

## (f) immunovia





## **Key Indicators**

SEK thousand unless otherwise stated	2020 Oct-Dec	2019 Oct-Dec	2020 Full year	2019 Full year
Net sales	152	45	362	356
Operating earnings	-38,112	-29,584	-134,343	-114,248
Earnings before tax	-46,120	-32,616	-146,033	-114,517
Net earnings	-46,120	-32,616	-146,033	-114,521
Earnings per share before dilution (SEK)	-2.04	-1.66	-6.84	-5.85
Earnings per share after dilution (SEK)	-2.04	-1.66	-6.84	-5.85
Equity ratio (%)	91	85	91	85
Number of shares at the end of the period	22,631,581	19,654,853	22,631,581	19,654,853

## Significant events October-December 2020

Immunovia presented the results of the verification study for IMMray™ PanCan-d at a webinar on October 26, 2020. The results showed an high accuracy of 94% when it comes to differentiating pancreatic cancer patients (Pancreatic ductal adenocarcinoma or PDAC) from healthy controls and 91% in differentiating early stages I and II of pancreatic cancer vs. all controls. The control tests included patients with non-specific but worrying symptoms, including type II diabetes and healthy people.

Immunovia's new CEO Patrik Dahlen took office on November 1. Patrik Dahlen has extensive experience from previous positions as CEO of several diagnostic companies and succeeds Mats Grahn, who over the past seven years has successfully steered the company from the development phase to becoming a commercial company.

Immunovia presented additional data from the verification study. As reported earlier, the results showed an accuracy of 94% in distinguishing stage I/II PDAC patients from healthy controls. Other test results for this comparison showed: specificity of 99%, a sensitivity of 78% and a high NPV of 99.3%. Stage I/II PDAC patients could be distinguished from all controls with 91% accuracy, with a reported specificity of 93% and a sensitivity of 78%. The analysis was performed with the signature that is now locked for clinical use commercially.

Immunovia conducted Webinar in the series on IMM-ray™ PanCan-d: This third webinar presented the results of the verification study for IMMray™ PanCan-d and the clinical use of the test, including feedback from experts on pancreatic cancer and pancreatic diseases.

## Significant events after the period's end

Immunovia announced the publication of a scientific article in which the IMMRay™ platform showed good results in the differential diagnosis of hard-to-assess autoimmune diseases. Lead author Mattias Ohlsson, Professor of Computational Biology and Biological Physics at Lund University comments:

"In this study we were able to classify the included individual, IRD (Inflammatory Rheumatic Diseases) clinical states with high accuracy, We believe that this data supports the use of IMMray $^{\text{TM}}$  to reflect the biological complexity of autoimmune diseases."

Immunovia presented an update on the status of the company's operations and as previously reported (webinar on December 17, 2020), Immunovia will initiate the start of sales of the company's first test, IMMray™ Pan-Can-d. The test has been developed for early detection of pancreatic cancer.

**Immunovia's PanFAM-1 prospective study** gathers over 3000 familial hereditary pancreatic cancer risk samples and will be analysed In the second half of 2021.

## CEO's statement

Immunovia is approaching commercial breakthrough: A sales start is planned for the first quarter of 2021. We look forward to helping patients through early detection of pancreatic cancer.

All Immunovia employees are incredibly proud of the progress we have made in 2020, especially with regard to the October 2020 milestone when we were able to document 94 percent accuracy for IMMray™ PanCan-d, the company's first blood test for the diagnosis of pancreatic cancer in the early stages of the disease when it is still possible to conduct surgery. The result opens the way for significantly improved care and survival of patients suffering from this deadly disease.

The entire business is now focusing wholeheartedly on reaching the introduction of our blood test in the first quarter of 2021.

As 2020 ends, we continue to take major steps forward to launch our first diagnostic test IMMray™ PanCan-d on the U.S. market in the first quarter of 2021. We concluded the year with extraordinarily good results from the Verification Study, confirming the unique ability of our product to differentiate pancreatic cancer stages I to IV compared to clinically relevant control groups (i.e. patients with non-specific but worrying symptoms, including type II diabetes, as well as healthy individuals). Like the rest of the world, we had several challenges in 2020 due to the COVID-19 pandemic, which led to closing the Immunovia Dx laboratory in the United States for several months during the "lockdown" period. Additionally, the clinicians involved in our clinical studies have had difficulty collecting relevant samples for long periods of time. However, despite the difficulties, our staff showed strong commitment and perseverance to find solutions for achieving our milestones.

