

First product launched in US, well positioned for market penetration

Fourth quarter

- Net sales amounted to kSEK 305 (152) divided between sales of tests kSEK 278 (0) and royalties kSEK 27 (152)
- Net earnings amounted to MSEK -47 (-46) and earnings per share before and after dilution were SEK -2.08 (-2.04)
- Cash flow from operating activities amounted to MSEK -50 (-36)
- Cash and cash equivalents at the end of the period amounted to MSEK 287 (468)
- In December PanDIA-1, the world's most comprehensive prospective study for the early detection of pancreatic cancer in the new onset diabetes type 2 high risk group, achieved the milestone of having collected 6 000 samples, the targeted sample size
- Immunovia honored World Pancreatic Cancer Day by a grand opening celebration of the US Subsidiary Immunovia, Inc

 After year-end, on January 20, Philipp Mathieu assumed the role as Acting CEO and President. He replaced Patrik Dahlen who announced his intention to step down in November

January-December

- Net sales amounted to kSEK 844 (362) divided between sales of tests kSEK 344 (0) and royalties kSEK 500 (362)
- Net earnings amounted to MSEK -156 (-146) and earnings per share before and after dilution were SEK -6.89 (-6.84)
- Cash flow from operating activities amounted to MSEK -153 (-121)
- Cash and cash equivalents at the end of the period amounted to MSEK 287 (468)

"Immunovia's IMMray™ PanCan-d, is the first ever blood test dedicated to early detection of pancreatic cancer with best-in-class performance, as compared to standard of care testing methods. This positions the company at the absolute forefront of new pancreatic cancer surveillance testing"

Philipp Mathieu, Acting CEO and President, Immunovia AB

Key indicators

SEK thousand unless otherwise stated	2021 Oct-Dec	2020 Oct-Dec	2021 Full year	2020 Full year
Net sales	305	152	844	362
Operating earnings/loss	-50 877	-38 112	-166 628	-134 343
Earnings before tax	-47 129	-46 120	-155 966	-146 033
Net earnings	-47 129	-46 120	-155 966	-146 033
Earnings per share before dilution (SEK)	-2.08	-2.04	-6.89	-6.84
Earnings per share after dilution (SEK)	-2.08	-2.04	-6.89	-6.84
Equity ratio (%)	88	91	88	91
Number of shares at the end of the period	22 631 581	22 631 581	22 631 581	22 631 581

CEO's comments

Immunovia's IMMray[™] PanCan-d, is the first ever blood test dedicated to early detection of pancreatic cancer with best-in-class performance, as compared to standard of care testing methods. This positions the company at the absolute forefront of new pancreatic cancer surveillance testing.

The commercial launch of IMMray™ PanCan-d in the US in August 2021 was a major milestone in Immunovia's mission to change the testing paradigm and increase the survival rates for pancreatic cancer patients. In targeting pancreatic cancer, which is expected to become the second leading cause of cancer-related deaths by 2040 in the US, Immunovia is the front-runner in addressing a huge and increasing unmet medical need. With a global 5-year survival rate today of only 5–9 percent, pancreatic cancer is today the third deadliest form of cancer, taking more lives than e.g, breast cancer, prostate cancer, and leukemia. Early detection as provided by Immunovia has the potential to increase the five years survival rate up to 50 percent.

I feel honored to lead Immunovia as CEO in this pivotal phase of the company's development as it transitions from a research company to an early-commercial company establishing itself as a leader in the field of early detection of pancreatic cancer.

In my initial weeks with Immunovia, I have witnessed the passion and professional excellence of our employees in Europe and the US. The team has industry-leading competences, is hugely dedicated and energized by its commitment to the mission of improving the survival rates of pancreatic cancer.

In constructive conversations with both the Board and employees I had the opportunity to make an initial assessment of the company's situation and the road which lies ahead. Immunovia's road ahead requires focus and strategic direction, however, I feel very confident that we will succeed.

