

# Immunovia

## Full Year Report 2018



Throughout 2018, we continued to build on our mission to develop and validate accurate blood-based diagnostic tests that can make a real and significant impact on healthcare worldwide and to initiate the exciting activities to commercialize those efforts.

As we accelerated the preparations for the commercialization of IMMray™ PanCan-d, our lead diagnostic candidate for the early detection of pancreatic cancer, Immunovia completed the expansion of our production and sample testing facilities, IMMray™ Dx Laboratories, at our headquarters in Lund, Sweden. This new state-of-the-art facility, working in conjunction with our IMMray™ Dx Laboratories at our subsidiary in Marlborough, MA, allows us the capacity and capability to produce slides to not only meet the current foreseen demands for commercial testing but at the same time meet the demands of the large prospective studies to be performed in parallel.

We worked diligently to establish and expand the world's most comprehensive set of prospective clinical trials within the area of detection of pancreatic cancer for IMMray™ PanCan -d consisting of three large studies, PanSYM-1, PanFAM-1 and PanDIA-1.

We also identified two additional strategic focus areas adding to our pipeline activities in 2018 – non-small cell lung cancer (NSLC) and Rheumatoid Arthritis (RA). Both indication areas address very large unmet clinical needs, in focus of the global healthcare systems, and thereby represent tremendous commercial opportunities for Immunovia adding to our main focus on earlier detection of pancreatic cancer.

On the corporate side, we rounded out the first quarter of 2018 with the announcement of an important corporate milestone: Immunovia's application to move its shares to the Main Market, Mid Cap segment on Nasdaq Stockholm. Our shares commenced trading on April 3, 2018. This move not only reflects that we have matured as a company, but it also strengthens our brand and furthers awareness of our work as we move closer to commencing commercial activities.



*Mats Grahn*  
CEO of Immunovia AB

Key indicators				
	Oct-Dec 2018	Oct-Dec 2017	Full year 2018	Full year 2017
SEK thousand unless otherwise stated				
Net sales	91	26	333	149
Operating earnings	-25,756	-15,362	-87,708	-45,520
Earnings before tax	-25,655	-15,318	-86,531	-45,232
Net earnings	-25,655	-15,318	-86,538	-45,232
Earnings per share before and after dilution (SEK/share)	-1.31	-0.88	-4.67	-2.67
Equity ratio, %	97	94	97	94
No. of shares at the end of the period	19,531,353	17,318,059	19,531,353	17,318,059

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

### Outlook

Immunovia is focused on fundamentally transforming diagnosis of complex forms of cancer and autoimmune diseases. The antibody-based platform, IMMray™, is the result of 15 years of research at CREATE Health – the Center for Translational Cancer Research at Lund University, Sweden. IMMray™ is a technology platform for the development of diagnostic tests and the company's primary test, IMMray™ PanCan-d, is the first test in the world for early diagnosis of pancreatic cancer.

The company's financial targets remain in place from the previous quarter. The company expects to receive the first revenues from self-pay sales in the latter part of 2019. The following financial targets have been established:

- Immunovia's target is to achieve turnover of SEK 250-300 million by 2022 based on self-pay for IMMray™ PanCan-d.
- Immunovia's target is to achieve total turnover, including payment via self-pay and cost remuneration from insurance systems, of SEK 800-1,000 million by 2024.

## CEO's statement

# IMMray<sup>®</sup> PanCan-d is now a part of the largest clinical study ever

Dear shareholders,

Throughout 2018, we continued to build on our mission to develop and validate accurate blood-based diagnostic tests that can make a real and significant impact on healthcare worldwide and to initiate the exciting activities to commercialize those efforts.

As we accelerated the preparations for the commercialization of IMMray<sup>™</sup> PanCan-d, our lead diagnostic candidate for the early detection of pancreatic cancer, Immunovia completed the expansion of our production and sample testing facilities, IMMray<sup>™</sup> Dx Laboratories, at our headquarters in Lund, Sweden. This new state-of-the-art facility, working in conjunction with our IMMray<sup>™</sup> Dx Laboratories at our subsidiary in Marlborough, MA, allows us the capacity and capability to produce slides to not only meet the current foreseen demands for commercial testing but at the same time meet the demands of the large prospective studies to be performed in parallel.

In 2018, we advanced our important clinical collaborations and entered into new ones, which expanded the utilization of our IMMray<sup>™</sup> platform for our product pipeline.

We worked diligently to establish and expand the world's most comprehensive set of prospective clinical trials within the area of detection of pancreatic cancer for IMMray<sup>™</sup> PanCan -d consisting of three large studies, PanSYM-1, PanFAM-1 and PanDIA-1.

PanSYM-1, is a large clinical study in collaboration with University College of London, UK, which has already provided us with several hundreds of samples from high risk patients with symptoms suggestive of pancreatic cancer, these samples will now be analysed with IMMray<sup>™</sup> PanCan-d and be included as part of the validation program with results expected during 2019.

Turning to our second clinical study, we worked on obtaining new participants in our PanFAM-1 study, which is a multicenter prospective validation study for early diagnosis of people with a high risk of hereditary or familial pancreatic cancer. The PanFAM-1 study now includes close to 20 leading pancreatic cancer centers across US, Canada, UK, Spain

and Sweden together covering more than 2,000 at risk persons. The overall objective of the study is to show the overall benefit of early testing of patients with hereditary pancreatic cancer.

Another key development with the PanFAM-1 clinical trial, it is now registered on ClinicalTrials.gov, the largest clinical trials database in the world, enabling risk individuals and patient organizations easier access to information of PanFAM-1.

The third, groundbreaking, prospective study PanDIA-1 has become the world's largest study of new onset of Type 2 diabetics over 50 and their associated risk of developing pancreatic cancer. Supported by the Swedish Government Programme SWELife, the sample collection provides access of up to 6 000 new onset diabetic patients based on a collaboration with two major Swedish universities in Lund and Uppsala, Lund University Diabetic Center, as well as Skåne and Uppsala healthcare regions.

