immunovia

INTERIM REPORT JANUARY – SEPTEMBER 2021

Key indicators

SEK thousand unless otherwise stated	2021 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Full year
Net sales	377	37	539	210	362
Operating earnings	-39,938	-35,432	-115,752	-96,232	-134,343
Earnings before tax	-36,131	-38,064	-108,838	-99,914	-146,033
Net earnings	-36,131	-38,064	-108,838	-99,914	-146,033
Earnings per share before dilution (SEK)	-1.60	-1.68	-4.81	-4.78	-6.84
Earnings per share before after dilution (SEK)	-1.60	-1.68	-4.81	-4.78	-6.84
Equity ratio (%)	88	91	88	91	91
Number of shares at the end of the period	22,631,581	22 ,603,081	22,631,581	22,603,081	22,631,581

Significant events July-September 2021

On August 3, Immunovia Inc. received a clinical laboratory licensure from the Massachusetts Department of Public Health. This means that Immunovia, Inc. has been approved, and now has begun, to sell its blood test for early detection of pancreatic cancer IMMray™ PanCan-d in the USA, exclusively through the laboratory in Marlborough, Massachusetts.

In August, Immunovia provided two updates regarding the IMMray™ PanCan-d test. First, the test was launched at a list price of USD 995 per test. Second, the test was launched for those individuals with CA 19-9 levels greater than 2.5 U/ml. The overall sensitivity of the test then improves to 89 percent in stages I and II, and 92 percent in all stages. The specificity of the test is 99 percent for stage I & II.

In September, Immunovia entered a license agreement with the South Korean company JW Bioscience for pancreatic cancer biomarkers to strengthen it´s IP portfolio. The license agreement secures Immunovia global commercial rights for two biomarkers in the IMMray™ PanCan-d biomarker signature. Immunovia discovered these biomarkers independently of JW Bioscience and has now fully secured the intellectual property rights.

In September, Pancreatic Cancer Action Network (PanCAN), which is one of the most influential patient advocacy groups in the USA, informed its constituents about Immunovia's IMMray™ PanCan-d test on its website, in their social media channels and through direct email contacts. A special training for the PanCAN's Patient Services team about the test has been performed for the team to be able to inform and answer incoming questions about the test.

Significant events after the period

In October, it was communicated that Karin Almqvist Liwendahl will join Immunovia as new Chief Financial Officer (CFO) at the latest by April 1st, 2022. Karin is an experienced CFO and Investor Relations professional with a background in the telecom and life sciences industries. Current CFO Hans Liljenborg will continue with Immunovia in the position as Finance Director.

CEO's COMMENTS

All energy directed towards the USA to secure a successful market penetration

I am very pleased that we right from the start of the commercialization of our blood test IMMray™ PanCan-d in the USA have received so much positive feedback from the pancreatic cancer community. The largest patient organization with more than 1 million constituents, Pancreatic Cancer Action Network (PanCAN), informed about our test underlining that it is the first-ever blood test specific for pancreatic cancer available to high risk individuals. This strong support is important in achieving the prioritized goal for Immunovia: A successful market penetration in the US market.

Additional support for our test came from National Pancreas Foundation (NPF). I am extremely proud that we as a company can make impact in so many people's lives. Individuals who have lived with pancreatic cancer in the family for years, now have the chance of being surveilled with our highly accurate, non-invasive blood test. This is important since pancreatic cancer is becoming the third deadliest cancer in the USA and finding the tumor in an early stage is the only way to increase survival for these patients.

First phase of commercialization

After the sales start in August, we are now seeing an upgoing trend with increasing number of orders. As we analyze this first phase of commercialization, based on self-pay, there are some circumstances to have in mind. Firstly, there is still a pandemic that constrains physical visits to clinics in the USA. Secondly, there is an ordering process of some weeks from that a person decides to take the test and until a blood sample is sent to our lab and a test is being invoiced. Thirdly, established surveillance centers are awaiting a peer reviewed article on our validation study, before they decide on whether to recommend our test to the patients enrolled in the programs. I am convinced that as soon as the validation study article is published in a peer-reviewed journal, which we expect to take place before year-end, the established surveillance centers will also start employing our test. Therefore, a real boost in sales can be expected when the society opens fully again and reimbursement is in place. Over time, IMMray™ PanCan-d has the potential to increase the number of patients being surveilled within the programs since it is non invasive and much more cost efficient than current diagnostic methods such as computerized tomography (CT), magnetic resonance imaging (MRI) and endoscopic ultrasound (EUS).

CAP accreditation - the process that opens for all remaining states

Another important step for Immunovia in the USA will be the College of American Pathologists' (CAP) accreditation of Immunovia, Inc.'s laboratory outside Boston. The CAP accreditation will make our test available in New York, California, Maryland, Pennsylvania, and Rhode Island, the only five states where Immunovia's test still not is available. The CAP application has been filed and an on-site inspection is scheduled in the first quarter 2022. The CAP accreditation is part of a standard procedure for Laboratory Developed Tests like IMMray™ PanCan-d. It follows the CLIA licensure and is the gold standard for laboratories in the USA.

Solid reimbursement plan
As earlier communicated, we aim for reimbursement agreements with most US payers prior to year-end 2022. An important part of the reimbursement process is to present necessary evidence for the clinical utility of the test. Immunovia has a major, ongoing prospective clinical study in the familial/hereditary high risk group called PanFAM-1 that will be used for reimbursement purposes. The study is progressing according to plan, expected to be finalized before end of the year, and we will present interim results in the first quarter of 2022.