In 2020 a successful share issue was carried out. Currently, Immunovia is in a strong financial position in preparation for a crucial milestone for the business – the launch of the first commercial test, IMMray™ PanCan-d for early detection of pancreatic cancer.

## Early detection is crucial for improving treatment outcomes in cancer care

Cancer diseases have recently overtaken cardiovascular diseases as the leading cause of death in the industrialized world. With the globally increased burden of cancer, the need and demand to diagnose cancer at an early stage is rapidly growing. Healthcare systems all over the world are being transformed towards applying more proactive methods, including more preventive care, early diagnosis and personalized treatments. Regulatory authorities are implementing processes for priority approvals and new value-based payment models are also being introduced.

Since pancreatic cancer is one of the deadliest forms of cancer and the diagnosis is often made too late, early detection is crucial. Globally, around 350,000 people are diagnosed each year and the figure is rising rapidly. An early-stage pancreatic cancer detection test, such as IMMray™ PanCan-d, has the potential to dramatically increase the survival rate for patients. Immunovia's goal is to make early diagnosis a priority for all stake holders.

## Intensified preparations for the launch in 2021

With one milestone remaining – a final validation study before the start of sales of IMMray™ PanCan-d in the first quarter of 2021, we are now stepping up the final preparations for launch. We have been successful in establishing a large network of world-renowned Key Opinion Leaders (KOL) and healthcare specialists. They have not only collaborated with us on how to use the test in practical clinical work, but also provided us with the necessary blood tests, collected in a real clinical environment, to test and validate our IMMray™technology. Immunovia's team in the United States and the laboratory in Marlborough, MA have implemented a logistics and distribution system that provides rapid test results, supporting all our US customers. We have established a scalable sales and marketing organization that caters for our top clinical customers across the United States. Collaborating with different patient organizations has also been a focus area for us, as they play an important role in creating awareness of the disease and supporting patients and their families.

## Successful results from the verification study pave the way for sales start during the first quarter 2021

As communicated thorough press releases and webinar during the third and fourth quarters, our verification study was successful. The study was conducted with signature and bioinformatics algorithms from the commercial test model study (CTMS). As reported, IMMray™ PanCan-d in combination with tumor marker CA 19-9, showed an accuracy of 94% when it comes to distinguishing stage I/II PDAC patients from *healthy controls*. We reported a specificity of 99% and a sensitivity of 78%, as well as a high NPV of 99.3% for this patient group.

There is an increasing need for early diagnosis of cancer from the perspective of all stakeholders in healthcare. Immunovia's technology is positioned to address and meet these needs.

## Programme with prospective clinical studies continues as planned

To validate the clinical benefit of IMMray<sup>™</sup> PanCan-d, especially important for obtaining reimbursement from insurance systems, Immunovia's three major prospective studies covering the three main risk groups for pancreatic cancer continued in 2020:

- Familial/Hereditary PanFAM-1 study,
- New diabetes diagnosis after the age of 50,"NOD type 2" PanDIA-1 study,
- Patients who show symptoms that may indicate pancreatic cancer PanSYM-1study.

These three clinical studies, among the largest studies in the world for these three risk groups, involve 30 cancer centers in the United States and Europe and over 10,000 individuals.

All three studies are proceeding according to plan. Interim results will be reported already in the second half of 2021

## Early stage development projects

In addition to our main focus on pancreatic cancer, Immunovia conducts early projects in other cancer applications and autoimmune diseases. These are in early stages of development ("Discovery Studies") and we are establishing Key Opinion Leader collaborations to gain access to expertise on clinical needs, as well as high-quality blood tests with clinical information represents these indications. These collaborations mark the most important key activity for succeeding in subsequent studies, results of which will be crucial for deciding on investing in further development phases ("Development Studies"), leading to product development, a much larger financial commitment than "Discovery studies". Since these project are part of our discovery program we do not set timelines for them.