We are in the middle of refining the strategic roadmap for the company over the next 12-18 months. I nevertheless would like to take the opportunity to already now provide an update on some of the company's most important projects:

- Ensuring reimbursement coverage for IMMray™ PanCan-d in the US will enable an increasing population of patients with a family history of pancreatic cancer in the US to get insurance coverage for testing. During 2021 Immunovia has further refined its reimbursement plan in collaboration with Precision for Medicine Inc, a team of leading experts in the field of diagnostic reimbursement in the US. Through our extensive payer surveys and targeted research publications we feel confident about Immunovia's ability to achieve positive reimbursement coverage decisions.
- The results of the blinded validation study of IMMray™ PanCan-d were announced on the 29th of March 2021. The peer-reviewed study results have already been accepted for publication by the Journal for Clinical and Translational Gastroenterology and the full study will be published in the coming weeks. This is an important step for attaining the PLA-code (Proprietary Laboratory Analysis) and moves us a step closer towards our goal of reimbursement in the US.
- PanFAM-1 is a multicenter prospective study for early detection of pancreatic cancer in individuals presenting with hereditary/familial risk factors. The main goal of the study is to provide actionable information to the clinicians regarding diagnosis of pancreatic cancer. Furthermore, the study will deliver clinical performance data for IMMray™ PanCan-d from a cohort of highrisk asymptomatic individuals compared with currently used surveillance methods i.e. imaging technologies. We have concluded sample collection across the 23 global study sites (starting December 2017 and ending April 2021) with a total of over 3 000 samples from 1 265 subjects. Currently, these samples are being analyzed at our CLIA laboratory in Marlborough and the results will be made public in mid 2022.

- PanDIA-1 started in January 2018 as the world's most comprehensive prospective sample collection for early detection of pancreatic cancer in the new onset diabetes type 2 high risk group. In December 2021, 6 000 samples had been collected from new onset diabetes patients, of which approx. 5 100 are above the age of 50 years. The samples were collected from new onset diabetic patients starting at the time of diabetes diagnosis over a 3-year period, the time span during which patients with new-onset diabetes type 2 have up to 6-8 times higher risk of developing pancreatic cancer than the normal population. In collaboration with ANDIS (All New Diabetics in Skåne) and ANDIU (All New Diabetics in Uppsala) the team is currently obtaining the associated clinical records related to the collected samples. An update will be provided during Q2 this year.
- PanSYM-1 started in November 2018 as a prospective validation study for the early diagnosis of pancreatic cancer in patients with nonspecific but concerning symptoms and other risk factors. The sample collection was conducted at the University College Hospital, London, and The Royal Free Hospital. The study was intended to demonstrate that IMMray™ PanCan-d was equal or better than the standard of care diagnostic pathway. The target sample collection size was 2 000, which was not achieved due to the impact of Covid-19 on patient attendance at the hospitals enrolled in the study. Due to the shortage of samples, the primary endpoints, sensitivity, and specificity of the IMMray™ PanCan-d assay as compared to the standard of care could not be evaluated as intended. Study samples were instead included in the Commercial Test Model and other studies of IMMray™ PanCan-d. In particular more than 200 patient samples from PanSYM-1 were used in the performance study announced on 29th of March 2021 that showed 92 percent specificity and 80 percent sensitivity in discriminating early stage I/II pancreatic cancer from high-risk symptomatic patients. This underscores the promising potential IMMray™ PanCan-d has in this patient group. We are currently investigating our options to fully validate the promising results for IMMray™ PanCan-d in the symptomatic risk group. At the same time, we continue to work with our Key Opinion Leader-network to focus on pancreatic cancer detection in symptomatic patients.
- **IMMray**™ **in other indications** continue to be in the discovery phase. We are currently assessing options to maximize the potential of each of our discovery programs in other cancer indications and autoimmune diseases.

Following the commercial launch in the US, the near-term focus of Immunovia will be the US market, but we also see a strong potential in other markets and we continue to review market access and prioritize according to its potential.

Looking forward into 2022, the initial launch of IMMray™ PanCan-d has been very positively received by early adopters amongst both doctors and patients in the US, who see it as a highly needed addition to the diagnostic tool set for pancreatic cancer as exemplified by the following physician quotes:



Dr. Rajesh Keswani, Gastroenterologist, Northwestern University, remarks "Patients seem to be very pleased with the testing, and all my patients undergoing testing have been appreciative of the opportunity to get this testing and certainly those with normal testing have expressed relief with this further reassurance. As of now, I think the IMMray™ PanCan-d test is another step towards reducing mortality from pancreatic cancer."