Update on the market launch
To maximize our impact, we will initially prioritize the USA. To secure the successful market penetration in the USA, the leading market for cancer tests in the world, we have initiated a search for a CEO for Immunovia Inc. with experience from the US diagnostic market who will advance the introduction of our test in the US. We are now also signficantly expanding the US sales and marketing capabilities. The test will, however, be available in Europe through our collaborating clinics and we will continue to work towards a general launch in Europe by maintaining our close working relation with these clinics.

Finally, I want to reiterate our goal of a long-term market penetration in the USA of 30 percent after reimbursement and widespread coverage has been achieved. Our estimates show that the addressable market size for IMMray™ PanCan-d in the USA is over USD 4 billion.

We have a unique position as a pioneer within early detection of pancreatic cancer. Thank you for your continued support for Immunovia.

We aim for reimbursement agreements with most US payers prior to year-end 2022. An important part of the reimbursement process is to present necessary evidence to establish the clinical utility of the test.

November, 2021
Patrik Dahlen, CEO, Immunovia AB

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About the report
This information was submitted for publication on November 11, 2021, at 16.00 (CET)

This financial statement has been produced in accordance with IFRS for the Immunovia Group Immunovia which comprises Immunovia AB and the wholly-owned subsidiaries Immunovia Inc, Immunovia GmbH, Immunovia Dx Laboratories AB and Immunovia Incentive AB.

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JANUARY-SEPTEMBER 2021

The Group's performance over the period

Net sales

Net sales for Q3 2021 amounted to SEK 377,000 (37,000). Net sales are divided between sales of tests SEK 65,000 and royalties SEK 312,000. For the period January to September, sales amounted to SEK 539,000 divided between sales of tests SEK 65,000 and royalties SEK 474,000

Earnings

The net loss for Q3 2021 was SEK -36.13 million (-38.06). Study costs have fallen at the same time as depreciation has increased due to the depreciation of the capitalization of development costs that started in Q2 2021.

Other external costs and personnel costs fell by SEK 9.84 million during Q3 compared with the corresponding period last year and totaled SEK 31.23 million. The reduction is due to a reduction in the costs of clinical trials.

Research & Development

Total R&D costs for Q3 2021 amounted to SEK 8.31 million (9.10), equivalent to 22% (21) of the Group's total operating expenses.

Financing and cash flow

The cash flow from operating activities for Q3 2021 amounted to SEK -38.29 million (-33.26). The corresponding cash flow for the period January to September 2021 amounted to SEK -102.54 million (-84.95).

Cash and cash equivalents as of September 30, 2021 amounted to SEK 339.17 million (510.59).

Equity at the end of the period amounted to SEK 484.41 million (668.75) and the equity ratio was 88% (91).

The management believes that there is sufficient working capital to cover working capital needs, given the current business and development plan for approximately 1.5 years.

Investments

In Q3 2021, intangible assets totaling SEK 1.81 million (8.80) were acquired, consisting of capitalized development expenditure of SEK 0 million (8.09) and patents of SEK 1.81 million (489,000) and other intangible assets 0 (244,000). During the period January to September 2021, intangible assets totaling SEK 20.91 million (33.39) were acquired, consisting of capitalized development expenditure of SEK 18.41 million (30.37), patents of SEK 2.49 million (1.57 m) and other intangible assets 0 (1.47 m).

During Q2 2021, development was completed on the company's test for the early detection of pancreatic cancer and with this, the capitalization of development costs for this ended and depreciation of the capitalized costs began.

Investments in tangible fixed assets in the form of equipment were made of SEK 1.02 million (2.19) during Q3 2021. For the period January – September 2021, investments in tangible fixed assets amounted to SEK 2.57 million (3.33).

No financial investments were made during the period January to September 2021.

Employees

The average number of employees during Q3 2021 was 68 (63) and at the end of the period the number of employees was 68 (67).

Share information

The number of registered shares amounted to 22,631,581 shares at the end of the reporting period. The share's nominal value is SEK 0.05.

Share capital development

Year	Event	Total share capital (SEK	Change (SEK)	Total no. of shares	Change in shares	Nominal value (SEK)
May 24, 2007	Formation	100,000.00	100,000.00	1,000,000	1,000,000	0.10
Oct 19, 2011	New share issue	105,263.00	5,263.00	1,052,630	52,630	0.10
Oct 27, 2011	Share split 5:1	105,263.00	-	5,263,150	4,210,520	0.02
July 5, 2012	New share issue	108,869.92	3,606.92	5,443,496	180,346	0.02
May 21, 2013	New share issue	122,483.76	13,613.84	6,124,188	680,692	0.02
Sep 10, 2013	New share issue	124,899.76	2,416.00	6 ,244,988	120,800	0.02
Jun 5, 2014	New share issue	220,924.32	96,024.56	11,046,216	4,801,228	0.02
Aug 13, 2015	Bonus issue	552,310.80	331,386.48	11,046,216	-	0.05
Dec 17, 2015	New share issue	714,560.80	162,250.00	14,291,216	3,245,000	0.05
Sep 15, 2016	New share issue	823,728.40	109,167.60	16,474,568	2,183,352	0.05
Oct 17, 2016	New share issue	840,202.95	16,474.55	16,804,059	329,491	0.05
Oct 4, 2017	New share issue via warrants	865,902.95	25,700.00	17,318,059	514,000	0.05
Jun 8, 2018	New share issue	974,042.65	108,139.70	19,480,853	2,162,794	0.05
Sep 19, 2018	New share issue via warrants	976,567.65	2,525.00	19,531,353	50,500	0.05
Sep 9, 2019	New share issue via warrants	982,742.65	6,175.00	19,654,853	123,500	0.05
June 4, 2020	New share issue	1,130,154.05	147,411.40	22,603,081	2,918,228	0.05
Oct 4, 2020	New share issue via warrants	1,131,579.05	1,425.00	22,631,581	28,500	0.05
At end of period		**1,131,579.05**		**22,631,581**		**0.05**