We also identified two additional strategic focus areas adding to our pipeline activities in 2018 – non-small cell lung cancer (NSLC) and Rheumatoid Arthritis (RA). Both indication areas address very large unmet clinical needs, in focus of the global healthcare systems, and thereby represent tremendous commercial opportunities for Immunovia adding to our main focus on earlier detection of pancreatic cancer. We look forward to providing updates as follow up studies are performed during 2019.

The advantage of the IMMray<sup>™</sup> platform is that the infrastructure that was built during the development of IMMray<sup>™</sup> PanCan-d can, to a very large extent, be repurposed for other products in the pipeline. This leads to very efficient development, production, clinical commercial testing and quality control for products in the pipeline.

During the third quarter of 2018 we announced a delay to the launch of IMMray<sup>®</sup> Pan Can-d due to the addition of an optimization test, which we are in the process of completing and is another important part of the launch preparations.

On the corporate side, we rounded out the first quarter of 2018 with the announcement of an

important corporate milestone: Immunovia's application to move its shares to the Main Market, Mid Cap segment on Nasdaq Stockholm. Our shares commenced trading on April 3, 2018. This move not only reflects that we have matured as a company, but it also strengthens our brand and furthers awareness of our work as we move closer to commencing commercial activities.

In conjunction with the change of market listing, we launched a new website and adopted financial targets on initial sales of IMMray™ PanCan -d, the first of several applications with significant market potential for the IMMray™ platform.

The company has a target of SEK 250-300 million in revenue in 2022 based only on self-pay sales, to penetration of approximately 5 percent of the inherited risk group for pancreatic cancer, and approximately 1 percent penetration of the market potential for use by patients with early symptoms of pancreatic cancer.

We also announced a second target of achieving total turnover of SEK 800-1,000 million in 2024. This includes self-pay and cost reimbursement from the insurance systems in Europe and the United States. Our target for 2024 corresponds to about 20 percent market penetration in the hereditary category risk for pancreatic cancer and 9 percent market penetration within the category for early symptoms of pancreatic cancer, as well as an initial use within the area of diabetics with increased risk for pancreatic cancer.

Immunovia also completed a directed share issue in June 2018 of approximately SEK 324 million in gross proceeds. With this share issue, we expanded our shareholder base and generated a strong demand from reputable institutions in Sweden and internationally, such as Swedbank Robur, Handelsbanken Fonder, Alfred Berg Kapitalförvaltning AB, Nyenburgh Investment Partners, Apus Capital and Bonit Capita.

To reiterate, the net proceeds from the share issue are intended to be used to accelerate our commercial launch preparations, help build a US sales and key accounts organization, marketing campaigns and other sales efforts, and contribute to further investments in Immunovia's product development platform, as the company plans for a broader and deeper development portfolio in the coming years.

As you can see, we worked intensely throughout the year on the preparations for our sales launch targeted for the end of 2019. I am excited to report that we focus all our efforts to reach this pivotal milestone in the continued development of Immunovia.

Another new and inspiring initiative that we undertook last year was partnering with several prominent patient organizations to sponsor fundraising walks to help build awareness of the IMMray™ PanCan-d test and educate on the risk factors and the symptoms for pancreatic cancer. We connected with over 24,000 participants in 24 walks in 15 states in the US. We plan to continue take part in these events in 2019 as one of our market access activities leading up to sales start.

2018 was an exciting year at Immunovia and one that we believe is a forecast for things to come. All of this is possible due to the hard work of Immunovia's staff, the tremendous backing by our Board and the support of our Shareholders. As we are half way through the first quarter of 2019, we remain committed to our mission and feel this year is shaping up to be even more promising for the company.

Mats Grahn  
*CEO, Immunovia*

# Important events

## **Important events in the fourth quarter of 2018**

*Registration of Immunovia's PanFAM-1 prospective clinical trial at ClinicalTrials.gov, the world's largest database for clinical trials.*

During the reporting period, the PanFAM-1 prospective clinical trial was registered at ClinicalTrials.gov, an online register of clinical trials. This will make information about the PanFAM-1 trial available for patients, relatives, healthcare staff and the general public.

*Immunovia announced strategic focus centered on IMMray™ blood-based biomarker signatures for rheumatoid arthritis within autoimmunity*

Encouraged by the promising discovery study results previously reported, Immunovia announced that its focus in autoimmunity testing will be to develop IMMray™ blood-based biomarker signatures for the management of rheumatoid arthritis.

*Immunovia appointed the nomination committee for AGM 2019*

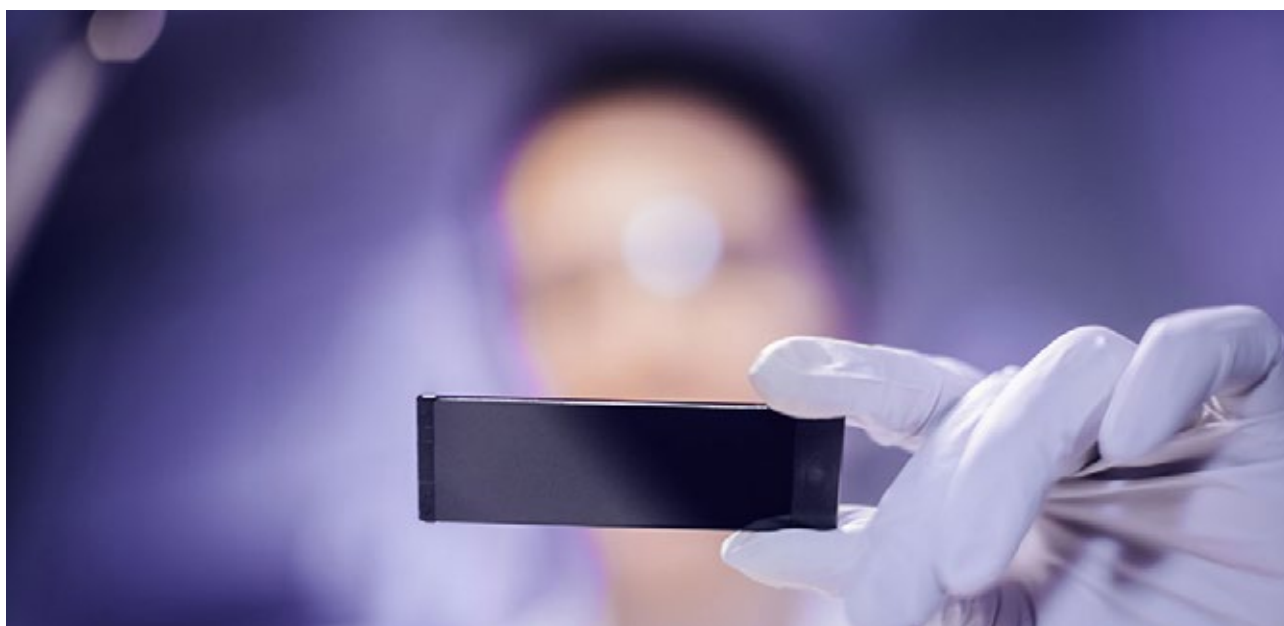
The nomination committee for the 2019 AGM will consist of Sara Ek, Chairman of the Nomination Committee, Carl Borrebaeck, Chairman of the Board, Mikael Löfman, a large shareholder and Astrid Samuelsson, representing Handelsbanken.