Geoffrey M. Burns MD, Family Physician at the Renaissance Family Medicine of Wellesley, remarks: "Given the high specificity of the IMMray™ PanCan-d test, I feel I can offer reassurance and peace of mind to my patients who are concerned about their family history of pancreatic cancer. I appreciate the streamlined process for ordering the test and the ease of receiving the results."



Steven Rubin M.D., Family Physician from Paramus, New Jersey, says: "The test developed by Immunovia, IMMray™ PanCan-d, is an important diagnostic tool to assist in early detection in high-risk patients for Pancreatic carcinoma, along with MRCP/MRI and endoscopic ultrasound with biopsy." He continues, "I personally had the IMMray™ PanCan-d done and probably will have this done alternating with the other above mentioned diagnostic modalities for surveillance of my medical condition. Anything that can be done to find early stage 1 or 2 disease with the potential for cure of pancreatic carcinoma which has a high mortality, is warranted and imperative."

We expect the volumes of tests to significantly increase once insurance coverage is available, with the ambition to have initial coverage in place towards the end of 2022. Until then we see self-pay tests to continue at moderate volumes, which are no indication for the full potential of IMMray™ PanCan-d, as seen with comparable diagnostics tests pre reimbursement in the US.

In short, Immunovia is well positioned as the frontrunner in the early detection of pancreatic cancer, and I very much look forward to working with Immunovia's employees and its Board as well as our community including Key Opinion Leaders to make IMMrayTM PanCan-d available to as many patients as possible. The company's mission of increasing the survival rates for this lethal cancer are a hugely motivating and driving force for all of us.

I also want to thank our shareholders for their trust as well as continued support.



February 17, 2022 Philipp Mathieu, Acting CEO and President, Immunovia AB

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About the report

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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-DECEMBER 2021

The Group's performance over the period

Net sales

Net sales for Q4 2021 amounted to kSEK 305 (152) and are divided between sales of tests kSEK 278 and royalties kSEK 27. For the period January to December 2021, sales amounted to kSEK 844 (362), divided between sales of tests kSEK 344 (0) and royalties kSEK 500 (362).

Earnings

The net loss for Q4 2021 amounted to MSEK -47 (-46). Depreciation has increased due to the depreciation of the capitalization costs that started in Q2 2021. For the full year 2021, the net loss was MSEK -156 (-146). Compared with the previous year, the results were negatively affected by the capitalization of costs being stopped and depreciation on these being started, as well as positively affected by net financial items for the year being positive.

Other external costs and personnel costs fell by MSEK 3 during Q4 compared with the corresponding period last year and totaled MSEK 43. The fall is due to a reduction in the costs of clinical trials.

Research & Development

Total R&D costs for Q4 2021 amounted to MSEK 10 (11), equivalent to 21 percent (23) of the Group's total operating expenses.

Financing and cash flow

Cash flow for Q4 2021 from operating activities amounted to MSEK -50 (-36). The corresponding cash flow for the period January to December 2021 was MSEK -153 (-121).

Cash and cash equivalents as of December 31, 2021, amounted to MSEK 287 (468).

Equity at the end of the period amounted to MSEK 434 (599) and the equity ratio was 88 percent (91).

The company management makes the assessment that, based on the cash of MSEK 287 and the financing plans that exist, the company's continued operations are ensured.

Investments

In Q4 2021, intangible assets totaling kSEK 178 (10) were acquired, consisting of capitalized development expenditure of kSEK 0 (10) and patents kSEK 178 (455). During the period January to December 2021, intangible assets totaling MSEK 21 (43) were acquired, consisting of capitalized development expenditure MSEK 18 (40), patents MSEK 3 (2) and other intangible assets 0 (1).

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 kSEK 531 (694) during Q4 2021. For the period January – December 2021, investments in tangible fixed assets amounted to MSEK 3 (4).