The 10 largest shareholders on September 30, 2021

Shareholders	No. of shares	Share (capital and votes)
Carl Borrebaeck	1,709,900	7.56%
Ålandsbanken (on behalf of owner)	1,419,406	6.27%
Avanza Pension	1,252,465	5.53%
Per Mats Ohlin	848,950	3.75%
Sara Andersson Ek	848,907	3.75%
Christer Wingren	748,525	3.31%
Vincent Saldell	628,830	2.78%
Credit Suisse (Switzerland) LDT	564,184	2.49%
Nordnet Pensionsförsäkring	465,609	2.06%
Coeli Wealth Management AB	416,983	1.84%
Ten largest owners	8,903,759	39.34%
Others	13,727,822	60.66%
Total	**22,631,581**	**100.00%**

Incentive schemes

Immunovia has three outstanding warrant schemes comprising 515,650 options with the right to subscribe for 515,650 shares. There is no dilution effect on earnings per share as long as the Group's earnings are negative.

Warrant scheme

The warrant schemes are aimed at employees and key personnel in the company. At the time of allotment, all warrants have been valued according to Black & Scholes' valuation model. A summary of the company's warrant schemes can be found below.

Alternative cash-based incentive schemes

In countries where the allotment of warrant schemes is not appropriate for various reasons, it has been decided to introduce alternative cash-based incentive schemes for employees and key personnel in the company. The alternative incentive schemes are designed in such a way that their financial effect corresponds to the terms of the corresponding warrant scheme. The total cost to the company for the cash-based incentive schemes is shown in the breakdown below

All warrant schemes are subject to customary recalculation terms in connection with share issues, etc.

Breakdown of outstanding incentive scheme

Incentive scheme	Decision date	Utilization period	Number of outstanding warrants	Sub-scription price/ share	Change in share capital at full utilization	Total cost of alternative cash-based incentive schemes (USD)
Warrant scheme 2018/2021	May 3, 2018	Sep 7, 2021 -- Oct 7, 2021	156,150	271.05	7,807.50	
Warrant scheme 2019/2023	Apr 26, 2019	Jun 1, 2023 -- Jun 30, 2023	79,500	342.06	3,975.00	
Warrant scheme 2020/2024	Sep 23, 2020	Jun 1, 2024 -- Jun 30, 2024	280,000	455.59	14,000.00	
Alternative cash-based incentive scheme 2018/2021	May 3, 2018	Sep 7, 2021 -- Oct 7, 2021				250,000
Alternative cash-based incentive scheme 2019/2023	Apr 26, 2019	Jun 1, 2023 -- Jun 30, 2023				520,000
Alternative cash-based incentive scheme 2020/2024	Sep 23, 2020	Jun 1, 2024 -- Jun 30, 2024				192,000
Total			**515,650**		**25,782.50**	**962,000**

Consolidated income statement, summary

SEK thousands	2021 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Full Year
Operating income etc					
Net sales	377	37	539	210	362
Other operating income	9	63	74	299	624
Total, operating income	**386**	**100**	**612**	**509**	**986**
Operating expenses					
Raw materials and consumables	-2,674	0	-2,674	0	0
Other external expenses	-16,183	-20,759	-65,551	-70,017	-91,147
Personnel costs	-15,046	-20,305	-53,351	-49,311	-73,968
Capitalized work for own account	0	8,097	18,502	30,372	40,020
Amortization of tangible and intangible assets	-6,215	-2,444	-12,871	-7,313	-9,763
Other operating expenses	-207	-121	-419	-471	-471
Total operating expenses	**-40,324**	**-35,532**	**-116,364**	**-96,740**	**-135,329**
Operating earnings/loss	**-39,938**	**-35,432**	**-115,752**	**-96,232**	**-134,343**
Profit/loss from financial items					
Financial income	4,159	237	10,363	5,465	5,692
Financial expenses	-351	-2,869	-3,449	-9,147	-17,382
Total financial items	3,808	-2,632	6,914	-3,682	-11,690
Earnings/loss after financial items	**-36,131**	**-38,064**	**-108,838**	**-99,914**	**-146,033**
Income tax	0	0	0	0	0
Earnings/loss for the period	**-36,131**	**-38,064**	**-108,838**	**-99,914**	**-146,033**
Earnings per share before dilution (SEK)	-1.60	-1.68	-4.81	-4.78	-6.84
Earnings per share after dilution (SEK)	-1.60	-1.68	-4.81	-4.78	-6.84
Average number of shares	22,631,581	22,603,081	22,631,581	20,910,580	21,340,672
Number of shares at year's end	22,631,581	22,603,081	22,631,581	22,603,081	22,631,581

Consolidated comprehensive income, summary

SEK thousands	2021 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Full year
Earnings/loss for the period	-36 131	-38,064	-108 838	-99,914	-146,033
Items that may be reclassified later in the income statement					
Exchange rate differences for foreign net investment	-215	2,380	-6,592	2,708	9,317
Other earnings/loss for the period	-215	2,380	-6,592	2,708	9,317
Comprehensive income for the period	**-36,346**	**-35,684**	**-115,429**	**-97,206**	**-136,716**

