

# Immunovia Interim Report, January-September 2017

"The important prospective studies for the pancreas test within the diabetes group ("PANDIA-1") and the early symptoms group ("PANSYM-1") have in discussions with clinical partners made progress for both PANDIA-1 and PANSYM-1. At the end of October, collection of blood samples began from patients with early symptoms at University College London Hospital. This was a very significant milestone for PANSYM-1. The retrospective, diabetes risk-group study based on the biobank from Region Skåne is also now under way."

"We are working intensively to industrialize IMMray™M PanCan—d in order to reach the start of sales, which is our most important milestone. This involves development work and all the preparations ahead of ISO 13485 certification and other accrediting that is needed to begin selling in the US and in Europe. Preparations for the market launch and CE-marking also entail scaling up production and the laboratory processes with the same robustness and reproducibility used in the retrospective validation studies."

"During October we have within the autoimmune efforts announced a collaboration with Linköping University in Sweden. In addition to expertise in RA, SLE, Vasculitis and Sjögren's Syndrome, the university has valuable biobanks that cover all four diseases. All of the sample collections have now been delivered to us, and validation and complementary studies have started with our extended resources for the autoimmunity project."



Mats Grahn, CEO of Immunovia AB

<b>Key indicators</b> SEK thousand unless otherwise stated	1 July – 30 Sept. 2017	1 July – 30 Sept. 2016	1 July – 30 Sept. 2017	1 July – 30 Sept. 2016	Full year 2016
Net sales	27	5	122	71	177
Operating earnings	-11,641	-4,048	-30,157	-9,451	-14,978
Earnings before tax	-11,589	-4,048	-29,914	-9,346	-14,723
Net earnings	-11,589	-4,048	-29,914	-9,346	-14,723
Earnings per share before dilution (SEK/share)	-0,69	-0,28	-1,78	-0,65	-0,98
Equity ratio, %	97	97	97	97	98
No. of shares at the end of the period	16,804,059	16,474,568	16,804,059	16,474,568	16,804,059

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

## **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.

- It is planned to launch IMMray™ PanCan-d on the American and European markets with sales to out-of-pocket customers, to start when the accreditation and production upscaling have been completed, with revenues expected to begin from the latter stages of 2018. In coming years Immunovia will address a market that in total is worth around SEK 35 billion.
- Immunovia sees great potential in the development of tests for other unsolved problems in cancer and autoimmune diseases via its IMMray™
  platform. The next focus area will be tests within SLE, based on the positive results announced in early 2017.

## **CEO's statement**

Dear shareholders.

As always, we are staying focused on bringing our patented test for pancreatic cancer to the market. The prospective studies and certifications, accreditations and scaling up of production, both of the product itself and of laboratory capacity, will continue to be the main activities that will take us to the commercial phase. Important milestones were reached during the quarter, and work continues unchanged ahead of our planned sales launch towards the end of 2018. During Q3 we also worked to establish and equip our American office and reference laboratory in Boston, USA.

The retrospective study of diabetes patients who have developed pancreatic cancer, based on the biobank from Region Skåne, is now under way. The important prospective studies for the diabetes group ("PANDIA-1") and the early symptoms group ("PANSYM-1") are now in the planning stage. Significant progress has been made in discussions with partners about these prospective studies for starting both PAN-DIA-1 and PANSYM-1.

Following the good results reported in Q2, Immunovia's focus on autoimmunity continued when we announced a collaboration with Linköping University and the delivery of valuable biobanks concerning RA, SLE, Vasculitis and Sjögren's Syndrome.

#### On the road to reimbursement with PANFAM-1 study

In December 2016 we announced the start of a prospective study on hereditary risk groups, "PANFAM-1". During Q3, in addition to the commitment from the existing cancer centre participants, we have worked intensively to involve more cancer centers in the study, both in the US and the EU. We will continue to involve key partners during the remainder of the year, for both analytical and marketing purposes. A very important milestone will be an interim reading at the half way stage of the study, when a sufficient number of cancer cases has arisen.