*McGill, Yale and Universities of Pennsylvania and Massachusetts joined PanFAM-1, the prospective multicenter clinical study for early detection of pancreatic cancer*

During the period Immunovia announced that four additional North American Familial Pancreatic Cancer (FPC) sites are participating in PanFAM-1. The new centers give the PanFAM-1 study near complete coverage of North American FPC sites in drive to validate IMMray™ PanCan-d.

## **Important events after the end of 2018**

No important events have occurred after the end of the period.



# Consolidated financial results for January-December 2018

## Net sales

Net sales for the final quarter of 2018 were SEK 91 thousand (126 k). For the full year 2018 net sales were SEK 333 thousand (149 k). Net sales principally comprise royalties.

Capitalization of costs for the final quarter of 2018 were SEK 5,224 thousand (8,482 k). Capitalization development costs are financed through approved and paid grants, the reported amounts are reduced by a comparable amount. For the full year 2018, grants for development costs were received amounting to SEK 2,791 thousand (8,406 k).

## Earnings

The net loss for the final quarter of 2018 was SEK 25,655 thousand (15,318 k). The loss for the full year was SEK 86,538 thousand (45,232 k).

The net loss in 2018 increased due to higher costs, relating to organizational enlargement, increased marketing activity and costs for set-up of prospective activities. Other external costs and personnel costs increased by a total of SEK 42,281 thousand compared with 2017 and resulting in SEK 110,532 thousand during 2018.

## Research and development

Research and development is going as planned, taking into account the changes communicated during the third quarter. The total cost of research and development in Q4 2018 was SEK 5,808 thousand (8,482 k), which corresponds to 19% (36%) of the Group's total operating costs.

The total cost of research and development for the full year 2018 was SEK 26,049 thousand (24,041 k), which corresponds to 23% (34%) of the Group's total operating costs. The decrease in R&D activity is due to the increase of marketing costs and costs for set-up of prospective clinical studies.

## Financial position and cash flow

Cash flow for Q4 2018 from operating activities amounted to SEK -25,816 thousand (-16,7001 k) and total cash flow for the year amounted to SEK -84,111 thousand (-46,525 k). Cash and cash equivalents as at 31 December 2018 amounted to SEK 386,136 thousand (192,425 k).

A total of 2,213,294 shares were issued in 2018, raising SEK 311,352 thousand net profits after issue costs.

Shareholders' equity at the end of the period was SEK 461,953 thousand (236,795 k) and the equity ratio was 97% (94).

Management believes that there is sufficient working capital to meet working capital needs, given the current business and development plan, for approximately 2 years going forward.

## Investments

In Q4 2018 intangible assets were acquired for SEK 5,937 thousand (9,043 k), consisting of capitalized development expenditure for SEK 5,224 thousand (8,482 k) and patents for SEK 935 thousand (561 k), and other intangible assets for SEK -222 thousand (0).

For the full year, intangible assets were acquired for a total of SEK 27,996 thousand (25,919 k), consisting of capitalized development expenditure for SEK 25,052 thousand (23,329 k), patents for SEK 2,288 thousand (2,590 k) and other intangible assets for SEK 656 thousand (0 k).

Investments in tangible assets in the form of inventories were made during the Q4 2018 amounting to SEK 4034 thousand. For the corresponding period last year the total was SEK 2,614 thousand. For the full year investment in tangible assets amounted to SEK 9,056 thousand (5,268 k).

## Employees

The number of employees in the Group during Q4 2018 averaged 45 (30) and at the end of the period the number of full-time employees were 45.

# Share information

Since 3 April 2018, Immunovia's shares have been listed on Nasdaq Stockholm's primary market (Mid Cap) under the IMMNOV ticker.

## Subscription warrants scheme

Immunovia has four outstanding warrants schemes covering 340,650 warrants entitling to subscription of 340,650 shares. There will be no dilution as long as the Group's earnings are negative. For more information about the warrants, see page 7.

## Share data

At the end of the reporting period the total number of shares was 19,531,353. The nominal value of each share is SEK 0.05.

## The ten largest shareholders as of 31 December 2018

Name	No. of shares	Share capital and votes
Carl Borrebaeck	1,709,900	8.75 %
Ålandsbanken, on behalf of the owner	1,624,251	8.32 %
Handelsbanken Svenska Småbolag	1,000,000	5.12 %
Sara Andersson Ek	888,950	4.55 %
Per Mats Ohlin	888,950	4.55 %
Christer Wingren	883,384	4.52 %
Vincent Saldell	747,319	3.83 %
Försäkringsbolaget Avanza Pension	586,170	3.00 %
Catella Småbolagsfond	527,804	2.70 %
Swedbank Robur Folksam LO Sverige	500,000	2.56 %
10 largest owners	9,356,728	47.91 %
Others	10,174,625	52.09 %
Total	19,531,353	100.00 %

## Share capital development

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



# Incentive schemes

## Warrants

The Annual General Meeting held on 3 May 2018 resolved to offer a warrants scheme (series 2018/2021) to employees and key persons in the company. The warrants (156,150) can be used to subscribe for newly issued shares of the Company during the utilization period from 7 September 2021 to 7 October 2021. Each warrant entitles the holder to subscribe for one share at a subscription price of SEK 271.05 per share. Full utilization would increase the company's share capital by SEK 7,739.50.