Consolidated financial position, summary

SEK thousands	2021 Sep 30	2020 Sep 30	2020 Dec 31
ASSETS			
Fixed assets			
Intangible fixed assets	151,227	125,014	134,935
Tangible fixed assets	49,044	51,225	48,701
Financial fixed assets	2,948	3,014	2,746
Total fixed assets	**203,219**	**179,253**	**186,382**
Current assets			
Inventory	1,312	0	0
Accounts receivable	52	0	0
Other short term receivables	8,051	7,243	6,334
Cash and cash equivalents	339,165	510,593	468,462
Total current assets	**348,580**	**517,836**	**474,796**
TOTAL ASSETS	**551,799**	**697,089**	**661,178**
EQUITY AND LIABILITIES			
Equity			
Share capital	1,132	1,130	1,132
Other contributed capital	1,015,730	1,009,450	1,015,291
Translation reserve	1,723	1,705	8,315
Retained earnings incl. total comprehensive income	-534,171	-379,214	-425,334
Total equity	**484,414**	**633,071**	**599,404**
Long-term liabilities			
Interest-bearing liabilities	28,674	30,900	27,988
Total long-term liabilities	**28,674**	**30,900**	**27,988**
Current liabilities			
Interest-bearing liabilities	5,861	3,475	5,143
Other liabilities	32,850	29,643	28,643
Total current liabilities	**38,711**	**33,118**	**33,786**
TOTAL EQUITY AND LIABILITIES	**551,799**	**697,089**	**661,178**

Change in consolidated equity, summary

SEK thousands	Share capital	Other contributed equity	Reserves	Accumulated earnings/loss for the period	Total equity
Opening balance January 1, 2020	**983**	**636,924**	**-1,002**	**-279,301**	**357,604**
Comprehensive income for the period			2,707	-99,913	-97,206
Transactions with owners in their capacity as owners					
New share issue	147	397,863			398,010
Share issue cost		25,337			-25,337
Closing balance September 30, 2020	**1,130**	**1,009,450**	**1,705**	**-379,214**	**633,071**
Comprehensive income for the period			6,610	-46,120	-39,509
Transactions with owners in their capacity as owners					
New share issue	2	5,840			5,842
Closing balance December 31, 2020	**1,132**	**1,015,291**	**8,315**	**-425,334**	**599,404**
Comprehensive income for the period			-6,592	-108,838	-115,430
Transactions with owners in their capacity as owners					
Deposited share warrant premiums		440			440
Closing balance September 30, 2021	**1,132**	**1,015,731**	**1,723**	**-534,172**	**484,414**

Consolidated cash flow statement, summary

SEK thousands	2021 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan -Sep	2020 Full year
Operating activities					
Operating earnings/loss	-39,938	-35,432	-115,752	-96,231	-134,343
Adjustment for items not included in cash flow	6,212	2,507	12,751	7,280	9,945
Interest received	155	237	558	350	577
Interest paid	-351	-348	-1,092	-1,079	-1,415
Tax paid	0	0	0	0	0
Cash flow from operating activities before changes in working capital	**-33,922**	**-33,036**	**-103,535**	**-89,680**	**-125,236**
Cash flow from changes in working capital					
Change in inventory	694	0	-1,289	0	0
Change in operating receivables	2,174	108	-1,641	-1,501	-579
Change in operating liabilities	-7,234	-338	3,927	6,234	5,111
Cash flow from operating activities	**-38,288**	**-33,266**	**-102,538**	**-84,947**	**-120,704**
Investment activities					
Investment in intangible assets	-1,813	-8,830	-20,905	-33,394	-43,497
Investment in tangible assets	-1,019	-2,192	-2,568	-3,305	-3,998
Investment in financial fixed assets	0	0	0	0	0
Sale of fixed assets	0	0	186	0	537
Cash flow from investment activities	**-2,831**	**-11,022**	**-23,287**	**-36,699**	**-46,958**
Financing activities					
Amortization of leasing liability	-1,429	-1,197	-4,267	-3,690	-4,936
New share issue	0	0	0	372,673	378,516
Received warrants premiums	0	0	440	0	0
Cash flow from financing activities	**-1,429**	**-1,197**	**-3,827**	**368,983**	**373,580**
Cash flow for the period	**-42,549**	**-45,485**	**-129,652**	**247,337**	**205,918**
Cash and cash equivalents at start of period	381,550	556,191	468,462	263,345	263,345
Exchange rate difference in cash and cash equivalents	164	-113	355	-89	-801
Cash and cash equivalents at end of period	**339,165**	**510,593**	**339,165**	**510,593**	**468,462**