#### New diabetes patients are largest target group

One of the highest risk groups for pancreatic cancer are newly-onset Type II diabetes patients diagnosed after 50 years of age. Our work continues on the study of the biobank from Lund University Diabetes Centre (LUDC) that was delivered to us within the framework of the collaboration that was announced earlier. LUDC has collected samples from virtually all newly diagnosed diabetes patients since 2008 in the Skåne region of Sweden, a total of around 12,000 patients.

We have access to samples taken during diabetes diagnosis for patients who later developed pancreatic cancer, and we will be able to compare them in our study with diabetes patients who did not develop pancreatic cancer. The results of this study are expected to be completed in Q1 2018. The results are expected to provide important information in our work aimed at establishing IMMray<sup>TM</sup> PanCan –d as standard for the diabetes risk group, while also facilitating the start of prospective studies.

During the quarter we made significant progress in the planning and discussions taking place with clinical partners. This was despite the fact that NCI has received changed budgetary requirements that will add to the time needed for this process. Meanwhile, direct discussions are progressing well with clinical centers that serve patients.

### Early-symptom risk group are a new growing opportunity

As previously reported, our Key Opinion Leaders have pointed to the opportunity for using IMMray™ PanCan-d in another area, solving the delay that occurs from the time a patient seeks medical help for vague symptoms that could be the early stages of pancreatic cancer to the time when the cancer is diagnosed. Often, it is a question of something other than pancreatic cancer. However, for a patient with a developing cancer it has been shown that it takes on average 18 visits to a doctor over 6-9 months before pancreatic cancer is diagnosed. This delay can mean that a treatable situation becomes one that is no longer treatable.

'As we announced in July, one of the world's leading experts in this field, Professor Stephen Pereira at University College London, has begun working with Immunovia as a clinical adviser."

As we announced in July, one of the world's leading experts in this field, Professor Stephen Pereira at University College London, has begun working with Immunovia as a clinical adviser. We now intend to start prospective studies in this field as we believe that there are good opportunities for early market penetration regarding this risk group. During the quarter, progress was made in planning for the start of prospective studies for early-symptom risk groups. As announced in early November, University College London Hospital has begun collection of blood samples from the risk group in the first phase. We will announce interim results from 360 patients in 2018. Provided that results are positive, we will then perform a full-scale prospective study.

Our assessment is that the market potential for this risk group may exceed one million tests per year in Europe and the United States at full penetration.

#### Certifications and accreditations continue

We are working intensively to industrialize IMMray<sup>™</sup> PanCan-d and start sales, which is our most important milestone. This includes development and all preparation for ISO 13485 certification and other accreditations required for starting sales in the US and Europe.

The preparation for the market introduction and the CE marking has included scaling up the production of the antibody microarray while maintaining the same robustness and reproducibility as in the retrospective validation studies. A number of important targets in this area were achieved during the quarter.

Industrialization, software verification, validation according to ISO 13485:2016 and upscaling of production are being performed in parallel. Certifications and accreditations, which are linked and dependent on the scaling up of production, are still planned for the latter part of 2018.



# Extension of autoimmunity program based on good results in first 6 months of 2017

Following the good results reported in Q1 and Q2, we are continuing as planned with three important activities that will be performed in parallel over the coming year:  $\frac{1}{2} \left( \frac{1}{2} \right) = \frac{1}{2} \left( \frac{1}{2} \right) \left( \frac{1}{2$ 

- Definition and implementation of complementing and validating retrospective studies,
- Expansion of Key Opinion Leader network within autoimmunity and greater cooperation among the network. The first meetings were held during Q2.
- Strategy and planning for commercial market access

During October we announced a collaboration with Linköping University. In addition to expertise in RA, SLE, Vasculitis and Sjögren's Syndrome, the university has valuable biobanks that cover all four diseases. All of the sample collections have now been delivered to us, which has meant that validation and complementary studies have started for our extended resources for the autoimmunity project. We look forward to reporting in the future on the progress we hope to make within the field of autoimmunity.