## **New CEO**

As the new CEO, I am honoured to start serving Immunovia at this crucial and exciting time in the company's history. I believe that Immunovia is in a position to advance into a dominant market leader for blood-based diagnosis of pancreatic cancer and I look forward to the exciting further development of the company.

I would like to underline that Immunovia continues to set its goal to reach a long-term market penetration of 30 percent after achieving reimbursement with extensive geographical coverage. The current size of the addressable market for IMMray™ PanCan-d is estimated to exceed USD 4 billion in the EU and the US, from the three risk groups targeted by the company: hereditary/familial, differential diagnosis of early symptoms and recently diagnosed type II diabetes in individuals over 50 years of age. We look forward to continuing to work with healthcare providers around the world.

On behalf of the Board of Directors and the entire Immunovia Team, I thank you for your continued support for Immunovia's efforts to contribute to a positive impact on the lives of those at risk of pancreatic cancer.

n

February 2021 Patrik Dahlen CEO, Immunovia AB

## Table of contents



Group's performance over the period	5
Share information	6
Incentive scheme	7
Consolidated income statement in summary	8
Consolidated comprehensive income in summary	8
Consolidated financial position in summary	9
Change in consolidated equity in summary	10
Consolidated cash flow statement in summary	
Consolidated key indicators	12
Definitions	
Parent company's income statement in summary	14
Parent company's comprehensive income in summary	
Parent company's balance sheet in summary	15
Parent company's cash flow statement in summary	
Accounting principles	17
Glossary	20
Immunovia in brief	22

**About the report •** This information was submitted for publication February 17, 2021, kl. 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.

**Contact** Immunovia AB (publ), Medicon Village, Scheelevägen 8, 223 63 Lund, Sweden

• +46 (0)46-2756 000

• ir@immunovia.com

For further information please contact Patrik Dahlen, CEO

• patrik.dahlen@immunovia.com

## JANUARY-DECEMBER 2020

## The Group's performance over the period

## **Net sales**

• Net sales for Q4 2020 amounted to SEK 152,000 (45). For the period January-December 2020, sales amounted to SEK 362,000 (356). Sales mainly consist of royalties.

#### **Earnings**

• The net loss for Q4 2020 was SEK 46.12 million (-32.62). The loss for the year 2020 was SEK 146.03 million (-114,52). The net loss for Q4 2020 is greater because of increased costs, which are mainly due to increased activity with development and greater marketing and launch activities. Other external costs and personnel costs rose by SEK 32.22 million during the period January-December 2020 compared with the corresponding period last year and amounted to a total of SEK 165,12 million.

## **Research & Development**

• Research and development work is going according to plan. Total R&D costs for Q4 2020 amounted to SEK 10.88 million (10.73), which corresponds to 23% (31%) of the Group's total operating expenses.

## Financing and cash flow

• The cash flow from operating activities for Q4 2020 amounted to SEK -35.76 million (-22.65). The corresponding cash flow for the period January-December 2020 was SEK -120.70 million (-91.95). Cash and cash equivalents as of December 31, 2020 amounted to SEK 468.46 million (263.35).

Equity at the end of the period amounted to SEK 599.40 million (357.60) and the equity/assets ratio was 91% (85%).

The management believes that there is sufficient working capital to cover working capital needs, given the current business and development plan for around 2 years ahead.

## **Investments**

• In Q4 2020, intangible assets totaling SEK 10.10 million (9.05) were acquired, consisting of capitalized development expenditure, SEK 9.65 million (8.13), and patents SEK 455,000 (922).

During 2020, intangible assets totaling SEK 43.50 million (30,568) were acquired, consisting of capitalized development expenditure SEK 40.02 million (26.72), patents SEK 2.02 million (3,852) and other intangible assets SEK 1.45 million (0).

To the extent that the capitalized expenses are financed with decided and paid grants, a direct impairment is made of the capitalized expenses with the corresponding amount. In 2020, there were no grants received for development expenses. In the corresponding period last year SEK 291,000 was received in grants.

Investments in tangible fixed assets in the form of equipment were made during Q4 2020 of SEK 694,000, corresponding to the previous year's SEK 1.11 million. For the period January-December 2020, investments were made in tangible fixed assets of SEK 3.99 million (6.03).