Consolidated key indicators

	2021 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Full year	2019 Full year
Operating earnings/loss (SEK 000)	-39,938	-35,432	-115,752	-96,232	-134,343	-114,248
Earnings/loss for the year (SEK 000)	-36,131	-38,064	-108,838	-99,914	-146,033	-114,521
Earnings per share before dilution (SEK)	-1.60	-1.68	-4.81	-4.78	-6.84	-5.85
Earnings per share after dilution (SEK)	-1.60	-1.68	-4.81	-4.78	-6.84	-5.85
R&D expenses (SEK 000)	-8,314	-9,103	-24,245	-35,200	-48,078	-34,273
R&D expenses as percentage of operating expenses (%)	22	21	25	28	28	26
Cash and cash equivalents at the period's end (SEK 000)	339,165	510,593	339,165	510,593	468,462	263,345
Cash flow from operating activities (SEK 000)	-38,288	-33,266	-102,538	-84,947	-120,704	-91,954
Cash flow for the period (SEK 000)	-42,549	-45,485	-129,652	247,337	205,918	-122,797
Equity (SEK 000)	484,414	633,071	484,414	668,755	599,404	357,604
Equity per share (SEK)	21.40	28.01	21.40	28.01	26.49	18.19
Equity / assets ratio (%)	88	91	88	91	91	85
Average number of employees	68	63	68	60	63	48
Average number of employees in R&D	22	22	22	22	21	19

Definitions

Key indicator	Definition	Motivation for using financial key indicator not defined pursuant to IFRS
Net sales	Revenues from goods and services sold, and royalties received relating to the main activity during the relevant period.	
Operating earnings/loss	Earnings/loss before financial items and tax.	Operating earnings/loss provides a view of the earnings that the company's ordinary activities have generated.
Basic and diluted earnings per share	Earnings/loss divided by the weighted number of shares in the period before and after dilution respectively.	
Average number of shares before and after dilution	The average number of outstanding shares in the period before and after dilution respectively. Because the group is generating a loss, there is no dilution, despite the subscription price being lower than the share price.	
R&D expenses	The company's direct expenses for research and development. Expenses for staff, materials and external services.	The company's main activity is research and development. Management considers that R&D expenses are an important parameter to monitor as an indicator of activity levels.
R&D expenses as a percentage of operating expenses	R&D expenses divided by operating expenses, which include other external expenses, personnel expenses, depreciation and amortization.	Management considers that the company's R&D expenses in relation to total expenses are an important indication of the proportion of total expenses that are used for the company's main activity.
Cash and cash equivalents	Cash and bank balances.	
Cash flow from operating activities	Cash flow before cash flow from investing activities and financing activities.	
Cash flow for the period (SEK 000)	The change in cash and cash equivalents for the period excluding effective unrealized exchange rate gains and exchange rate losses.	
Equity per share (SEK)	Equity divided by the number of shares at the end of the period.	Management follows this indicator to monitor the value of equity per share.
Equity/assets ratio	Equity as a percentage of total assets.	Management follows this indicator of the company's financial stability.
Average number of employees	The average number of employees is the total of working-hours in the period divided by scheduled working hours for the period.	
Average number of employees in R&D	The average of the number of employees in the company's research and development functions.	

Parent company's income statement, summary

SEK thousands	2021 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Full year
Operating income etc.					
Net sales	3,516	37	4,379	210	362
Capitalized work for own account	0	8,097	18,502	30,372	40,020
Other operating income	7	72	67	308	451
Total operating income	**3,523**	**8,206**	**22,948**	**30,890**	**40,833**
Operating expenses					
Raw material and consumables	-704	0	-867	0	0
Other external expenses	-13,142	-19,748	-59,286	-67,029	-89,134
Personnel costs	-8,984	-8,769	-34,082	-29,484	-48,835
Amortization of intangible and tangible fixed assets	-4,336	-829	-7,386	-2,471	-3,310
Other operating expenses	-207	-120	-419	-471	-471
Total operating expenses	**-27,373**	**-29,466**	**-102,040**	**-99,455**	**-141,750**
Operating earnings/loss	**-23,850**	**-21,260**	**-79,092**	**-68,565**	**-100,917**
Operating expenses					
Financial incomes	5,049	761	12,708	6,955	7,982
Financial expenses	0	-2,522	-2,356	-8,068	-15,967
Total financial items	**5,049**	**-1,761**	**10,352**	**-1,113**	**-7,985**
Earnings/loss after financial items	**-18,801**	**-23,021**	**-68,739**	**-69,678**	**-108,902**
Allocations					
Group contributions received	0	0	0	0	88
Total allocations	**0**	**0**	**0**	**0**	**88**
Earnings/loss before tax	**-18,801**	**-23,021**	**-68,739**	**-69,678**	**-108,814**
Income tax	0	0	0	0	0
Earnings/loss for the period	**-18,801**	**-23,021**	**-68,739**	**-69,678**	**-108,814**

Parent company's comprehensive income, summary

SEK thousands	2021 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Full Year
Earnings/loss for the period	**-18,801**	**-23,021**	**-68,739**	**-69,678**	**-108,814**
Other earnings/loss for the period	0	0	0	0	0
Comprehensive income for the period	**-18,801**	**-23,031**	**-68,739**	**-69,678**	**-108,814**

Parent company's balance sheet, summary

SEK thousands	2021 Sep 30	2020 Sep 30	2020 Dec 31
ASSETS			
Fixed assets			
Intangible fixed assets	149,830	123,494	133,550
Tangible fixed assets	10,864	11,887	11,384
Financial fixed assets	328	329	328
Total fixed assets	**161,022**	**135,710**	**145,262**
Current assets			
Inventory	1,001	0	0
Receivables from Group companies	132,251	78,151	85,556
Current receivables	2,929	3,150	3,850
Prepaid expenses and accrued income	2,718	3,586	3,088
Cash and cash equivalents	334,999	507,914	461,730
Total current assets	**473,898**	**592,801**	**554,224**
TOTAL ASSETS	**634,920**	**728,511**	**699,486**
EQUITY AND LIABILITIES			
Equity			
Restricted equity	1,132	1,130	1,132
Fund for development expenses	120,140	95,941	105,589
Total equity and liabilities	**121,272**	**97,071**	**106,721**
Non-restricted equity			
Premium fund	0	372,526	378,367
Retained earnings including comprehensive income	482,147	235,856	187,070
Total non-restricted equity	**482,147**	**608,382**	**565,437**
Total equity	**603,419**	**705,453**	**672,158**
Current liabilities			
Other liabilities	31,501	23,058	27,328
Total current liabilities	**31,501**	**23,058**	**27,328**
TOTAL EQUITY AND LIABILITIES	**634,920**	**728,511**	**699,486**

