201	-157,972
Total equity	103,841	170,452	182,661
LIABILITIES	103,841	170,452	934
Right-of-use liabilities	8,153	687	460
Deferred tax liability	2,500	368	0
Total non-current liabilities	10,653	1,055	1,394
Right-of-use liabilities	4,532	1,295	1,486
Advance payments from customers	1,315	1,216	1,213
Accounts payable	3,673	929	1,085
Current tax liabilities	84	53	154
Other liabilities	417	692	634
Accrued expenses and deferred income	7,591	2,262	4,023
Current liabilities	17,612	6,446	634
TOTAL EQUITY AND LIABILITIES	132,106	177,953	192,650

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Consolidated statement of changes in equity, in summary

Amount in SEK thousands	Share capital	Other contributed capital	Reserves	Retained earnings	Total equity
Opening balance, 1 May 2021	1,895	338,758	-20	-157,971	182,661
New share issue		855			855
lssue costs					0
New issue of shares via exercise of warrants Share-based payments, employees	5	436 94			440
Transaction with owners	1,899	340,048	-20	-157,971	183,957
Profit (loss) for the year	_,	,		-60,003	-60,003
Other comprehensive income			135		135
Comprehensive income for the year (loss)	0	0	135	-60,003	-59,868
Closing balance, 30 April 2022	1,899	340,048	116	-217,974	124,088
Opening balance, 1 May 2022	1,899	340,048	116	-217,974	124,088
New share issue	3	684			686
Issue costs					0
New issue of shares via exercise of warrants Share-based payments, employees		32			32
Transaction with owners	1,902	340,763	116	-217,974	124,807
Profit (loss) for the year				-21,004	-21,004
Other comprehensive income			39		39
Comprehensive income for the year (loss)	0	0	39	-21,004	-20,965
Closing balance, 31 July 2022	1,902	340,763	156	-238,978	103,841

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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	-19,045	-10,777	-53,844	-34,340
Changes in working capital	2,071	-2,486	1,719	-866
Cash flow from operating activities	-16,974	-13,263	-52,126	-35,204
Cash flow from investing activities	-1,049	-883	-3,398	-3,560
Cash flow from financing activities	-81	-304	-136	142,661
Cash flow for the period	-18,104	-14,451	-55,659	103,897
Cash and cash equivalents at the				
beginning of the period Translation difference, cash and cash	89,792	145,364	145,364	40,777
equivalents Cash and cash equivalents at the end of	16	14	88	-105
the period	71,705	130,927	89,792	145,364

Parent Company income statement, in summary

	Q1 2022/2023	Q1 2021/2022	May-April 2021/2022	May-April 2020/2021
Amount in SEK thousands				
Net sales	545	381	2,045	2,077
Work performed by the company and				
capitalized	446	883	2,992	3,560
Other operating income	100	69	178	2,071
Sales	1,091	1,333	5,215	7,708
Goods for resale	-123	-96	-371	-367
Other external costs	-13,893	-6,873	-32,736	-22,119
Employee benefit expenses	-6,709	-5,457	-28,755	-22,243
Depreciation/amortization	-1,236	-1,251	-4,986	-4,887
Other expenses	-174	0	-239	0
Operating expenses	-22,136	-13,677	-67,086	-49,615
Operating profit (loss)	-21,045	-12,344	-61,871	-41,907
Net financial income/expense	-277	44	277	758
Profit (loss) before tax	-21,322	-12,300	-61,594	-41,150
Appropriations	0	0	1,054	1,146
Tax on profit for the year	0	0	0	0
Profit (loss) for the period	-21,322	-12,300	-60,540	-40,004
Earnings per share				
Earnings per share, before dilution (SEK)	-0.75	-0.43	-2.13	-1.41
Average number of shares, before dilution	28,508,372	28,418,372	28,418,372	28,418,372
Earnings per share, after dilution (SEK)	-0.75	-0.43	-2.13	-1.41
Average number of shares, after dilution	29,574,372	29,111,372	29,111,372	29,111,372
Comprehensive income (loss) equals the loss for t	he period			

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

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Parent Company balance sheet, in summary

Amount in SEK thousands	2022-07-31	2021-07-31	2022-04-30
ASSETS			
Intangible assets	39,672	41,869	41,869
Machinery, equipment, tools, fixtures and			
fittings	692	704	704
Financial assets	4,687	2,217	2,217
Total fixed assets	45,052	44,790	44,790
Inventories	1,614	527	527
Current receivables	2,170	1,511	1,511
Cash and cash equivalents	67,864	142,920	142,920
Total current assets	71,647	144,958	144,958
TOTAL ASSETS	116,699	189,748	189,748
EQUITY			
Total restricted equity	30,076	28,543	29,105
Total non-restricted equity	72,137	153,519	152,956
Total EQUITY	102,213	182,061	182,061
LIABILITIES			
Total non-current liabilities	0	0	0
Total current liabilities	14,486	7,686	7,686
Total LIABILITIES	14,486	7,686	7,686
TOTAL EQUITY AND LIABILITIES	116,699	189,748	189,748

Glossary

Abstract - A short summary of a longer document, such as a dissertation or research article. It briefly states the purposes and results of the research. Abstracts are submitted to scientific conferences in order to spread knowledge of new research.