Thank you for your continuing support of Immunovia!

Mats Grahn
CEO, Immunovia AB

## **Group performance in January-September 2017**

#### Net sales

Net sales for Q3 2017 were SEK 27 thousand (5 k). For the first nine months of 2017 net sales were SEK 122 thousand (71 k). Net sales principally comprise royalties.

In Q3 2017, capitalisation of costs amounted to SEK 4,544 thousand (5,581 k). Where capitalised development costs are financed through approved and paid grants, the reported amounts are reduced by a comparable amount. In the first nine months of 2017 grants amounting to SEK 164 thousand were received. In the corresponding period in 2016, grants amounting to SEK 800 thousand were received.

#### **Earnings**

The net loss for Q3 2017 was SEK 11,589 thousand (-4,048 k). The loss for the first nine months of 2017 was SEK 29,914 (-9,346 k). The net loss for the first nine months of 2017 was mainly due to higher costs, which in turn were due to an expanded organization and increased market activity. Other external costs and personnel costs increased by a total of SEK 18,482 thousand compared with the previous year to reach SEK 44,746 thousand in the first nine months of 2017.

#### Research and development

Research and development follows established plans. The total cost of research and development in Q3 2017 was SEK 7,427 thousand (5,170 k), which corresponds to 48% (57%) of the Group's total operating costs. The decrease in the proportion of R&D activity was mainly due to the increase in activities and costs for marketing and production.

#### Financial position and cash flow

Cash flow for Q3 2017 from operating activities amounted to SEK -13,467 thousand (-2,251 k) and total cash flow for the first nine months of 2017 amounted to SEK -29,825 thousand (-5,484 k). Cash and cash equivalents as at 30 September 2017 were SEK 215,300 thousand (231,382k).

Shareholders' equity at the end of the period was SEK 252,113 thousand (256,170 k) and the equity ratio was 97% (97%).

Management believes that there is sufficient working capital to meet working capital needs, given the current business and development plan, for approximately 18 months going forward.

#### Investments

In Q3 2017, intangible assets were acquired for SEK 4,544 thousand (5,581 k), consisting of capitalized development expenditure for SEK 4,351 thousand (4,907) and patents for SEK 193 thousand (674 k).

Investments were made in Q3 2017 in tangible assets in the form of inventories amounting to SEK 102 thousand. For the corresponding period last year the total was SEK 2,035 thousand.

#### **Employees**

The number of employees in the Group during the period averaged 28 (15) and at the end of the period the number of full-time positions was 31, divided across 31 individuals.

## Key events during the quarter

#### Important events in Q3 2017

#### Väsentliga händelser under kvartalet

Global expert in pancreatic cancer, Professor Stephen Pereira from University College London, appointed to Immunovia's Scientific Advisory Board. Professor Stephen Pereira from University College London, one of the globally leading experts in the diagnosis of early symptoms of pancreatic cancer and a pioneer in multidisciplinary diagnostic centers, was appointed to Immunovia's Scientific Advisory Board. Professor Pereira is currently Professor of Hepatology & Gastroenterology at University College London, and an honorary consultant in pancreaticobiliary medicine at UCL Hospitals and The Royal Free Hospital.

In the past two years, Professor Pereira has been involved in setting up multidisciplinary diagnostic centers in London, of which the first was at UCLH.

Immunovia started a collaboration with Lund University Diabetes Centre focusing on early detection of pancreatic cancer among the diabetes risk group

Immunovia started a collaboration with the researchers at Lund University Diabetes Centre (LUDC) to validate the company's biomarker signature in high risk group of newly-onset type 2 diabetics (NoD) patients over the age of 50. The risk of these patients to develop pancreatic cancer is over 8 times greater than that of the general population.