The Annual General Meeting held on 25 April 2017 resolved to offer a warrants scheme (series 2017/2020) to employees and key persons in the company. The warrants (61,000) can be used to subscribe for newly issued shares of the Company during the period from registration of the decision until 15 October 2020. Each warrant entitles the holder to subscribe for one share at a subscription price of SEK 205.00 per share. Full utilization would increase the company's share capital by SEK 3,050.

The Annual General Meeting held on 30 May 2016 resolved to offer a warrants scheme (series 2016/2019) to employees and key persons in the company. The warrants (123,500) can be used to subscribe for newly issued shares of the Company during the period from registration of the decision until 15 October 2019. Each warrant entitles the holder to subscribe for one share at a subscription price of SEK 82.90 per share. Full utilization would increase the company's share capital by SEK 6,175.

The Annual General Meeting held on 1 June 2015 resolved to offer a warrants scheme (series 2015/2018) to employees and key persons in the company. The warrants (47,000) can be used to subscribe for newly issued shares of the Company during the period from registration of the decision until 15 October 2018. 10,000 warrants have been exercised, therefore 37,000 warrants remain for subscription. Each warrant entitles the holder to subscribe for one share at a subscription price of SEK 13.50 per share. Full utilization would increase the company's share capital by SEK 1,850.

The Annual General Meeting held on 3 May 2018 resolved to introduce an alternative cash-based incentive scheme for key individuals in countries where allocation of warrants in accordance with the 2018/2021 scheme was not applicable for various

reasons. Such an incentive scheme has been introduced for employees and key individuals and is designed so that the economic effects correspond to the terms of the 2018/2021 options scheme. The total cost for the company can be at most USD 250,000.

The Annual General Meeting held on 25 April 2017 resolved to introduce an alternative cash-based incentive scheme for key individuals in countries where allocation of warrants in accordance with the 2017/2020 scheme was not applicable for various reasons. Such an incentive scheme has been introduced for 6 key individuals and is designed so that the economic effects correspond to the terms of the 2017/202 options scheme. The total cost for the company can be at most USD 920,000.

The warrants are subject to customary recalculation terms in connection with share issues, etc.



# 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 establishing financial reports. The applied accounting principles are in agreement with the information in the 2017 annual report.

From 1 January 2018, the Group is applying IFRS 9 Financial instruments and IFRS 15 Revenues from contracts with customers. Otherwise, the applied accounting principles are consistent with those applied in the 2017 annual report.

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

## Financial assets

The Group classifies and values its financial assets based on the business model that manages the asset's contracted cash flows as well as the nature of the asset. The financial assets are classified in one of the following categories: financial assets valued at accrued acquisition value, financial assets valued at fair value in comprehensive income, and financial assets valued at fair value in the income statement.

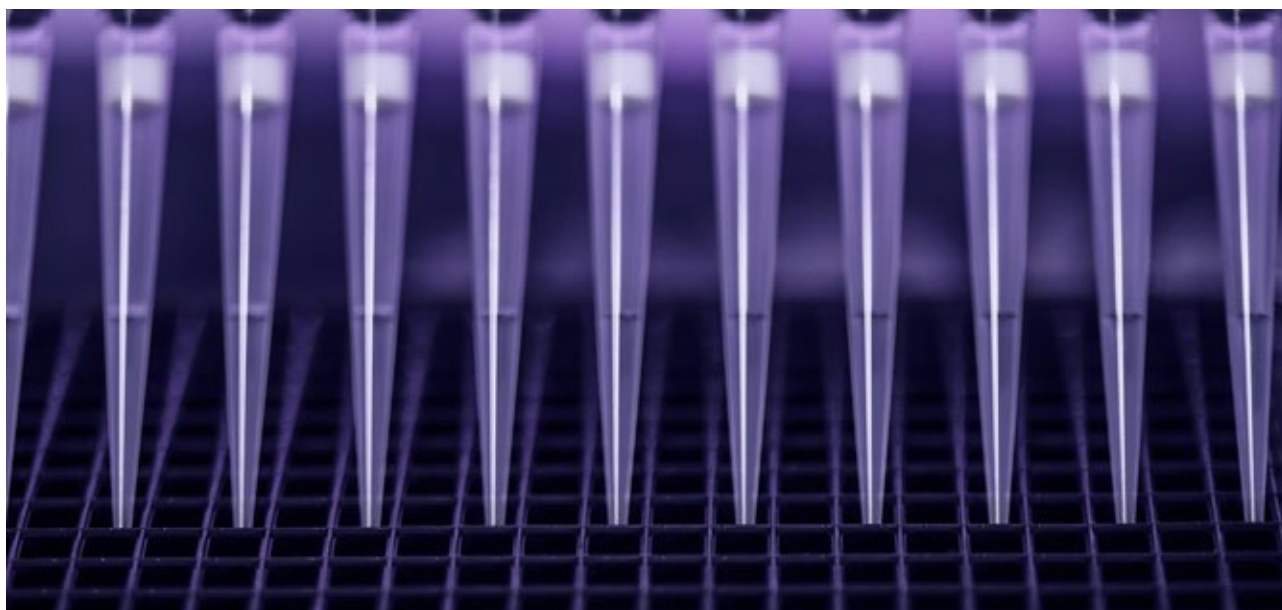
At present, the Group has only financial assets that

are not normally sold outside the Group and where the purpose of the holding is to obtain contractual cash flows. Most of the financial assets consist of bank balances. All financial assets are classified as financial assets valued at accrued acquisition value. These financial assets are included in current assets with the exception of items expired for more than 12 months after the end of the reporting period, which are classified as non-current assets. Valuation is made at accrued acquisition value using the effective interest rate method.

