

# Full Year Report for Immunovia, January-December 2017



Mats Grahn, CEO of Immunovia AB

"The fourth quarter of 2017 marked an important inflection point for Immunovia in many aspects. We ended our final year of purely pre-commercial activity, and have now started what is planned as our first business year that will lead to the start of sales in the second half of 2018."

"During 2018 we expect to reach our target of starting commercial sales of iMMray™ PanCan – d by providing the test to customers, both private individuals and health organizations, so-called self-pay customers."

"The internal work aimed at preparing the company for a listing on Nasdaq Stockholm's main market was completed in 2017. We have submitted our application and we are expecting to receive a decision in the first quarter of 2018."

<b>Key indicators</b> SEK thousand unless otherwise stated	1 Oct-31 Dec 2017	1 Oct-31 Dec 2016	Full year 2017	Full year 2016
Net sales	26	106	149	177
Operating earnings	-15,362	-5,527	-45,520	-14,978
Earnings before tax	-15,318	-5,377	-45,232	-14,723
Net earnings	-15,318	-5,377	-45,232	-14,723
Earnings per share before dilution (SEK/share)	-0.88	-0.32	-2.67	-0.98
Equity ratio, %	94	98	94	98
No. of shares at the end of the period	17,318,059	16,804,059	17,318,059	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 product. 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 selfpay customers, to start when the accreditation and production upscaling have been completed. Revenues expected to begin in 2018. In coming years Immunovia will address a market that in total is worth more than 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.

The fourth quarter of 2017 marked an important inflection point for Immunovia in many aspects. We ended our final year of purely precommercial activity, and have now started what is planned as our first business year that will lead to the start of sales in the second half of 2018. During 2017 we carried out preparations for moving the trading in the company's shares from First North to the main Nasdaq Stockholm market and we are currently undergoing the Nasdaq process to achieve this goal. During 2017 we have continued to work determinedly to take our patented, blood-based test for pancreatic cancer, iMMray™ PanCan −d to the market. The primary activities currently taking place aimed at reaching the commercialization phase are prospective studies, certification, accrediting and scaling up of production capacity, both for the product itself and regarding laboratory capacity. In each area, the focus is on the goal of starting sales during 2018.

#### Prospective studies prepare the way for cost reimbursement

In 2017 our prospective study program was extended as planned to cover the use of IMMray™ PanCan –d by all three risk patient target groups. The main purpose of these studies is to validate our blood-based IMMray™ PanCan –d test so that it meets the criteria for reimbursement from health insurance systems while also following national guidelines.

PANDIA-1, our prospective study for the diabetes risk groups, which focus on patients newly-onset Type II diabetes patients diagnosed with pancreatic cancer after 50 years of age (NOD), which are one of the largest risk groups for pancreatic cancer.

"In December 2017 we initiated PanDIA-1, the world's most comprehensive prospective study of the newly-diagnosed diabetic risk group."

We have a collaboration with Lund University Diabetes Centre (LUDC). LUDC has collected samples from virtually all newly diagnosed diabetes patients since 2008 in the Skåne region of Sweden, a total of over 17,000 patients. In December 2017 we initiated PanDIA-1, the world's most comprehensive prospective study of this risk group, through a consortium that includes Lund University and Uppsala University, Lund University Diabetes Center, Region Skåne and Region Uppsala. This consortium will receive a SEK 7.6 million grant from SWElife, the Swedish government's strategic innovation program, for the project "Improved diagnostics and treatment of diabetes-related comorbidities". Through this project, Immunovia will be able to access up to 6,000 new-onset diabetics, over 50 years of age, for prospective testing with the IMMray™ PanCan −d biomarker signature assay. In January 2018 the Danish Center for Strategic Research into Type 2 Diabetes (DD2) joined the PanDIA-1 study, adding up to 3,500 patients

"In 2018 we expect to reach our goal of starting sales of IMMray™ PanCan –d commercially."

in what is planned to be a global collaborative study.

PANSYM-1, our prospective study for early symptom risk groups, started with the collection of samples in a pilot study in collaboration with University College London Hospital, under the leadership of Professor Steve Pereira, one of the world's most prominent key opinion leaders in this field.