ASCO American Society of Clinical Oncology The world's leading professional organization for physicians and oncology professionals caring for people with cancer. Together with the Association for Clinical Oncology, ASCO represents nearly 45,000 oncologists.

Imaging These are methods that currently serve as the cornerstones for diagnostics and treatment planning for essentially all types of solid tumors. It includes computer tomography (CT) scans and other X-ray methods, magnetic resonance tomography (MRT) scans, positron emission tomography (PET) scans and ultrasound.

CDK4/6 inhibitors are a new type of targeted, selective drugs that have been shown to be effective against several forms of cancers, including hormone receptor-positive breast cancer.

CLIA laboratory (The Clinical Laboratory Improvement Amendments): a clinical laboratory that has been certified to accept human samples from people in the USA for diagnostic testing. The Center for Medicare and Medicaid Services (CMS) is the regulatory body that grants certification.

ctDNA Circulating tumor DNA is found in the bloodstream and it is DNA that comes from cancerous cells and tumors. Most DNA is found inside the nucleus of a cell. As a tumor grows, cells die and are replaced by new ones. The dead cells are broken down and their contents, including DNA, are released into the bloodstream. ctDNA is small pieces of DNA, usually comprising less than 200 building blocks (nucleotides) in length.

Fulvestrant (Faslodex) is a drug that is used to treat hormone receptor (HR)-positive metastatic breast cancer in postmenopausal women with disease progression and HR-positive, HER2-negative advanced breast cancer in combination with palbociclib in women with disease progression after endocrine treatment. Fulvestrant is a Selective Estrogen Receptor Degrader (SERD). It works by binding to the estrogen receptor and destabilizing it, causing the cell's normal protein degradation processes to destroy it.

IVD In vitro diagnostics (IVD) are generally defined as a product which, regardless of whether they are used alone or in combination, are designed for performing in vitro tests on samples that have been taken from the human body. The main purpose is to obtain information for diagnostic, monitoring or compatibility purposes.

Palbociclib is a new type of targeted, selective drug that has been shown to be effective against several forms of cancers, including hormone receptor-positive breast cancer.

Pemetrexed (Alimta) is a type of chemotherapy for treating pleural mesothelioma (cancer of the outer covering of the lungs) and non-small cell lung cancer (NSCLC).

Poster session - These are sessions held at a congress or conference with an academic or professional focus to present research information in the form of a paper poster that conference participants may view. A poster session is an event at which many such posters are presented.

Posters - These are used to summarize information or research and present it in an attractive way as a means of generating interest in publishing it and sparking discussion at events such as scientific conferences.

Predictive - anticipation about what will happen in the future and used in the contexts like the predictive ability of a particular test.

PREDIX study – a randomized trial of neoadjuvant chemotherapy to treat HER2-positive breast cancer that was carried out during the period 2014–2019 at nine Swedish clinics under the supervision of Karolinska Institutet (KI).

Prospective studies are used to study the relationship between various risk factors and a particular disease. This type of study follows individuals both with risk factors and without (the control group), for a period of time into the future. At the end of the study, a comparison is made of the percentage that fell ill in each group.

PYTHIA study - A clinical study of patients with metastatic breast cancer. The primary aim of the PYTHIA study is to discover potentially innovative biomarkers for the selection of patients to Palbociclib/Fulvestrant treatment.

Reimbursement - Compensation for costs (in this context, it is payment from insurance companies to cover treatment costs)

RUO Research Use Only - An ROU product is an IVD (In Vitro Diagnostic) product that is in the

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development stage and may only be used for laboratory research and clinical studies.

Tymidine kinaseis an enzyme (kinase), subclass of phosphotransferase.

Estrogen receptor-positive - To determine whether a patient might benefit from hormone treatment,

the tumor is studied to assess whether receptors for either estrogen or progesterone. If so, it is hormone-receptor positive, which is the case for around 70 percent of all breast cancer tumors. It is primarily estrogen that has a stimulating effect on tumor growth.

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 2022

Board of Directors

Calendar

AGM

Interim Report for Q2: August-October 2022/ 2023 Interim Report for Q3: November-January 2022/ 2023 Interim Report for Q4: May-July 2022/2023

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Biovica - Treatment decisions with greater confidence

Biovica's vision is to improve the lives of cancer patients. Biovica's mission is to transform how cancer care by offering innovative biomarker assays. Biovica's assay DiviTum®TKa measures cell proliferation by detecting a biomarker in the blood stream. The first application for DiviTum®TKa is evaluation of the treatment effect on metastatic breast cancer. Biovica collaborates with world-leading cancer institutes and pharmaceutical companies. DiviTum®TKa has obtained FDA 510(k) clearance and has CE marking. 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.

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