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

Employees

The average number of employees during Q4 2021 was 66 (63) and at the end of the period the number of employees was 65 (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	2 948 228	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 December 31, 2021

Shareholders	No. of shares	Share (capital and votes)
Carl Borrebaeck	1 709 900	7.56%
Ålandsbanken ADP (Finland) Svensk filial	1 439 415	6.36%
Försäkringsbolaget Avanza Pension	1 384 980	6.12%
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	640 784	2.83%
RBC Investor Services Bank S.A.	571 432	2.52%
Nordnet Pensionsförsäkring	411 309	1.82%
Ten largest owners	9 233 032	40.80%
Others	13 398 549	59.20%
Total	22 631 581	100.00%

Incentive schemes

Immunovia has three outstanding warrant schemes comprising 359 500 options with the right to subscribe for 359 500 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 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 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			359 500		17 975	712 000

Consolidated income statement, summary

	2021	2020	2021	2020
SEK thousands	Oct-Dec	Oct-Dec	Full year	Full year
Operating income etc				
Net sales	305	152	844	362
Other operating income	39	325	113	624
Total operating income	344	477	956	986
Operating expenses				
Raw materials and consumables	-859	0	-3 533	0
Other external expenses	-17 056	-21 130	-82 607	-91 147
Personnel costs	-26 136	-24 657	-79 487	-73 968
Capitalized work for own account	0	9 684	18 502	40 020
Amortization of tangible and intangible assets	-6 192	-2 450	-19 063	-9 763
Other operating expenses	-978	0	-1 397	-471
Total operating expenses	-51 221	-38 589	-167 584	-135 329
Operating earnings/loss	-50 877	-38 112	-166 628	-134 343
Profit/loss from financial items				
Financial income	4 096	227	14 459	5 692
Financial expenses	-348	-8 235	-3 797	-17 382
Total financial items	3 748	-8 008	10 662	-11 690
Earnings/loss after financial items	-47 129	-46 120	-155 966	-146 033
Income tax	0	0	0	0
Earnings/loss for the period	-47 129	-46 120	-155 966	-146 033
Earnings per share before dilution (SEK)	-2.08	-2.04	-6.89	-6.84
Earnings per share after dilution (SEK)	-2.08	-2.04	-6.89	-6.84
Average number of shares	-2.06 22 631 581	22 630 948	22 631 581	21 340 672
Number of shares at year's end	22 631 581	22 630 946	22 631 581	22 631 581

Consolidated comprehensive income, summary

	2021	2020	2021	2020
SEK thousands	Oct-Dec	Oct-Dec	Full year	Full year
Earnings/loss for the period	-47 129	-46 120	-155 966	-146 033
Items that may be reclassified later in the income statement				
Exchange rate differences for foreign net investment	-3 381	6 609	-9 973	9 317
Other earnings/loss for the period	-3 381	6 609	-9 973	9 317
Comprehensive income for the period	-50 510	-39 511	-165 939	-136 716

Consolidated financial position, summary

577.	2021	2020
SEK thousands	Dec 31	Dec 31
ASSETS		
Fixed assets	4 47 4 47	474075
Intangible fixed assets	147 147	134 935
Tangible fixed assets	46 528	48 701
Financial fixed assets	3 033	2 746
Total fixed assets	196 707	186 382
Current assets		
Inventory	2 150	0
Accounts receivable	72	0
Other short term receivables	7 474	6 334
Cash and cash equivalents	287 406	468 462
Total current assets	297 102	474 796
TOTAL ASSETS	493 809	661 178
EQUITY AND LIABILITIES		
Equity		
Share capital	1 132	1 132
Other contributed capital	1 015 730	1 015 291
Translation reserve	-1 658	8 315
Retained earnings incl. total comprehensive income	-581 300	-425 334
Total equity	433 903	599 404
Long-term liabilities		
Interest-bearing liabilities	27 156	27 988
Total long-term liabilities	27 156	27 988
Current liabilities		
Interest-bearing liabilities	6 106	5 143
Other liabilities	26 644	28 643
Total current liabilities	32 750	33 786
TOTAL EQUITY AND LIABILITIES	493 809	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			9 317	-146 033	-136 716
Transactions with owners in their capacity as owners					
New share issue	149	403 704			403 853
Share issue cost		-25 337			-25 337
Closing balance December 31, 2020	1 132	1 015 290	8 315	-425 334	599 404
Comprehensive income for the period			-9 973	-155 966	-165 939
Transactions with owners in their capacity as owners					
Deposited share warrant premiums		440			440
Closing balance December 31, 2021	1 132	1 015 730	-1 658	-581 300	433 903