The collaboration is designed as a retrospective validation study, in which LUDC, a consortium of research groups at Lund University, will deliver blood samples to Immunovia from NoD patients who subsequently developed pancreatic cancer. These samples will be analysed using Immunovia's IMMray™ PanCan-d test with the goal of detecting pancreatic cancer at the early stages when the tumor is still treatable.

#### Significant events after the end of Q3 2017

Immunovia starts major collaboration with Linköping University concerning discovery of autoimmune biomarkers

Immunovia has started a major research collaboration on discovery of diagnostic biomarkers for autoimmune diseases with the Faculty of Medicine and Health Sciences, Linköping University. The collaboration aims to accelerate the development of a new generation of diagnostic tests based on Immunovia's leading IMMray™ antibody array platform.

Immunovia awarded SEK 4.9 million from the Swelife Accelerator Innovation Program

After the end of Q3, Immunovia received a follow-on grant of SEK 4.9 million from the Swelife Accelerator Innovation Program to support the last development studies of IMMray™ PanCan-d, the first blood-based test for early detection of pancreatic cancer. These studies are performed in close collaboration with CREATE Health Translational Cancer Center at Lund University.

University College London starts collection of blood samples in order to assess IMMray PanCan-d

Professor Pereira and his team at the Institute for Liver and Digestive Health, University College London (UCL) have started the collection of 360 blood samples for a study that aims to assess IMMray PanCan-d utility in patients with abdominal symptoms attending secondary care centers such as clinics, multidisciplinary diagnostic centers and endoscopy/gastrointestinal units.

### **Share information**

#### Share information

Immunovia's shares have been listed on Nasdaq First North, Stockholm (ticker: IMMNOV) since 1 December 2015.

First North is Nasdaq's European growth market and has a less extensive regulatory framework than the main market. Each company on First North has a Certified Adviser to ensure that companies meet requirements and regulations. Shares on First North and the main Nasdaq market are traded in the same trading system.

At the end of the period the total number of shares was 16,804,059. On 30 September 2016 there were 16,474,568 shares. The nominal value of each share is SEK 0.05.

#### Subscription warrants scheme

Immunovia has three outstanding warrants schemes covering 235,000 warrants entitling to subscription of 235,000 shares. All outstanding options have an exercise price less than the market price on the balance sheet date. There will be no dilution as long as the Group's earnings are negative. For more information about he warrants, see page 8.

The largest shareholders as of 30 September 2017

Name	No. of shares	Share capital and votes
Carl Borrebaeck	1,709,900	10.18 %
Vincent Saldell	1,000,000	5.95 %
Sara Andersson Ek	888,950	5.29 %
Christer Wingren	888,950	5.29 %
Per Mats Ohlin	888,950	5.29 %
Försäkringsbolaget Avanza Pension	662,637	3.94 %
Handelsbanken Svenska Småbolag	650,000	3.87 %
Michael Löfman	504,887	3.00 %
Ålandsbanken, on behalf of the owner	395,184	2.35 %
Catella Småbolagsfond	323,882	1.93 %
Ten largest	7,889,320	46.95 %
Others	8,914,739	53.05 %
Total	16,804,059	100.00 %

## **Risks**

#### Significant risks and uncertainties

Immunovia's business operations and market are subject to a number of risks that are wholly or partly outside the company's control and that affect or may in future affect Immunovia's business operations, financial position and earnings. The following risk factors are described in no special order and with no claim to be comprehensive:

- Immunovia is a development company with a relatively short operating history, which means that it may be some time before the company can report sales revenue.
- The company is in a commercialization phase that means there is a risk that sales revenue will be less than expected or zero.
- Validation studies could result in unexpected or negative research results.
- Development costs are difficult to anticipate. These costs may be higher than planned.
- The company is dependent on collaboration and licensing agreements and there is a risk that the company cannot enter into the necessary partnerships.
- There is a risk that Immunovia does not receive the necessary registrations to sell and promote its products.
- There is a risk that the company will not receive accreditation to ISO 17025.
- Immunovia is subject to a number of government regulations that may change.
- There is a risk that Immunovia cannot defend granted patents, registered trademarks and other intellectual property rights or that submitted registration applications are not granted.
- For a description of financial risks, see page 7.