No investments in financial assets were made during the year 2020.

## **Employees**

• The average number of employees during Q4 2020 was 63 (48) and at the end of the period the number of employees was 67 (49).

## 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 December 31, 2020

Shareholders	No. of shares	Share (capital and votes)
Carl Borrebaeck	1,709,900	7.56%
Ålandsbanken i ägares ställe	1,691,512	7.47%
Swedbank Robur Folksams LO Sverige	980,000	4.33%
Försäkringsbolaget Avanza Pension	907,198	4.01%
Per Mats Ohlin	888,950	3.93%
Sara Andersson Ek	848,907	3.75%
Christer Wingren	748,525	3.31%
Vincent Saldell	631,430	2.79%
State Street Bank Boston	492,400	2.18%
Nordnet Pensionsförsäkring	417,739	1.85%
Ten largest owners	9,316,561	41.17%
Others	13,315,020	58.83%
Total	22,631,581	100.00%

## Incentive schemes

Immunovia has three outstanding warrant schemes comprising 685,650 options with the right to subscribe for 685,650 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	Seo 23, 2020	Jun 1, 2024 Jun 30, 2024	450,000	455.59	22,500.00	
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				795,000
Total			685,650		34,282.50	1,565,000

## Consolidated income statement, summary

	2020	2019	2020	2019
SEK thousands	Oct-Dec	Oct-Dec	Full year	Full year
Operating income etc				
Net sales	152	45	362	356
Other operating income	325	60	624	458
Total, operating income	477	105	986	814
Operating expenses				
Other external expenses	-21,130	-20,354	-91,147	-78,321
Personnel costs	-24,657	-15,289	-73,968	-54,576
Capitalized work for own account	9,648	8,125	40,020	26,716
Amortization of tangible and intangible assets	-2,450	-2,171	-9,763	-8,446
Other operating expenses	0	0	-471	-435
Total operating expenses	-38,589	-29,689	-135,329	-115,062
Operating earnings/loss	-38,112	-29,584	-134,343	-114,248
Profit/loss from financial items				
Financial income	227	53	5,692	3,820
Financial expenses	-8,235	-3,085	-17,382	-4,089
Total financial items	-8,008	-3,032	-11,690	-269
Earnings/loss after financial items	-46,120	-32,616	-146,033	-114,517
Income tax	0	0	0	-4
Earnings/loss for the period	-46,120	-32,616	-146,033	-114,521
Earnings per share before dilution (SEK)	-2.04	-1.66	-6.84	-5.85
Earnings per share after dilution (SEK)	-2.04	-1.66	-6.84	-5.85
Average number of shares	22,630,948	19,654,853	21,340,672	19,569,089
Number of shares at year's end	22,631,581	19,654,853	22,631 581	19,654,853

# Consolidated comprehensive income, summary

	2020	2019	2020	2019
SEK thousands	Oct-Dec	Oct-Dec	Full year	Full year
Earnings/loss for the period	-46,120	-32,616	-146,033	-114,521
Items that may be reclassified later in the income statement				
Exchange rate differences for foreign net investment	6,609	2,179	9,317	-409
Other earnings/loss for the period	6,609	2,179	9,317	-409
Comprehensive income for the period	-39,511	-30,437	-136,716	-114,930

# Consolidated financial position, summary

	2020	2019
SEK thousands	Dec 31	Dec 31
ASSETS		
Fixed assets		
Intangible fixed assets	134,935	91,860
Tangible fixed assets	48,701	55,224
Financial fixed assets	2,746	3,124
Total fixed assets	186,382	150,208
Current assets		
Accounts receivable	6,334	5,813
Cash and cash equivalents	468,462	263,345
Total current assets	474,796	269,158
TOTAL ASSETS	661,178	419,366
FOURTY AND LIABILITIES		
EQUITY AND LIABILITIES		
Equity  Share conite!	1 170	007
Share capital Other contributed capital	1,132 1,015,291	983 636,924
Translation reserve	8,315	-1,002
Retained earnings incl. total comprehensive income	-425,334	-279,301
otal equity	599,404	357,604
out equity	377,101	337,001
Long-term liabilities		
Interest-bearing liabilities	27,988	33,121
Total long-term liabilities	27,988	33,121
Current liabilities		
Interest-bearing liabilities	5,143	4,945
Other liabilities	28,643	23,696
Total current liabilities	33,786	28,641
TOTAL EQUITY AND LIABILITIES	661,178	419,366