Consolidated cash flow statement, summary

SEK thousands	2021 Oct-Dec	2020 Oct-Dec	2021 Full year	2020 Full year
Operating activities			,	,
Operating earnings/loss	-50 876	-38 112	-166 628	-134 343
Adjustment for items not included in cash flow	7 297	2 666	20 048	9 945
Interest received	152	227	711	577
Interest paid	-348	-335	-1 441	-1 415
Tax paid	0	0	0	0
Cash flow from operating activities before changes in working capital	-43 775	-35 554	-147 310	-125 236
Cash flow from changes in working capital				
Change in inventory	-749	0	-2 038	0
Change in operating receivables	540	921	-1 098	-579
Change in operating liabilities	-6 126	-1 124	-2 202	5 111
Cash flow from operating activities	-50 110	-35 757	-152 648	-120 704
Investment activities				
Investment in intangible assets	-178	-10 103	-21 083	-43 497
Investment in tangible assets	-531	-694	-3 101	-3 998
Investment in financial fixed assets	0	0	0	0
Sale of fixed assets	170	537	358	537
Cash flow from investment activities	-539	-10 260	-23 826	-46 958
Financing activities				
Amortization of leasing liability	-1 442	-1 245	-5 709	-4 936
New share issue	0	5 842	0	378 516
Received warrants premiums	0	0	440	0
Cash flow from financing activities	-1 442	4 597	-5 269	373 580
Cash flow for the period	-52 091	-41 420	-181 743	205 918
Cash and cash equivalents at start of period	339 165	510 593	468 462	263 345
Exchange rate difference in cash and cash				
equivalents	332	-711	687	-801
Cash and cash equivalents at end of period	287 406	468 462	287 406	468 462

Consolidated key indicators

	2021 Full year	2020 Full year	2019 Full year	2018 Full year	2017 Full year
0 1 1 1 (57)	•		-	-	•
Operating earnings/loss (SEK 000)	-166 628	-134 343	-114 248	-87 709	-45 520
Earnings/loss for the year (SEK 000)	-155 966	-146 033	-114 521	-86 539	-45 232
Earnings per share before dilution (SEK)	-6.89	-6.84	-5.85	-4.67	-2.67
Earnings per share after dilution (SEK)	-6.89	-6.84	-5.85	-4.67	-2.67
R&D expenses (SEK 000)	-42 850	-48 078	-34 273	-26 048	-24 041
R&D expenses as percentage of operating expenses (%)	24	29	26	23	34
Cash and cash equivalents at the period's end (SEK 000)	287 406	468 462	263 345	386 136	192 425
Cash flow from operating activities (SEK 000)	-152 648	-120 704	-91 952	-84 111	-46 318
Cash flow for the period (SEK 000)	-181 743	205 918	-122 797	193 680	-66 661
Equity (SEK 000)	433 903	599 403	357 604	461 953	236 795
Equity per share (SEK)	19.17	26.49	18.19	23.65	13.67
Equity / assets ratio (%)	88	91	85	97	94
Average number of employees	67	63	48	39	30
Average number of employees in R&D	23	21	19	17	16

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

	2021	2020	2021	2020
SEK thousands	Oct-Dec	Oct-Dec	Full year	Full year
Operating income etc.				
Net sales	5 068	152	9 987	362
Capitalized work for own account	0	9 648	18 502	40 020
Other operating income	29	143	96	451
Total operating income	5 637	9 943	28 585	40 833
Operating expenses				
Raw material and consumables	-1 217	0	-2 084	0
Other external expenses	-28 555	-22 105	-87 841	-89 134
Personnel costs	-14 018	-19 351	-48 100	-48 835
Amortization of intangible and				
tangible fixed assets	-4 299	-839	-11 685	-3 310
Other operating expenses	-977	0	-1 397	-471
Total operating expenses	-49 066	-42 295	-151 107	-141 750
Operating earnings/loss	-43 430	-32 352	-122 522	-100 917
Operating expenses				
Financial incomes	5 160	1 027	17 869	7 982
Financial expenses	0	-7 900	-2 356	-15 967
Total financial items	5 161	-6 873	15 513	-7 985
Earnings/loss after financial items	-38 270	-39 225	-107 009	-108 902
Allocations				
Group contributions received	437	88	437	88
Total allocations	437	88	437	88
Earnings/loss before tax	-37 832	-39 137	-106 572	-108 814
Income tax	0	0	0	0
Earnings/loss for the period	-37 832	-39 137	-106 572	-108 814