#### 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.

## Development of share capital

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
At end of perio	d	840,202.95		16,804,059		0.05
4 Oct 2017	New share issue via warrants	865,902.95	25,700.00	17,318,059	514,000	0.05

#### 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.

#### 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 18 months.

# **Information about Nasdaq First North**

Nasdaq First North is an alternative market, operated by the different exchanges within NASDAQ. Companies whose shares are traded on First North are not obliged to follow the same rules as companies whose shares are traded on a regulated market, but are subject instead to a more limited regulatory framework adapted for small growth companies. An investment in a company whose shares are traded on First North may therefore be more risky than an investment in a company whose shares are traded on a regulated market. All companies whose shares are traded on First North have a Certified Advisor who ensures that the company complies with First North's rules for disclosure of information to the market and investors.

# **Financial reports**

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

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### Other information

#### Certified Adviser

Wildeco Ekonomisk Information AB is the company's Certified Adviser on Nasdaq First North.

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Immunovia's annual report is available on the company's website: www.immunovia.com

#### Telephone conference:

13 November 2017, 16.00 (CET)

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US: +18558315946

## Financial calendar

Thursday 15 February 2018 2017 Financial statement (Q4)
Friday 27 April 2018 Q1 2018 interim report
Thursday 3 May 2018 Annual General Meeting
Friday 24 August 2018 Q2 2018 interim report
Wednesday 7 November 2018 Q3 2018 interim report
Thursday 14 February 2019 2018 Financial statement (Q4)

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## **Accounting principles**

The Group complies with the Swedish annual accounts act and applies International Financial Reporting Standards (IFRS) as adopted by the EU along with RFR 1 Complementary accounting rules for groups in the preparation of financial statements. The parent company complies with the Swedish annual accounts act and applies RFR 2 Accounting for legal entities in the preparation of financial statements. The accounting principles that have been applied are in agreement with those presented in the company's 2016 annual report.

This interim report has been prepared in accordance with IAS 34 Interim Financial Reporting. New and amended standards adopted from 2017 have not had any significant impact on the Group's financial position

## **Transactions with related parties**

No transactions have occurred 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.

## **Financial instruments**

The Group currently has no financial instruments measured at fair value. Instead all financial assets and liabilities are measured at amortized cost. There is not expected to be any significant differences between the fair value and the carrying value of the financial assets and liabilities. The carrying amount of financial assets on the closing day amounted to SEK 218,238 (232,189) thousand.

### Incentive schemes

#### Warrants

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 (137,000) 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 6,850.

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. A total of 10,000 warrants have been utilised, and 37,000 warrants remain to be utilised. 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.

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

# Consolidated income statement, summary

SEK thousand	1 Jul-30 Sep 2017	1 Jul-30 Sep 2016	1 Jan-30 Sep 2017	1 Jan-30 Sep 2016	Full year 2016
Operating income, etc.					
Net sales	27	5	122	71	177
Capitalized work for own account	4,479	5,170	15,559	17,054	24,293
Other income	35	0	59	7	33
Total income	4,541	5,175	15,740	17,132	24,503
Operating costs					
Other external costs	-11,959	-6,082	-27,472	-17,111	-24,115
Personnel costs	-3,702	-3,000	-17,274	-9,153	-14,815
Depreciation and amortization of tangible and					
intangible assets	-369	-127	-876	-302	-549
Other operating expenses	-152	-14	-275	-17	-2
Total operating expenses	-16,182	-9,223	-45,897	-26,583	-39,481
Operating profit/loss	-11,641	-4,048	-30,157	-9,451	-14,978
Financial items					
Financial income	53	0	244	106	256
Financial costs	-1	0	-1	-1	-1
Total financial items	52	0	243	105	255
Profit/loss after financial items	-11,589	-4,048	-29,914	-9,346	-14,723
Tax on income	0	0	0	0	0
Profit/loss for the period	-11,589	-4,048	-29,914	-9,346	-14,723
Earnings per share before and after dilution (SEK)	-0.67	-0.28	-1.78	-0.65	-0.98
Average number of shares before and after dilution	16,804,059	14,655,108	16,804,059	14,412,513	14,985,688
No. of shares at the end of the period	17,318,059	16,474,568	17,318,059	16,474,568	16,804,059