Parent company's cash flow statement, summary

SEK thousands	2021 Jan-Sep	2020 Jan-Sep	2020 Full year
Operating activities			
Operating earnings/loss	-79,092	-68,565	-100,917
Adjustment for items not included in cash flow	7,405	2,471	3,221
Interest received	558	349	576
Interest paid	-2	-3	-3
Tax paid	0	0	0
Cash flow from operating activities before changes in working capital	**-71,131**	**-65,748**	**-97,123**
Cash flow from changes in working capital			
Change in inventory	-1,001	0	0
Change in operating receivables	-35,606	-26,097	-40,715
Change in operating liabilities	4,173	152	4,420
Cash flow from operating activities	**-103,565**	**-91,693**	**-133,418**
Investment activities			
Investment in intangible fixed assets	-20,991	-32,766	-42,882
Investment in tangible fixed assets	-2,361	-1,922	-2,645
Investment in financial fixed assets	0	-25	-25
Sale of fixed assets	186	0	537
Cash flow from investment activities	**-23,166**	**- 34,713**	**-45,015**
Financing activities			
New share issue	0	372,673	378,516
Cash flow from financing activities	**0**	**372,673**	**378,516**
Cash flow for the period	**-126,731**	**246,267**	**200,083**
Cash and cash equivalents at start of period	461,730	261,647	261,647
Cash and cash equivalents at period's end	**334,999**	**507,914**	**461,730**

Accounting principles

Accounting principles

The Group applies the Swedish Annual Accounts Act and International Financial Reporting Standards (IFRS) as adopted by the EU, and RFR 1 complementary accounting rules for Groups when preparing financial reports. The parent company applies the Swedish annual accounts act and RFR 2 Accounting for legal entities when preparing financial reports. The applied accounting principles are consistent with those applied in the 2020 annual report.

This interim report has been prepared in accordance with IAS 34 Interim.

New and amended standards adopted with effect from 2021 are not expected to have any significant impact on the Group's financial position.

OTHER INFORMATION

Financial instruments

The Group currently has no financial instruments valued at fair value. Instead, all financial assets and liabilities are valued at accrued acquisition cost. It is estimated that there are no significant differences between fair value and book value relating to financial assets and liabilities.

Inventory

Inventory is reported by applying the first-in-first-out principle (FIFU). Raw materials and finished and half-finished products purchased are valued at the lower out of acquisition and net sales value. Manufactured finished and half-finished products are valued at the lower of the manufacturing cost of the goods (including a reasonable share of indirect manufacturing costs) and the net sales value. When trading between Group companies, market conditions are applied. In the case of obsolescence and internal profits, the necessary provisions and eliminations are made.

Revenue recognition

Of this year's net sales, SEK 65,000 refers to sales of test results. These contracts contain a performance commitment, which means carrying out tests on blood samples for the customers, i.e. the patients. The test result is sent to the patients immediately after the analysis has been carried out. Revenue recognition takes place when the test result has been sent, i.e. transferred to the patient, which means that revenue recognition takes place at a certain time.

Transactions with related parties

In addition to salaries and other remuneration to the executive management and board fees, according to a resolution by the AGM, the company has also entered into a consultancy agreement with CB Ocean Capital AB for services to be performed by Immunovia's chairman and its second largest shareholder Carl Borrebaeck. The services provided do not include tasks that belong to board assignments, but the services are aimed at providing the company with scientific and strategic support for scientific presentations and conferences, for example. This agreement runs until further notice with three months' notice for both parties and remuneration per quarter amounts to SEK 41,000.

Risks

Immunovia is exposed to financial risks and business risks. Financial risk management and the financial risks are described below. The company's business risks are presented on page 37 of the 2020 annual report. In addition to the risks presented, the impact of the COVID-19 pandemic on the world's economy is currently difficult to predict, thus making it difficult to predict the general developments in Immunovia's future markets.

Market risk

Currency risk

The Group operates both nationally and internationally, which involves exposure to fluctuations in various currencies, in particular USD and EUR. Currency risk arises from future commercial transactions and recognized assets and liabilities. The scope of the company's operations currently means that net exposure in foreign currencies is limited. The company therefore does not have a currency hedging policy.

Interest risk in cash flow

Interest risk is the risk that the value of financial instruments will fluctuate due to changes in market interest rates. The Group currently only has interest-bearing financial assets in the form of bank deposits as well as interest-bearing liabilities in the form of leasing debt for premises.

Credit risk

Credit risk is the risk of one party in a transaction with a financial instrument failing to meet its obligations. The maximum exposure to credit risk on financial assets as of September 30, 2021 was SEK 342.7 million (513.6).

Liquidity risk

Prudent liquidity risk management implies maintaining sufficient cash or agreed credit options to close market positions. Based on the existing business plan, there is enough liquidity for approximately 1.5 years ahead.

OTHER INFORMATION

Review
This interim report has been reviewed by the company's auditors.