Parent company's comprehensive income, summary

	2021	2020	2021	2020
SEK thousands	Oct-Dec	Oct-Dec	Full year	Full Year
Earnings/loss for the period	-37 832	-39 137	-106 572	-108 814
Other earnings/loss for the period	0	0	0	0
Comprehensive income for the period	-37 832	-39 137	-106 572	-108 814

Parent company's balance sheet, summary

	2021	2020
SEK thousands	Dec 31	Dec 31
ASSETS		
Fixed assets		
Intangible fixed assets	145 778	133 550
Tangible fixed assets	10 185	11 384
Financial fixed assets	328	328
Total fixed assets	156 291	145 262
Current assets		
Inventory	1 722	0
Receivables from Group companies	147 557	85 556
Current receivables	3 951	3 850
Prepaid expenses and accrued income	2 594	3 088
Cash and cash equivalents	279 191	461 730
Total current assets	435 015	554 224
lotal current assets	433 013	334 224
TOTAL ASSETS	591 306	699 486
EQUITY AND LIABILITIES		
Equity Restricted equity	1 132	1 132
Restricted equity	117 177	105 589
Fund for development expenses Total equity and liabilities	118 309	105 369
Total equity and liabilities	110 309	100 / 21
Non-restricted equity		
Premium fund	0	378 367
Retained earnings including comprehensive income	447 277	187 070
	447 277	565 437
Total non-restricted equity	117 277	505 .57
Total non-restricted equity Total equity	565 586	672 158
Total equity		
Total equity Current liabilities	565 586	672 158

Parent company's cash flow statement, summary

	2021	2020
SEK thousands	Full year	Full year
Operating activities		
Operating earnings/loss	-122 522	-100 917
Adjustment for items not included in cash flow	12 542	3 221
Interest received	711	576
Interest paid	-3	-3
Tax paid	0	0
Cash flow from operating activities before changes in working capital	-109 272	-97 123
Cash flow from changes in working capital		
Change in inventory	-1 721	0
Change in operating receivables	-47 181	-40 715
Change in operating liabilities	-794	4 420
Cash flow from operating activities	-158 968	-133 418
Investment activities		
Investment in intangible fixed assets	-21 235	-42 882
Investment in tangible fixed assets	-2 522	-2 645
Investment in financial fixed assets	0	-25
Sale of fixed assets	186	537
Cash flow from investment activities	-23 571	-45 015
Financing activities		
New share issue	0	378 516
Cash flow from financing activities	0	378 516
Cash flow for the period	-182 539	200 083
Cash and cash equivalents at start of period	461 730	261 647
Cash and cash equivalents at period's end	279 191	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, kSEK 344 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 December 31, 2021 was MSEK 291 (471).

Liquidity risk

Prudent liquidity risk management implies maintaining sufficient cash or agreed credit options to close market positions. Based on the cash of MSEK 287 and the existing financing plans, the company's continued operations are ensured according to the Board's assessment.

OTHER INFORMATION

Review

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

Financial calendar

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

Thursday, April 7, 2022 Annual Report 2021 will be available from second week of March.

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The information in this report is information that Immunovia AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 08:30 am CET on February 17, 2022.

Conference call

Immunovia will hold a teleconference at 10:00 am CET on February 17 with President and CEO Philipp Mathieu.

To take part of the presentation, please dial one of the numbers or watch via the web link below.

Sweden: +46 8 50 55 83 53

United Kingdom: +44 33 33 00 92 62

United States: +1 63 19 13 14 22, PIN: 24290298#

Belgium: +32 26 20 05 47 Denmark: +45 78 15 01 08 France: +33 17 07 50 720 Germany: +49 69 22 22 20 377 Norway: +47 23 96 36 88 Switzerland: +41 22 56 75 632

Netherlands: +31 10 71 29 162

Link to the webcast: https://financialhearings.com/event/14003

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 February 17, 2022

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

Philipp Mathieu *CEO*

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 – New 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 people¹. 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.

First commercial test

The first test that Immunovia has commercialized 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 recognized as 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 at earliest towards the end of 2022.

Immunovia focuses 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.

Core competence 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 pancreatic 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 applicable 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).



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



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