# Consolidated comprehensive income, summary

SEK thousand	1 Jul-30 Sep 2017	1 Jul-30 Sep 2016	1 Jan-30 Sep 2017	1 Jan-30 Sep 2016	Full year 2016
Profit/loss for the year	-11,589	-4,048	-29,914	-9,346	-14,723
Items that may be later reclassified in the income statement	0	0	0	0	0
Exchange rate differences for foreign net investment	0	0	0	0	0
Other comprehensive income for the year	0	0	0	0	0
Comprehensive income for the period	-11,589	-4,048	-29,914	-9,346	-14,723

# Consolidated financial position in summary

SEK thousand	30 Sep 2017	30 Sep 2016	31 Dec 2016
ASSETS			
Fixed assets			
Intangible fixed assets	36,053	28,111	19,483
Tangible fixed assets	4,922	2,875	3,002
Financial fixed assets	0	0	0
Total fixed assets	40,975	30,986	22,485
Current assets			
Current receivables	3,927	1,375	1,830
Cash and cash equivalents	215,300	231,382	259,094
Total current assets	219,227	232,757	260,924
TOTAL ASSETS	260,202	263,743	283,409
EQUITY AND LIABILITIES			
Shareholders' equity			
Share capital	840	824	840
Unregistered share capital	26	0	0
Other contributed capital	314,170	282,978	308,800
Retained earnings including total comprehensive income	-62,923	-27,632	-33,009
Total shareholders' equity	252,113	256,170	276,631
Current liabilities			
Other liabilities	8,089	7,573	6,778
Total current liabilities	8,089	7,573	6,778
TOTAL EQUITY AND LIABILITIES	260,202	263,743	283,409

# Consolidated statement of change in equity

SEK thousand	Share capital	Unregistered share capital	Other contributed equity	Reserves	Retained earnings including total com- prehensive income	Total shareholders' equity
Equity, 1 January 2016	715	0	101,372	0	-18,286	83,801
Comprehensive income for the period				0	-9,346	-9,346
Transaction with owners in their role as owners						
Received subscription warrant premiums			311			311
New share issue	109		189,843			189,952
Costs of share issue			-8,548			-8,548
Equity 30 September 2016	824	0	282,978	0	-27,632	256 170
Comprehensive income for the period				0	-5,377	-5,377
Transaction with owners in their role as owners						
Received subscription warrant premiums			9			9
New share issue	16		28,650			28,666
Costs of share issue			-2,837			-2,837
Equity 31 December 2016	840	0	308,800	0	-33,009	276 631
Comprehensive income for the period				0	-29,914	-29,914
Transaction with owners in their role as owners						
Received subscription warrant premiums			473			473
New share issue		26	4,897			4,923
Costs of share issue						0
Equity 30 September 2017	840	26	314,170	0	-62,923	252,113