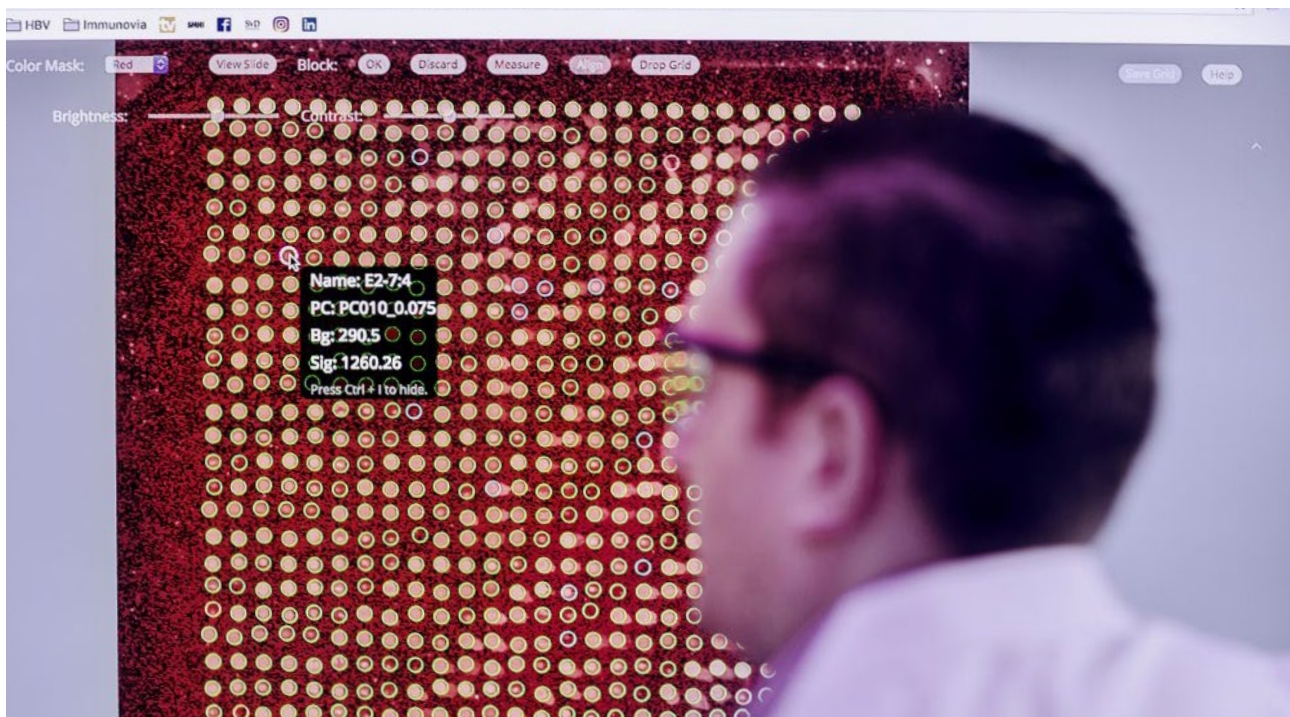
When financial assets are acquired, expected credit losses are reported continually during the ownership period, normally with consideration to the risk of credit losses within the coming 12 months. In the event that credit risks increase significantly, reserves are made for the credit losses expected throughout the full ownership period of the asset. Based on historic data for the payment patterns and payment capability of the counter party, the expected credit losses are considered to be limited.

## Financial liabilities

The Group only has financial liabilities that are classified and valued at accrued acquisition value using the effective interest rate method. Reporting is performed initially at fair value, net of transaction costs.







### Revenues from agreements with customers

Revenues from agreements with customers are reported when the performance commitment is fulfilled when a product or a service is transferred to the customer. The Group currently only has revenues in the form of royalties which are reported as the terms of each royalty is met.

### Effects of future accounting principles

The IFRS 16 Leases replaced the current standard IAS 17 Leases and related interpretations as of January 1, 2019. In 2018, Immunovia surveyed and evaluated the Group's leasing agreements and analyzed the effects of the transition to IFRS 16.

As the new standard is implemented, Immunovia will apply a simplified transition method, meaning that comparative information in earlier periods will not be recalculated. The leasing debt consists of the discounted remaining lease payments as of January 1, 2019. The Rights of Use amount corresponds to its leasing liabilities amount. The transition to IFRS 16 does not have any effect on equity. Immunovia will apply the relief rules regarding leasing agreements to assets with underlying low value.

Relief rules will also be applied during the transition to IFRS 16 for agreements that will terminate during 2019.

For example, leasing agreements where the underlying asset has a low value, consist of office equipment.

Immunovia's significant leasing agreements are for the rental of office premises. As a result of the introduction of IFRS 16, total assets will increase through the inclusion of utilization rights and leasing liabilities. Under IAS 17, lease payments were recorded under the other external expenses line item on the income statement, now it will be replaced by depreciation of the external assets, which has been reported as an expense in operating profit, and interest on the leasing debt, which is reported as a financial expense.

The leasing fee is divided between amortization on the lease debt and payment of interest.

As the company transitions to IFRS 16, all remaining leasing fees will be assigned the present value of Immunovia's marginal loan interest rate.

The average loan interest rate as of January 1, 2019 was 4%.

The right of use and the liability as of January 1, 2019 was estimated at SEK 35.8 million, which includes two option periods.

The change will affect the balance sheet and income statement and a number of key figures. Immunovia estimates depreciation for 2019 will increase by SEK 4.6 million, and financial expenses for 2019 will increase by SEK 1.3 million with profit after tax decreasing by SEK 0.5 million. The equity / assets ratio was negatively affected as of January 1, 2019, at which time it was 90% compared to 97% when applied of IAS 17.