# Change in consolidated equity, summary

SEK thousands	Share capital	Other paid up equityl	Reserves	Accumulated earnings/loss for the period	Total equity
Opening balance January 1, 2019	977	626,348	-593	-164,780	461,953
Comprehensive income for the period			-409	-114,521	-114,930
Transactions with owners in their capacity as owners					
Warrant premium received		344			344
New share issue	6	10,232			10,238
Closing balance Dec. 31, 2019	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 costs		-25,338			-25,338
Closing balance Dec. 31, 2020	1,132	1,015,290	8,315	-425,334	599,403

# Consolidated cash flow statement, summary

	2020	2019	2020	2019
SEK thousands	Oct-Dec	Oct-Dec	Full year	Full year
Operating activities				
Operating earnings/loss	-38,112	-29,584	-134,343	-114,249
Adjustment for items not included in cash flow	2,666	2,072	9,945	8,444
Interest received	227	53	577	285
Interest paid	-335	-311	-1,415	-1,316
Tax paid	0	0	0	-4
Cash flow from operating activities before changes in working capital	-35,554	-27,770	-125,236	-106,840
Cash flow from changes in working capital				
Change in operating receivables	921	726	-579	6,621
Change in operating liabilities	-1,124	4,399	5,111	8,267
Cash flow from operating activities	-35,757	-22,645	-120,704	-91,952
Investment activities				
Investment in Intangible assets	-10,103	-9,047	-43,497	-30,568
Investering i materiella anläggningstillgångar	-694	-1,106	-3,998	-6,034
Investment in financial fixed assets	0	3	0	0
Sale of fixed assets	537	0	537	0
Cash flow from investment activities	-10,260	-10,150	-46,958	-36,602
Financing activities				
Amortization of leasing liability	-1,245	-1,043	-4 936	-5 115
National and European grants for development	·	·		
costs	0	0	0	291
New share issue	5,842	0	378,516	10 238
Received warrants premiums	0	28	0	344
Cash flow from financing activities	4,597	-1,015	373,580	5,758
Cash flow for the period	-41,420	-33,810	205,918	-122,797
Cash and cash equivalents at start of period	510,593	297,217	263,345	386,136
Exchange rate difference in cash and cash equi-				
valents	-711	-62	-801	6
Cash and cash equivalents at end of period	468,462	263,345	468,462	263,345

## Consolidated key indicators

	2020 Full year	2019 Full year	2018 Full year	2017 Full year	2016 Full year
Operating earnings/loss (SEK 000)	-134,343	-114,248	-87,709	-45,520	-14,978
Earnings/loss for the year (SEK 000)	-146,033	-114,521	-86,539	-45,232	-14,723
Earnings per share before dilution (SEK)	-6.84	-5.85	-4.67	-2.67	0.98
Earnings per share after dilution (SEK)	-6.84	-5.85	-4.67	-2.67	0.98
R&D expenses (SEK 000)	-48,078	-34,273	-26,048	-24,041	-24,239
R&D expenses as percentage of operating expenses (%)	29	26	23	34	62
Cash and cash equivalents at the period's end (SEK 000)	468,462	263,345	386,136	192,425	259,094
Cash flow from operating activities (SEK 000)	-120,704	-91,952	-84,111	-46,318	-11,867
Cash flow for the period (SEK 000)	205,918	-122,797	193,680	-66,661	183,327
Equity (SEK 000)	599,403	357,604	461,953	236,795	276,631
Equity per share (SEK)	26.49	18.19	23.65	13.67	16.46
Equity / assets ratio (%)	91	85	97	94	98
Average number of employees	63	48	39	30	16
Average number of employees in R&D	21	19	17	16	11

## **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 rela-ting 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 out- stan-ding shares in the period be- fore 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 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 ope-rating expenses, which include other external expenses, person-nel 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 equi-valents for the period excluding effective unrealized exchange rate gains and exchange rate losses.	
Equity per share (SEK)	Equity divided by the number of shares.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 rese-arch and development functions.	