Financial calendar
Financial statement 2021, Thursday, February 17, 2022
Q1 interim report 2022, Thursday April 28, 2022
Q2 interim report 2022, Tuesday August 16, 2022
Q3 interim report 2022, Thursday November 10, 2022
Financial statement 2022, Thursday February 9, 2023

Annual General meeting
Tuesday, March 15, 2022

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Telephone conference
November 11, 2021, at 16.30 (CET)

Telephone numbers:
Sweden: +46 8 505 583 52
United Kingdom: +44 333 300 92 73
United States: +1 646 722 49 57
Belgium: +32 262 005 47
Denmark: +45 787 232 51
France: +33 170 750 719
Germany: +49 692 222 391 65
Norway: +47 239 636 88
Switzerland: +41 225 805 976
Netherlands: +31 207 219 496

Link to the webcast: https://financialhearings.com/event/14002

The Board and the CEO certify that the interim report gives a true and fair view of the company's and the Group's operations, position and results, and describes significant risks and uncertainties that the company and the companies making up the Group face.

Lund November 11, 2021

Carl Borrebaeck
Chairman of the board

Hans Johansson
Board member

Ann-Christine Sundell
Board member

Christofer Sjögren
Board member

Mimmi Ekberg
Board member

Peter Høngaard Andersen
Board member

Martin Møller
Board member

Patrik Dahlen
CEO

Auditor's Review Report

Introduction
I have reviewed the condensed interim financial information (interim report) of Immunovia AB (publ) as of September 30, 2021, , and the nine months period then ended. The Board of Directors and the CEO are responsible for the preparation and presentation of the interim report in accordance with IAS 34 and the Swedish Annual Accounts Act. My responsibility is to express a conclusion on this interim report based on my review.

Scope of the review
I conducted my review in accordance with the International Standard on Review Engagements ISRE 2410, Review of Interim Report Performed by the Independent Auditor of the Entity. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing, ISA, and other generally accepted auditing standards in Sweden. The procedures performed in a review do not enable me to obtain assurance that would make me aware of all significant matters that might be identified in an audit. Therefore, the conclusion expressed based on a review does not give the same level of assurance as a conclusion expressed based on an audit.

Conclusion
Based on my review, nothing has come to my attention that causes me to believe that the interim report is not prepared, in all material respects, in accordance with IAS 34 and the Swedish Annual Accounts Act, regarding the Group, and with the Swedish Annual Accounts Act, regarding the Parent Company.

Lund November 11, 2021

Mats-Åke Andersson
Authorized Public Accountant

Glossary

Antigen - A foreign body substance that elicits a reaction of the immune system in contact with the organism. The substance may be a chemical substance, a protein or a carbohydrate.

Autoimmunity – Autoimmunity is the immune system's harmful attack on the body's own tissue, which can take the form of disease or rejection of organs during transplantation.

Benign – If a tumor is benign it means that the tumor is not dangerous and will not spread.

Bioinformatics – Bioinformatics is an interdisciplinary field in which algorithms are developed for the analysis of biological (especially molecular biology) data.

Biomarker – A biomarker can be defined as a biological response to a change caused by disease or foreign substance. Biomarkers can be used as early warning signs of biological changes in an organism.

CAP -College of American Pathologists. The CAP has deemed status under CLIA to accredit laboratories performing testing on specimens from human beings or animals, using methodologies and clinical application within the expertise of the program. Laboratories must be appropriately licensed to perform testing when required by law.

CLIA -Clinical Laboratory Improvement Amendments. The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA). The objective of the CLIA program is to ensure quality laboratory testing. All clinical laboratories must be properly certified to receive Medicare or Medicaid payments.

Discovery Trial – Research carried out in order to verify a special hypothesis.

Histology – Histology is the study of biological tissue.

Invasive – Invasive means to penetrate or attack. Invasive medical examinations refer to examinations that include any form of penetration through a hole in the body or surgical operation.

Malignant – Malignant tumors tend to worsen and become mortal. They are termed cancer, and thus differ from benign tumors.

Metastasis – A metastasis is a tumor that has spread to other organs.

Microarray – A microarray is a molecular biology test format for simultaneously measuring the relative concentrations of proteins.

Molecular Diagnosis – A collection of technologies used to analyze biological markers at the genomic and protein levels (i.e., the genetic code of individuals and how their cells express their genes as proteins in the body), using molecular biology for medical testing. These technologies are used to diagnose and monitor disease, detect the risk of disease and to determine which treatment is likely to work best for the individual.

NOD type 2 – Newly Onset Diabetes type 2.

NPV– Negative Predicted Value.

NSCLC – Non-Small Cell Lung Cancer, the most common type of lung cancer, 80-85% of all lung cancer cases.

Palliative care – Palliative care is administered when the patient's disease is beyond the ability to cure. The purpose of palliative care is to provide support to patients and families using both psychological and medical practices.

PanDIA-1 – Prospective trial for the diabetes risk group of patients aged over 50 recently diagnosed with type-2 diabetes.

PanFAM-1 – Prospective trial for familiar and hereditary risk groups.

Pancreatologist – Doctor specializing in diseases relating to the pancreas.

PanSYM-1 – Prospective trial for early symptom risk groups.

PDAC – Pancreatic ductal adenocarcinoma, the most common form of pancreatic cancer.

Prospective trial – A trial in which a group of individuals is studied and followed often for a long time to see how a particular disease develops. A prospective trial is used to study the relationship between different risk factors and a certain disease. You follow individuals with and without risk factors going forwards over time. At the end of the trial, the proportion of individuals in the two groups who developed disease is compared.