# Other information

## Financial instruments

The Group currently has no financial instruments that are 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. The reported value of financial assets on the balance sheet date amounted to SEK 395,971 thousand (203,331).

## Transactions with related parties

In addition to salaries and other remuneration to company managers, and fees to Board members, as decided at the annual general meeting, the company has a consulting agreement with CB Ocean Capital AB regarding services performed by Immunovia's chairman and largest shareholder, Carl Borrebaeck. Services provided do not concern information relating to the Board role. Instead the services are to provide the company with scientific and strategic support at scientific presentations and conferences, for example. This agreement runs from 1 January 2018 until further notice with three months notice for both parties. The remuneration per quarter amounts to SEK 41,000.



## Risks

Immunovia is exposed to financial risks and business risks. The financial risks management and the financial risks are described below. The company's business risks are presented on page 33 of the 2017 annual report. No significant changes have occurred that affect these reported risks.

### Market risks

#### Currency risks

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

#### Interest rate risk in cash flow

Interest rate risk is the risk that the value of financial instruments will fluctuate because of changes in market interest rates. The Group currently only has interest-bearing financial assets in the form of bank deposits.

### Credit risk

Credit risk is the risk that one party to a transaction with a financial instrument fails to meet its obligation. The maximum exposure to credit risk on financial assets as of 31 December 2018 amounted to SEK 395,971 thousand (203,331 k).

### 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 around 24 months.

# Financial reports

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The company's annual report is available at the company's website: [www.immunovia.com](http://www.immunovia.com)

## Financial reports

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*In some cases figures have been rounded off, which means tables and calculations will not always appear to be correctly totalled.*

### Financial calendar

24 April 2019	Q1 2019 interim report
26 April 2019	AGM
23 August 2019	Q2 2019 interim report
8 November 2019	Q3 2019 interim report
14 February 2020	2019 Financial statement

### Telephone conference

14 February at 17:30 (CET)

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# Consolidated income statement, summary

SEK thousand	Oct-Dec 2018	Oct-Dec 2017	Full year 2018	Full year 2017
<b>Operating income, etc.</b>				
Net sales	91	26	333	149
Capitalized work for own account	5,224	8,482	25,052	24,041
Other income	257	0	744	59
<b>Total</b>	<b>5,572</b>	<b>8,508</b>	<b>26,129</b>	<b>24,249</b>
<b>Operating costs</b>				
Other external costs	-17,621	-11,640	-65,275	-39,113
Personnel costs	-12,817	-11,863	-45,257	-29,138
Depreciation and amortization of tangible and intangible assets	-781	-388	-2,777	-1,264
Other operating expenses	-109	21	-528	-254
<b>Total operating expenses</b>	<b>-31,328</b>	<b>-23,870</b>	<b>-113,837</b>	<b>-69,769</b>
<b>Operating profit/loss</b>	<b>-25,756</b>	<b>-15,362</b>	<b>-87,708</b>	<b>-45,520</b>
<b>Financial items</b>				
Financial income	101	53	1,178	298
Financial costs	0	-9	-1	-10
<b>Total financial items</b>	<b>101</b>	<b>44</b>	<b>1,177</b>	<b>288</b>
<b>Profit/loss after financial items</b>	<b>-25,655</b>	<b>-15,318</b>	<b>-86,531</b>	<b>-45,232</b>
Tax	0	0	-7	0
<b>Profit/loss for the period</b>	<b>-25,655</b>	<b>-15,318</b>	<b>-86,538</b>	<b>-45,232</b>
Earnings per share before and after dilution (SEK)	-1.31	-0.88	-4.67	-2.67
Average number of shares	19,531,353	17,318,059	18,545,795	16,932,559
No. of shares at the end of the period	19,531,353	17,318,059	19,531,353	17,318,059

# Consolidated comprehensive income, summary

SEK thousand	Oct-Dec 2018	Oct-Dec 2017	Full year 2018	Full year 2017
<b>Profit/loss for the period</b>	<b>-25,655</b>	<b>-15,318</b>	<b>-86,538</b>	<b>-45,232</b>
<i>Items that may be later reclassified in the income statement</i>				
Exchange rate differences for foreign net investment	449	0	-593	0
Other comprehensive income for the period	449	0	-593	0
<b>Comprehensive income for the period</b>	<b>-25,206</b>	<b>-15,318</b>	<b>-87,131</b>	<b>-45,232</b>

# Consolidated financial position, summary

SEK thousand	31-12-2018	31-12-2017
<b>ASSETS</b>		
<b>Fixed assets</b>		
Intangible fixed assets	61,786	36,791
Tangible fixed assets	14,019	7,211
Financial fixed assets	3,008	2,759
<b>Total fixed assets</b>	<b>78,813</b>	<b>46,761</b>
<b>Current assets</b>		
Accounts receivable	32	0
Current receivables	12,401	11,584
Cash and cash equivalents	386,136	192,425
<b>Total current assets</b>	<b>398,569</b>	<b>204,009</b>
<b>TOTAL ASSETS</b>	<b>477,382</b>	<b>250,770</b>
<b>EQUITY AND LIABILITIES</b>		
<b>Shareholders' equity</b>		
Share capital	977	866
Other contributed capital	626,348	314,170
Translation reserve	-593	0
Retained earnings including total comprehensive income	-164,779	-78,241
<b>Total shareholders' equity</b>	<b>461,953</b>	<b>236,795</b>
<b>Current liabilities</b>		
Other liabilities	15,429	13,975
<b>Total current liabilities</b>	<b>15,429</b>	<b>13,975</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>477,382</b>	<b>250,770</b>