The results of the pilot study, which covers 360 patients, can be expected in 2018. PANSYM-1 will be expanded if the results are positive.

Work has continued on our prospective study for familiar and hereditary risk groups, PANFAM-1, where we are working to sign up further cancer centers, both in the US and the EU. In December we announced that Sahlgrenska University Hospital in Göteborg, had become the first Swedish site to join the study, and that the University of Pittsburgh, one of the most renowned centers of pancreatic cancer expertise in the US, had also become involved. Their participation contributes a patient base that gives the study greater breadth and legitimacy. The breadth of collaboration not only has benefits for the study itself, it is also an important long-term market investment because participants are important potential customers in a future commercial phases. Other participant partners are: Mount Sinai in New York, Knight Cancer Institute at Oregon Health and Sciences University as well as the University of Michigan.

The European partners are IRYCIS in Madrid, the University of Liverpool in the UK and Sahlgrenska in Sweden.

### Final preparations for self-pay sales in 2018

In 2018 we expect to reach our goal of starting sales of IMMray™ PanCan –d commercially by offering the test to customers, both as private individuals or healthcare institutions, so-called self-pay customers. To achieve this we worked intensively during 2017 to industrialize IMMray™ PanCan -d. This work will be completed in 2018. The work has primarily involved development and documentation, preparations for ISO 13485 certification of the development and production processes, ISO 17025 accreditation of the clinical laboratory in Lund, CLIA/CAP accreditation of the laboratories in the US, and CE marking of the product. Authorities in both the US and the EU regularly update these standards. We comply with these updates and adapt continually to developments. Preparations ahead of the market launch also include scaling up production and laboratory processes with the same robustness and reproducibility maintained through the retrospective validation studies. We are making good progress and a large number of improvements were made during the period, including reducing turnaround times in the laboratory from five to two days. Even if a significant amount of this essential validation work remains, we expect to complete it as planned in the latter part of 2018. The company will then start generating its first sales revenue.



In November King Carl XVI Gustaf of Sweden and a delegation of industrial leaders and public officials visited Immunovia.

### Innovation achievements recognized

In November our business was honored with a visit by His Majesty King Carl XVI Gustaf of Sweden and a delegation of industrial leaders that included AstraZeneca chairman Leif Johansson, and Swedish public officials. The visit was part of a program of visits to Sweden's most innovative companies. Being chosen was a great honor and very welcome confirmation that our business involves a high level of innovation.

Another, more concrete confirmation that we are not alone in seeing the potential in our blood-based test, was the award during the final quarter of the year of an SEK 4.9 million grant from Swelife, the Swedish government's strategic innovation program, to be used in collaboration with CREATE Health at Lund University in our pancreatic work.

#### IMMray™ has great potential within autoimmunity

In the long term Immunovia sees great potential in the development of tests for other unsolved problems within the cancer and autoimmunity fields via its IMMray™ technology. Tests will next be carried out for SLE and RA, based on the very positive results announced in early 2017. During the year we announced a major collaboration with Linköping University,

which has expertise and valuable biobanks in RA, SLE, Vasculitis and Sjögren's Syndrome. The goal is to develop the next generation of diagnostics for autoimmune diseases based on our IMMray™ platform.

### Move to main Nasdaq Stockholm list

The internal work on preparing the company for a listing on the main Nasdaq Stockholm stock exchange was completed during the year. We have submitted our application and are expecting a decision in the first quarter of 2018. Listing on Nasdaq First North has served the company well. Since the introduction in 2015 we have had access to capital and an investor base that has given us the opportunity to make the necessary preparations for taking the company to a commercial phase. I would like to conclude the final interim report of the year by thanking shareholders for their support. I look forward to 2018 when we start sales of our test.

Thank you for your continuing support of Immunovia!

Mats Grahn
CEO, Immunovia AB

## Consolidated financial results for January-December 2017

#### Net sales

Net sales for the final quarter of 2017 were SEK 26 thousand (106 k). For the full year 2017 net sales were SEK 149 thousand (177 k). Net sales principally comprise royalties.

Capitalization of costs for the final quarter of 2017 amounted to SEK 9,043 thousand (9,065 k). Where capitalized development costs are financed through approved and paid grants, the reported amounts are reduced by a comparable amount. For the full year 2017, grants for development costs were received amounting to SEK 8,406 thousand (18,451 k).