# Consolidated cash flow statement in summary

SEK thousand	1 Jul-30 Sep 2017	1 Jul-30 Sep 2016	1 Jan-30 Sep 2017	1 Jan-30 Sep 2016	Full year 2016
Operating activities					
Operating profit/loss	-11,641	-4,048	-30,157	-9,451	-14,978
Adjustment for items not included in cash flow	369	127	876	302	548
Received interest	53	0	244	106	256
Paid interest	-1	0	-1	-1	-1
Paid tax	0	0	0	0	0
Cash flow from operating activities before changes in operating capital	-11,220	-3,921	-29,038	-9,044	-14,175
Cash flow from changes in operating capital					
Change in operating receivables	-568	-346	-2,096	-188	-645
Change in operating liabilities	-1,679	2,016	1,309	3,748	2,951
Cash flow from operating activities	-13,467	-2,251	-29,825	-5,484	-11,869
Investment activities					
Investment in intangible assets	-4,544	-5,581	-16,876	-18,965	-28,028
Investment in tangible assets	-102	-2,035	-2,654	-2,450	-2,781
Cash flow from investing activities	-4,646	-7,616	-19,530	-21,415	-30,809
Financing activities					
National and European grants for development costs	164	0	164	800	18,451
New share issue	4,923	181,404	4,923	181,404	207,233
Received subscription warrant premiums	0	117	473	311	321
Cash flow from financing activities	5,087	181,521	5,561	182,515	226,005
Cash flow for the period	-13,026	171,654	-43,794	155,615	183,327
Cash and cash equivalents at beginning of period	228,326	59,728	259,094	75,767	75,767
Cash and cash equivalents at end of period	215,300	231,382	215,300	231,382	259,094

# Consolidated key indicators

SEK thousand unless otherwise stated	1 Jan-30 Sep 2017	1 Jan-30 Sep 2016	Full year 2016
Operating profit/loss (SEK thousand)	-30,157	-9,451	-14,978
Profit/loss for the year (SEK thousand)	-29,914	-9,346	-14,723
Earnings per share before and after dilution (SEK)	-1.78	-0.65	-0.98
R&D costs (SEK thousand)	-15,559	-17,054	-24,293
R&D costs as percentage of operating costs (%)	34	64	62
Cash and cash equivalents at end of period (SEK thousand)	215,300	231,382	259,094
Cash flow from operating activities (SEK thousand)	-29,825	-5,484	-11,869
Cash flow for the period (SEK thousand)	-43,794	155,615	183,327
Equity (SEK thousand)	252,113	256,170	276,631
Equity per share (SEK)	14.56	15.55	16.46
Equity ratio (%)	97	97	98
Average no. of employees	28	15	16
Average no. of employees in R&D	16	9	11

# **Definitions**

Key indicator	Definition	Reason for using key indicator not defined in accordance with IFRS
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.
Earnings per share before and after dilution	Profit attributable to parent company share- holders divided by the weighted average number of shares during the period before and after dilution.	
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.	
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.
Cash and cash equivalents	Cash and bank balances.	
Cash flow from operating activities	Cash flow before cash flows from investing and financing activities.	
Cash flow	Net change in cash and cash equivalents excluding the impact of unrealized gains and losses.	
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.
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.	

# Parent company, income statement in summary

SEK thousand	1 Jan-30 Sep 2017	1 Jan-30 Sep 2016	Full year 2016
Operating income, etc.			
Net sales	122	71	177
Capitalized work for own account	15,559	17,054	24,293
Other income	59	7	33
Total income	15,740	17,132	24,503
Operating costs			
Other external costs	-27,472	-17,111	-24,115
Personnel costs	-17,274	-9,153	-14,815
Depreciation and amortization of tangible and intangible			
assets	-876	-302	-549
Other operating expenses	-275	-17	-2
Total operating expenses	-45,897	-26,583	-39,481
Operating profit/loss	-30,157	-9,451	-14,978
Financial items			
Financial income	244	106	256
Financial costs	-1	-1	-1
Total financial items	243	105	255
Profit/loss after financial items	-29,914	-9,346	-14,723
Tax on income	0	0	0
Profit/loss for the period	-29,914	-9,346	-14,723
Earnings per share before and after dilution (SEK)	-1.78	-0.65	-0.98
Average number of shares before and after dilution	16,804,059	14,412,513	14,985,688
No. of shares at the end of the period	17,318,059	16,474,568	16,804,059