# Change in consolidated equity, summary

SEK thousand	Share capital	Other contributed equity	Reserves	Retained earnings including total comprehensive income	Total shareholders' equity
<b>Equity, 1 January 2017</b>	<b>840</b>	<b>308,800</b>	<b>0</b>	<b>-33,009</b>	<b>276,631</b>
Comprehensive income for the period			0	-45,232	-45,232
Transactions with shareholders in their capacity as owners					0
Received subscription warrant premiums		473			473
New share issue	26	4,897			4,923
<b>Equity 31 December 2017</b>	<b>866</b>	<b>314,170</b>	<b>0</b>	<b>-78,241</b>	<b>236,795</b>
<b>Equity, 1 January 2018</b>	<b>866</b>	<b>314,170</b>	<b>0</b>	<b>-78,241</b>	<b>236,795</b>
Comprehensive income for the period			-593	-86,538	-87,131
Transactions with shareholders in their capacity as owners					0
Received subscription warrant premiums		936			936
New share issue	111	325,927			326,038
Issue costs		-14,685			-14,685
<b>Equity 31 December 2018</b>	<b>977</b>	<b>626,348</b>	<b>-593</b>	<b>-164,779</b>	<b>461,953</b>

## Consolidated key indicators

	Full year 2018	Full year 2017	Full year 2016
Operating profit/loss (SEK thousand)	-87,709	-45,520	-14,978
Profit/loss for the period (SEK thousand)	-86,539	-45,232	-14,723
Earnings per share before and after dilution (SEK)	-4.67	-2.67	-0.98
R&D costs (SEK thousand)	-26,048	-24,041	-24,239
R&D costs as percentage of operating costs (%)	23	34	62
Cash and cash equivalents at end of period (SEK thousand)	386,136	192,425	259,094
Cash flow from operating activities (SEK thousand)	-84,111	-46,525	-11,867
Cash flow for the period (SEK thousand)	193,680	-66,669	183,327
Equity (SEK thousand)	461,953	236,795	276,631
Equity per share (SEK)	23.65	13.67	16.46
Equity ratio (%)	97	94	98
Average no. of employees	39	30	16
Average no. of employees in R&D	17	16	11

# Consolidated cash flow statement, summary

SEK thousand	Oct-Dec 2018	Oct-Dec 2017	Full year 2018	Full year 2017
<b>Operating activities</b>				
Operating profit/loss	-25,756	-15,363	-87,709	-45,520
Adjustment for items not included in cash flow	859	388	2,682	1,264
Received interest	83	53	319	298
Paid interest	0	-9	-1	-10
Paid tax	0	0	-7	0
<b>Cash flow from operating activities before changes in operating capital</b>	<b>-24,814</b>	<b>-14,931</b>	<b>-84,716</b>	<b>-43,968</b>
<b>Cash flow from changes in operating capital</b>				
Change in operating receivables	-2,515	-7,655	-840	-9,751
Change in operating liabilities	1,747	5,885	1,445	7,194
<b>Cash flow from operating activities</b>	<b>-25,582</b>	<b>-16,701</b>	<b>-84,111</b>	<b>-46,525</b>
<b>Investment activities</b>				
Investment in intangible assets	-6,171	-9,043	-28,230	-25,919
Investment in tangible assets	-403	-2,614	-9,056	-5,268
Investment in financing assets	0	-2,759	-2	-2,759
<b>Cash flow from investing activities</b>	<b>-6,874</b>	<b>-14,416</b>	<b>-37,288</b>	<b>-33,946</b>
<b>Financing activities</b>				
National and European grants for development costs	2,718	8,242	2,791	8,406
New share issue	0	0	311,352	4,923
Received subscription warrant premiums	28	0	936	474
<b>Cash flow from financing activities</b>	<b>2,746</b>	<b>8,242</b>	<b>315,079</b>	<b>13,803</b>
<b>Cash flow for the period</b>	<b>-29,410</b>	<b>-22,875</b>	<b>193,680</b>	<b>-66,669</b>
Cash and cash equivalents at beginning of period	415,602	215,300	192,425	259,094
Exchange rate difference in cash and cash equivalents	-56	0	31	0
<b>Cash and cash equivalents at end of period</b>	<b>386,136</b>	<b>192,425</b>	<b>386,136</b>	<b>192,425</b>

# Parent company's income statement, summary

SEK thousand	Oct-Dec 2018	Oct-Dec 2017	Full year 2018	Full year 2017
<b>Operating income, etc.</b>				
Net sales	91	26	333	149
Capitalized work for own account	5,224	8,482	25,052	24,041
Other income	257	0	744	59
<b>Total income</b>	<b>5,572</b>	<b>8,508</b>	<b>26,129</b>	<b>24,249</b>
<b>Operating costs</b>				
Other external costs	-15,996	-17,491	-59,679	-44,984
Personnel costs	-8,705	-6,069	-32,003	-23,343
Depreciation and amortization of tangible and intangible assets	-565	-388	-1,996	-1,264
Other operating expenses	-110	21	-527	-254
<b>Total operating expenses</b>	<b>-25,375</b>	<b>-23,927</b>	<b>-94,205</b>	<b>-69,845</b>
<b>Operating profit/loss</b>	<b>-19,803</b>	<b>-15,419</b>	<b>-68,076</b>	<b>-45,596</b>
Financial items				
Interest income	308	101	1,743	366
Interest costs	0	0	-1	-2
<b>Total financial items</b>	<b>308</b>	<b>101</b>	<b>1,742</b>	<b>364</b>
<b>Profit/loss after financial items</b>	<b>-19,495</b>	<b>-15,318</b>	<b>-66,334</b>	<b>-45,232</b>
Tax	0	0	0	0
<b>Profit/loss for the period</b>	<b>-19,495</b>	<b>-15,318</b>	<b>-66,334</b>	<b>-45,232</b>
Earnings per share before and after dilution (SEK)	-1.00	-0.88	-3.58	-2.67
Average number of shares	19,531,353	17,318,059	18,545,795	16,932,559
No. of shares at the end of the period	19,531,353	17,318,059	19,531,353	17,318,059

# Consolidated comprehensive income, summary

SEK thousand	Oct-Dec 2018	Oct-Dec 2017	Full year 2018	Full year 2017
<b>Profit/loss for the period</b>	<b>-19,495</b>	<b>-15,318</b>	<b>-66,334</b>	<b>-45,232</b>
Other comprehensive income for the period	0	0	0	0
<b>Comprehensive income for the period</b>	<b>-19,495</b>	<b>-15,318</b>	<b>-66,334</b>	<b>-45,232</b>