# Parent company's income statement, summary

	•				
	2020	2019	2020	2019	
SEK thousands	Oct-Dec	Oct-Dec	Full year	Full year	
Operating income etc.					
Net sales	152	45	362	356	
Capitalized work for own account	9,648	8,125	40,020	26,716	
Other operating income	143	64	451	458	
Total	9,943	8,234	40,833	27 530	
Operating expenses					
Other external expenses	-22,105	-22,396	-89,134	-79,046	
Personnel costs	-19,351	-10,755	-48,835	-38,326	
Amortization of intangible and tangible fixed assets	-839	-793	-3,310	-2,950	
Other operating expenses	0	0	-471	-335	
Total operating expenses	-42,295	-33,944	-141,750	-120,657	
Operating earnings/loss	-32,352	-25,710	-100,917	-93,128	
Profit/loss from financial items					
Financial income	1,027	401	7,982	4,981	
Financial expenses	-7,900	-2,719	-15,967	-2,721	
Total financial items	-6,873	-2,318	-7,985	2,260	
Result after financial items	-39,225	-28,028	-108,902	-90,868	
Allocations					
Group contribution	88	337	88	337	
Total year-end appropriations	88	337	88	337	
Earnings/loss after financial items	-39,137	-27,691	-108,814	-90,531	
Income tax	0	0	0	0	
Earnings/loss for the period	-39,137	-27,691	-108,814	-90,531	

# Consolidated comprehensive income, summary

	2020	2019	2020	2019
SEK thousands	okt-dec	okt-dec	helår	helår
Earnings/loss for the period	-39 137	-27 691	-108 814	-90 531
Other results for the period	0	0	0	0
Comprehensive income for the period	-39 137	-27 691	-108 814	-90 531

# Parent company's financial position, summary

CEN the support	2020	2019
SEK thousands	Dec 31	Dec 31
ASSETS		
Fixed assets	177 [[0	00.007
Intangible fixed assets	133,550	90,907
Tangible fixed assets Financial fixed assets	11,384	12,257
Total fixed assets	328 <b>145,262</b>	303 <b>103,467</b>
Total fixed assets	173,202	103,407
Current assets		
Accounts receivable	85,556	53,579
Current receivables	3,850	3,254
Prepaid expenses and accrued income	3,088	3,416
Cash and cash equivalents	461,730	261,647
Total current assets	554,224	321,896
TOTAL ASSETS	699,486	425.767
EQUITY AND LIABILITIES	077,400	425,363
EQUITY AND LIABILITIES	077,400	423,303
EQUITY AND LIABILITIES Equity		
EQUITY AND LIABILITIES  Equity  Share capital	1,132	983
EQUITY AND LIABILITIES Equity		983 65,569
EQUITY AND LIABILITIES  Equity  Share capital  Fund for development expenses  Total equity and liabilities	1,132 105,589	
<b>EQUITY AND LIABILITIES Equity</b> Share capital  Fund for development expenses	1,132 105,589 <b>106,721</b>	983 65,569 <b>66,552</b>
EQUITY AND LIABILITIES  Equity Share capital Fund for development expenses Total equity and liabilities  Non-restricted equity Premium fund	1,132 105,589	983 65,569
EQUITY AND LIABILITIES  Equity Share capital Fund for development expenses Total equity and liabilities  Non-restricted equity	1,132 105,589 <b>106,721</b> 378,367	983 65,569 <b>66,552</b> 10,232 325,673
EQUITY AND LIABILITIES  Equity Share capital Fund for development expenses Total equity and liabilities  Non-restricted equity Premium fund Retained earnings including comprehensive income	1,132 105,589 <b>106,721</b> 378,367 187,070	983 65,569 <b>66,552</b> 10,232 325,673 <b>335,905</b>
EQUITY AND LIABILITIES  Equity Share capital Fund for development expenses Total equity and liabilities  Non-restricted equity Premium fund Retained earnings including comprehensive income Total non-restricted capitall	1,132 105,589 <b>106,721</b> 378,367 187,070 <b>565,437</b>	983 65,569 <b>66,552</b> 10,232
EQUITY AND LIABILITIES  Equity Share capital Fund for development expenses Total equity and liabilities  Non-restricted equity Premium fund Retained earnings including comprehensive income Total non-restricted capitall  Toatl equity	1,132 105,589 <b>106,721</b> 378,367 187,070 <b>565,437</b>	983 65,569 <b>66,552</b> 10,232 325,673 <b>335,905</b>
EQUITY AND LIABILITIES  Equity Share capital Fund for development expenses Total equity and liabilities  Non-restricted equity Premium fund Retained earnings including comprehensive income Total non-restricted capitall  Toatl equity  Current liabilities	1,132 105,589 <b>106,721</b> 378,367 187,070 <b>565,437</b> <b>672,158</b>	983 65,569 <b>66,552</b> 10,232 325,673 <b>335,905</b> <b>402,457</b>