Proteomics – Proteomics is a branch of biology and includes surveys of large amounts of data about proteins.

Reproducibility – Within the field of statistics, reproducibility is described as the correlation between results from repeated measurements performed by different observers with different instruments of the same type, which measurements are performed in order to reject any measurement error due to materials and personnel.

Resectable – Able to be removed by surgery.

Retrospective study – A study in which the focus is on something that has happened in the past, i.e. using historic data. This form of study starts with the answer, i.e. it is known which individuals became ill and which did not.

Screening – Screening refers to medical examinations to identify a disease. It is normally carried out before the patient has exhibited obvious symptoms.

Self-pay customers – Patients or organizations that pay without reimbursement from insurance companies or authorities.

Sensitivity – Sensitivity is a statistical measure of the reliability of a binary diagnostic test and the probability that a generated positive result is correct.

Serum – A serum is a transparent yellowish liquid obtained by allowing the blood to clot, and then removing the blood cells and the coagulation proteins. Serum contains proteins, including antibodies.

Specificity – Specificity is a statistical measure of the reliability of a binary diagnostic test and the probability that the generated negative result is de facto negative.

Immunovia in brief

Immunovia's vision is to revolutionize blood-based diagnostics and increase survival rates for patients with cancer. By developing and commercializing non-invasive blood tests, more patients can receive a timely diagnosis that can lead to improved treatment outcomes. Our initial area of focus is pancreatic cancer, which has a very poor prognosis as it is normally detected when the patient has only months to live. Immunovia has launched the world's first blood test dedicated to early detection of pancreatic cancer in the USA with the aim of improving the outlook for these patients.

Cancer is a leading and growing cause of death around the world and in 2020 resulted in the deaths of 10 million people[1]. Early detection of cancer and effective treatments are critical in addressing this challenge. Immunovia's expertise in blood-based biomarkers are used to develop tests to detect cancers with a significant medical need. In this way, Immunovia contributes to hope and improved outcomes for these patients.

IMMray™ PanCan-d enables diagnosis of patients with pancreatic cancer before symptoms are noted (stages I and II).

First commercial test

The first test that Immunovia has developed is a blood test for the early detection of pancreatic cancer. Available in the USA, this is the first time that patients with hereditary and familial risk of pancreatic cancer have a possibility for continued surveillance using a simple blood test. Because of its non-specific symptoms, most patients receive their diagnosis at a late stage when surgery is no longer an option. When detected too late very few patients live five years after their diagnosis. Pancreatic cancer is becoming the third deadliest form of cancer.

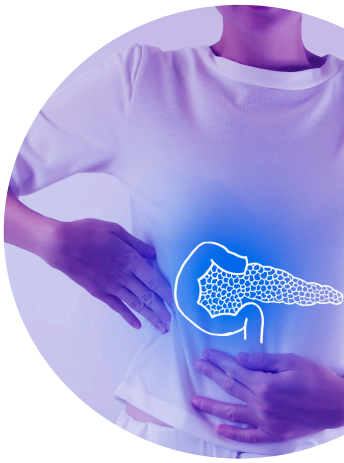
Early detection of pancreatic cancer is therefore crucial for increasing the survival rate of this patient group, when found at an early stage the five year survival increases tenfold. Other diagnostic methods available, such as MRI, CT and EUS, are expensive, invasive and require healthcare personnel with specialist knowledge. With Immunovia's more cost-effective and non-invasive blood test, more high-risk individuals can be tested and surveilled.

Large addressable market

As a Laboratory Developed Test, Immunovia markets the test exclusively through its subsidiary Immunovia Inc, which has its CLIA-certified laboratory located outside Boston, Massachusetts. The test is initially available for individuals to purchase out-of-pocket until sales with reimbursement start, which is expected to occur late 2022.

Immunovia focus on a successful commercialization in the USA as the largest market for non-invasive cancer tests. Using its own sales organization, Immunovia is engaging with the leading university hospitals, established surveillance programs and national centers for pancreatic diseases, other large hospitals and healthcare facilities, as well as local hospitals.

The addressable market in the USA for the detection of pancreatic cancer is over USD 4 billion. Immunovia has a long-term goal of achieving a market share of 30 percent once reimbursement has been achieved. In addition to the USA, Immunovia aims to launch the test in suitable markets in Europe and Asia with the aim of providing global access to the test.



It is estimated that early detection of pancreatic cancer would increase the five-year survival rate up to 50 percent.

Core competency in biomarker study design

Immunovia has a deep understanding of pancreatic cancer disease and diagnosis, with a strong connection to the pancreatic cancer community, having the world's largest network of key opinion leaders in pancreatic cancer. This has enabled Immunovia to develop and commercialize diagnostics with unmatched clinical performance.

Through the work in pancreactic cancer, Immunovia has extensive experience and expertise in designing clinical studies for biomarker discovery and validation. Immunovia's employees understand the importance of standardized sample collection, statistical design and bioinformatics for translating discoveries into diagnostic assays in Immunovia's CLIA certified laboratory.

Immunovia's core competences are transferable to other types of cancer in the pipeline.

1. Source: Ferlay J, Ervik M, Lam F, Colombet M, Mery L, Piñeros M, et al. Global Cancer Observatory: Cancer Today. Lyon: International Agency for Research on Cancer; 2020 (https://gco.iarc.fr/today, accessed February 2021).