# Parent company's financial position, summary

SEK thousand	31-12-2018	31-12-2017
<b>ASSETS</b>		
<b>Fixed assets</b>		
Intangible fixed assets	60,868	36,791
Tangible fixed assets	8,989	4,597
Financial fixed assets	253	0
<b>Total fixed assets</b>	<b>70,110</b>	<b>41,388</b>
<b>Current assets</b>		
Accounts receivable	32	0
Receivables from Group companies	29,984	5,618
Current receivables	8,465	9,909
Prepaid costs and accrued income	3,843	1,533
Cash and cash equivalents	385,517	192,216
<b>Total current assets</b>	<b>427,841</b>	<b>209,276</b>
<b>TOTAL ASSETS</b>	<b>497,951</b>	<b>250,664</b>
<b>EQUITY AND LIABILITIES</b>		
<b>Shareholder's equity</b>		
<i>Restricted equity</i>		
Share capital	977	866
Fund for development expenses	39,144	16,882
	<b>40,120</b>	<b>17,748</b>
<i>Unrestricted equity</i>		
Premium fund	312,178	4,923
Retained earnings including total comprehensive income	130,452	214,124
	<b>442,630</b>	<b>219,047</b>
<b>Total shareholders' equity</b>	<b>482,750</b>	<b>236,795</b>
<b>Current liabilities</b>		
Other liabilities	15,201	13,869
<b>Total current liabilities</b>	<b>15,201</b>	<b>13,869</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>497,951</b>	<b>250,664</b>

# Parent company's cash flow statement, summary

SEK thousand	Full year 2018	Full year 2017
<b>Operating activities</b>		
Operating profit/loss	-67,234	-45,596
Adjustment for items not included in cash flow	2,230	1,264
Received interest	306	366
Paid interest	-1	-2
Paid tax	0	0
<b>Cash flow from operating activities before changes in operating capital</b>	<b>-64,933</b>	<b>-43,968</b>
<b>Cash flow from changes in operating capital</b>		
Change in operating receivables	-24,667	-15,230
Change in operating liabilities	1,332	7,090
<b>Cash flow from operating activities</b>	<b>-88,268</b>	<b>-52,108</b>
<b>Investment activities</b>		
Investment in intangible assets	-27,341	-25,919
Investment in tangible assets	-6,149	-2,654
Investment in financing assets	-253	0
<b>Cash flow from investing activities</b>	<b>-33,509</b>	<b>-28,573</b>
<b>Financing activities</b>		
National and European grants for development costs	2,791	8,406
New share issue	311,352	4,923
Received subscription warrant premiums	936	474
<b>Cash flow from financing activities</b>	<b>315,079</b>	<b>13,803</b>
<b>Cash flow for the period</b>	<b>193,302</b>	<b>-66,878</b>
Cash and cash equivalents at beginning of period	192,215	259,094
<b>Cash and cash equivalents at end of period</b>	<b>385,517</b>	<b>192,216</b>



# Board assurance

The Financial Statement has not been reviewed by the company's auditors.

The Board and the CEO certify that the interim report gives a true and fair view of the group's operations, position and results, and describes significant risks and uncertainties that the group faces.

Lund, 14 February 2019

Carl Borrebaeck  
*Chairman*

Hans Johansson  
*Board member*

Åsa Hedin  
*Board member*

Mimmi Ekberg  
*Board member*

Christofer Sjögren  
*Board member*

Ann-Christine Sundell  
*Board member*

Mats Grahn  
*CEO*

# Definitions

Key indicator	Definition	Reason for using key indicator not defined in accordance with IFRS
Average number of employees	The average number of employees is calculated as the sum of hours worked during the period divided by the normal working hours for the period.	
Average number of employees in R & D	The average number of employees in the company's research and development departments.	
Average number of shares before and after dilution	Average number of shares outstanding during the period before and after dilution. As the Group's performance is negative, there is no dilution although the issue price is lower than the market price.	
Cash and cash equivalents	Cash and bank balances.	
Cash flow for the period	Net change in cash and cash equivalents excluding the impact of unrealized gains and losses.	
Cash flow from operating activities	Cash flow before cash flows from investing and financing activities.	
Earnings per share before and after dilution	Profit attributable to parent company shareholders divided by the weighted average number of shares during the period before and after dilution.	
Equity per share	Equity divided by number of shares at period end.	Management monitors this number to monitor how much value is equity per share.
Equity ratio	Equity as a percentage of total assets.	Management monitors this ratio as an indicator of the financial stability of the company.
Net sales	Revenues for goods and services sold in the main activity during the current period.	
Operating profit	Profit before financial items and tax.	Operating income provides a picture of the results that the company's regular operations have generated.
R & D costs	The Company's direct costs for research and development. Refers to the costs of personnel, materials and external services.	The company's main activity is research and development. Management believes that its R & D costs is an important parameter to follow as an indicator of the level of activity of the company.
R & D expenses as a percentage of operating expenses	R & D expenses divided by operating expenses, which include other external costs, personnel costs and depreciation.	Management believes that the company's R & D expenses in relation to total costs is an important parameter to follow as an indicator of how much of the total costs is used for the company's main business.

# Glossary

- Actionable information** – Information that is sufficiently authoritative and specific to be used in clinical decision making.
- 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.
- 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 tumour is benign it means that the tumour 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 tumours tend to worsen and become mortal. They are termed cancer, and thus differ from benign tumours.
- Metastasis** – A metastasis is a tumour 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 (ie, 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.
- 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 specialising 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 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.
- 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 commercialises 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.

## **Pancreatic cancer**

Each year about 338,000 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 per year.

## **Goals**

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 specially high-risk groups or when there is a suspicion of the aforementioned diseases.

## **Strategy**

As the first company, Immunovia's strategy is 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™ 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 First North. The Certified Advisor is Wildecó. For more information, visit [www.immunovia.com](http://www.immunovia.com)*

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