# Parent company's cash flow statement, summary

SEK thousands	2020 Full year	2019 Full year
Operating activities	•	•
Operating earnings/loss	-100,917	-93,128
Adjustment for items not included in cash flow	3,221	2,950
Interest received	576	270
Interest paid	-3	-2
Tax paid	0	0
Cash flow from operating activities before changes in working capital	-97,123	-89,910
Cash flow from changes in working capital		
Change in operating receivables	-40,715	-15,933
Change in operating liabilities	4,420	8,042
Cash flow from operating activities	-133,418	-97,801
Investment activities		
Investment in Intangible fixed assets	-42,882	-30,568
Investment in tangible fixed assets	-2,645	-5,980
Investment in financial fixed assets	-25	-50
Sale of fixed assets	537	0
Cash flow from investment activities	-45,015	-36,598
Financing activities		
National and European grants for development expenses	0	291
New share issue	378,516	10 238
Cash flow from financing activities	378,516	10 529
Cash flow for the period	200,083	-123,870
Cash and cash equivalents at start of period	261,647	385,517
Cash and cash equivalents at period's end	461,730	261,647

## 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 2019 annual report.

This interim report has been prepared in accordance with IAS 34 Interim New and amended standards adopted with effect from 2020 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

## 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 largest owner 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 39 of the 2019 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.

## Cradit 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, 2020 was SEK 471.21 million (266.6).

## 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 2 years.

## **OTHER INFORMATION**

#### **Review**

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

## Financial calendar

Q1 interim report Wednesday April 28, 2021 Q2 interim report Thursday, August 19, 2021 Q3 interim report Thursday, November 11, 2021 Financial statement 2021, Thursday, February 17, 2022

## **Annual General Meeting**

Thursday, May 6, 2021, 4.00 pm

## **Contact information:**

Immunovia AB (publ), Medicon Village, Scheelevägen 8, 223 63 Lund, Sweden

Tel: 046-2756 000 Email: ir@immunovia.com Web: www.immunovia.com

For further information please contact:

• Patrik Dahlen, VD • patrik.dahlen@immunovia.com

## Telephone conference February 17, 2021 at 16.30 (CET)

Sweden: +46 (0) 8 566 427 05

Telephone numbers:

United States: +1 (0) 833 249 8404 France +33 (0) 1 707 507 21 Denmark: +45 (0) 781 501 10 Germany: +49 (0) 69 2222 203 80 Belgium: +32 (0) 24 035 851 Netherlands: +31 (0) 20 721 9496 Norway: +47 (0) 239 636 88 Switzerland: +41 (0) 22 567 5632 United Kingdom: +44 (0) 33 3300 9273

Immunovia Webcast: https://financialhearings.com/event/13667

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, 2021

Carl Borrebaeck
Chairmen 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

Mats Grahn Board member Patrik Dahlen 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.

**Antibodies** – Antibodies, or immunoglobulins, are a type of protein used by the body's immune system to detect and identify foreign substances such as viruses, bacteria or parasites.

**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.

**Companion Diagnostics** – Diagnostics tools aimed at identifying which groups of patients will respond well to a particular treatment and thus ruling out ineffective treatments.