# Parent company, statement of comprehensive income in summary

SEK thousand	1 Jan-30 Sep	1 Jan-30 Sep	Full year
	2017	2016	2016
Profit/loss for the year Other comprehensive income for the year	-29,914	-9,346	-14,723
	0	0	0
Comprehensive income for the period	-29,914	-9,346	-14,723

# Parent company, statement of financial position in summary

SEK thousand	30 Sep 2017	30 Sep 2016	31 Dec 2016
ASSETS			
Fixed assets			
Intangible fixed assets	36,053	28,111	19,483
Tangible fixed assets	4,922	2,875	3,002
Financial fixed assets	0	0	0
Total fixed assets	40,975	30,986	22,485
Current assets			
Current receivables	6,072	1,375	1,831
Cash and cash equivalents	213,162	231,382	259,093
Total current assets	219,234	232,757	260,924
TOTAL ASSETS	260,209	263,743	283,409
EQUITY AND LIABILITIES			
Shareholders' equity			
Restricted equity			
Share capital	840	824	840
Unregistered share capital	26	0	0
Reserve for development expenses	39,381	12,108	24,293
	40,247	12,932	25,133
Unrestricted equity			
Premium fund	5,691	181,606	207,107
Retained earnings including total comprehensive income	206,175	61,632	44,391
	211,866	243,238	251,498
Total shareholders' equity	252,113	256,170	276,631
Current liabilities			
Other liabilities	8,096	7,573	6,778
Total current liabilities	8,096	7,573	6,778
TOTAL EQUITY AND LIABILITIES	260,209	263,743	283,409

# Parent company, cash flow in summary

SEK thousand	1 Jan-30 Sep 2017	1 Jan-30 Sep 2016	Full year 2016
Cash flow from operating activities	-31,962	-5,485	-11,870
Cash flow from investment activities	-19,530	-21,414	-30,809
Cash flow from financing activities	5,561	182,515	226,005
Cash flow for the period	-45,931	155,615	183,326
Cash and cash equivalents at beginning of period	259,093	75,767	75,767
Cash and cash equivalents at end of period	213,162	231,382	259,093

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

## **Board assurance**

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

Lund, 10 November 2017.

Carl Borrebaeck
Chairman

Ann-Christin Malmborg Hager
Board member

Mats Grahn
CEO

Ann-Christine Sundell
Board member

## **Glossary**

**Actionable information** – In this context this means information that is sufficiently reliable and specific to form the basis for clinical decisions.

**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 Study** – 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.

**Out-of-pocket customers** – Patients or organizations that pay for drugs without reimbursement from insurance companies or government agencies.

**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.

**PANFAM-1, PANDIA-1 and PANSYM-1** – Prospective studies that aim to show the capability of  $IMMray^{TM}$  PanCan –d in hereditary and familiar risk groups

**Pancreatologist** – Pancreatologists are doctors who specialize in diseases relating to the pancreas.

**Prospective study** – A study in which a group of individuals are studied and followed over a period of time (often long) to see how a disease develops. A prospective study is used to study the link between different risk factors and a specific disease. Individuals with or without risk factors are monitored over time. At the end of the study a comparison is made of the proportion of individuals who have developed the disease in both groups.

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

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

**Retrospective study** – A study in which you look back at something that has already occurred, i.e. historical data is used. A retrospective study begins with the answer, i.e. you already know which individuals will develop the disease.

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

**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 entering a commercialisation phase with a strong financial position. 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<sup>TM</sup>, 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 lupus (SLE), prostate cancer and breast cancer.

### 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 59%. 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<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 First North. The Certified Advisor is Wildeco. For more information, visit www.immunovia.com



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