**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.

**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.

**RA – Rheumatoid arthritis,** one of the most common autoimmune diseases.

**RA** double negative – Patients who have RA, but test negative for it using the current two single-marker standard tests, RF factor and anti-CCP.

**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.

**Retrospective study** – A study in which the focus is on some-thing 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.

**SLE (Systemic Lupus Erythematosus)** – SLE is an autoimmune inflammatory disease which means that the immune system attacks the body. The symptoms come and go in cycles, sometimes the patient is sick and sometimes has no sickness at all. Usually it is the joints, skin, blood and kidneys which become inflamed, but also the nervous system, lungs and heart can be affected. The disease is currently difficult to diagnose and is often confused with other autoimmune diseases.

**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.

**Vinnova** – Vinnova is a Swedish government agency under the Ministry of Industry which aims to promote sustainable growth by improving conditions for innovation and by funding needs-driven research.

## Immunovia in brief

Immunovia is a Swedish molecular diagnostic company with a strong financial position in a commercial phase. The company develops and commercializes diagnostic tools for complex forms of cancer and autoimmune diseases.

Immunovia AB was founded in 2007 by researchers from the Department of Immunotechnology at Lund University and CREATE Health, the Center for Translational Cancer Research in Lund, Sweden. The purpose was to establish a base from which to make scientific discoveries and gain patents within the fields of human antibodies, biomarkers and antibody arrays, covering the stages from research to clinical application. Immunovia's core technology platform, IMMray™, is based on microarray analysis of biomarker antibodies. IMMray™ PanCan-d is the company's primary diagnostic tool, capable of diagnosing with a high level of sensitivity and specificity. This enables diagnosis of patients with pancreatic cancer before symptoms are noted (stages I and II), which is not currently possible with existing methods. Immunovia is now performing clinical validation studies to prepare for the commercialization of IMMray™ PanCan-d, which could become the first blood-based test for early diagnosis of pancreatic cancer. The antibody-based technology platform, IMMray™, is the result of 15 years of research at CREATE Health, Lund University. It is used to decode mechanisms behind the body's immune system, the first system in the body that reacts to disease. The platform can also be used for the development of diagnostic tests for autoimmune diseases.



Each year about 350,000 patients fall ill with pancreatic cancer. This form of cancer has one of the worst survival forecasts and only about 5% of diagnosed patients live more than five years, making it one of the deadliest cancers in the world. It is estimated that early detection would increase the five-year survival rate by around 50%. The initial addressable market for Immunovia consists of two high-risk pancreatic cancer groups. The market in the US and Europe for diagnosis of these groups is estimated to be worth over SEK 30 billion anually.

## Goal

Immunovia's goal is to provide diagnostic tests that will enable earlier, more efficient and more accurate diagnosis of patients who run the risk of developing cancer or autoimmune disease. The aim is to make Immunovia's tests the first choice of specialist doctors and general practitioners across the world in the screening of especially high-risk groups or when there is a suspicion of the aforementioned diseases.

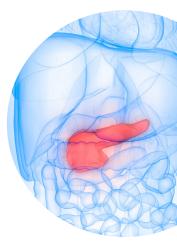
## Strategy

Immunovia's strategy is as the first company, to decipher the wealth of information in blood and translate it into clinically useful tools to diagnose complex diseases earlier and more accurately than previously possible. The focus is on unsolved problems in early diagnosis, monitoring of the course of a disease and the patient's response to treatment. These are areas where there are extensive clinical benefits for patients and the healthcare system, current solutions are lacking or insufficient, and where IMMray<sup>TM</sup> has significant competitive advantages.

Initially, the key focus for Immunovia is to bring IMMray™ PanCan-d to the market. Because early detection of pancreatic cancer constitutes a major clinical problem, Immunovia considers there to be good prospects for being the first to establish a strong position on the market.

Organization. no. 556730-4299

Immunovia has its head office in Lund, Sweden. Immunovia's shares (IMMNOV) are listed on Nasdaq Stockholm's main list (Mid Cap). For more information, please go to: www.immunovia.com



IMMray™ PanCan-d, could become the first blood-based test for early diagnosis of pancreatic cancer.



Early detection would increase the five-year survival rate by around 50%.