#### **Earnings**

The net loss for the final quarter of 2017 was SEK 15,318 thousand (–5,377 k). The loss for the full year was SEK 45,232 (–14,723 k). The net loss in 2017 rose due to organizational enlargement, establishing a laboratory in the US and increased marketing activity. Other operating costs and personnel costs increased by a total of SEK 29,320 thousand compared with last year to reach SEK 68,251 thousand in 2017.

#### Research and development

Research and development follows established plans. The total cost of research and development in Q4 2017 was SEK 8,482 thousand (8,067 k), which corresponds to 36% (63%) of the Group's total operating costs. The total cost of research and development for the full year 2017 was SEK 24,041 thousand (24,292 k), which corresponds to 34% (62%) 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 Q4 2017 from operating activities amounted to SEK -16,701 thousand (-6,380 k) and total cash flow for the year amounted to SEK -46,525 thousand (-11,869 k). Cash and cash equivalents as at 31 December 2017 amounted to SEK 192,425 thousand (259,094 k).

Shareholders' equity at the end of the period was SEK 236,795 thousand (276,631 k) and the equity ratio was 94% (98).

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 Q4 2017 intangible assets were acquired for SEK 9,043 thousand (9,065 k), consisting of capitalized development expenditure for SEK 8,482 thousand (8,067 k) and patents for SEK 561 thousand (998 k).

For the full year, intangible assets were acquired for a total of SEK 25,919 thousand (28,028 k), consisting of capitalized development expenditure for SEK 23,329 thousand (24,292 k), patents for SEK 2,590 thousand (3,074 k) and other intangible assets for SEK 0 thousand (662 k).

Investments in tangible assets in the form of inventories were made during the Q4 2017 amounting to SEK 2,614 thousand. For the corresponding period last year the total was SEK 331 thousand. For the full year investment in tangible assets amounted to SEK 5,268 thousand (2.781 k).

Investment in financial assets in the form of barred bank funds were made during Q4 2017 amounting to SEK 2,759 thousand (0 k). For full year 2017, investments were made in financial assets in the form of blocked bank funds amounting to SEK 2,759 thousand (0 k).

The blocked bank funds are secured as collateral for credit cards and deposit to the landlord.

#### **Employees**

The number of employees in the Group during Q4 2017 averaged 30 (16) and at the end of the period the number of full-time positions was 34, divided across 34 individuals.

# Parent company development, January-December 2017

During the period, the business of the parent company was in most respects the same as the Group. The comments made concerning the Group are therefore also applicable to the parent company.

## Key events in the quarter

#### Important events in the Q4 2017

Immunovia began major autoimmune biomarker discovery collaboration with Linköping University

Immunovia 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<sup>TM</sup> antibody array platform.

Immunovia awarded SEK 4.9 Million grant from Swelife Accelerator Innovation Program

Immunovia was awarded a follow-on grant of SEK 4.9 million from the Swelife Accelerator Innovation Program to support the final development studies of IMMray™ PanCan −d.

University College London Hospital started the collection of blood samples to evaluate IMMray™ PanCan – d in symptomatic patients
Immunovia announced that Prof. 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 gastrointestinal units or diagnostic centers. The study will be funded by London Cancer Vanguard and is expected to run for one year. It will also validate the use of a digital Clinical Decision Support Tool currently used in primary care as a risk assessment tool for pancreatic cancer.

Nomination committee appointed for 2018 AGM

The nomination committee for the 2018 Annual General Meeting comprises Sara Ek, representing Sara Ek, Chairman of the Nomination Committee, Carl Borrebaeck representing Carl Borrebaeck, Chairman of the Board, and Astrid Samuelsson, representing Handelsbanken.

Immunovia initiated the world's largest study of new onset diabetic patients in a prospective pancreas cancer study supported by SWElife
Immunovia announced the initiation of the world's largest prospective study of the new onset diabetes ("NOD") risk group for pancreatic cancer through a consortium that includes Lund and Uppsala Universities, Lund University Diabetes Center and Healthcare Region Skåne and Region Uppsala. The consortium will receive a 7.6 MSEK grant from SWElife, the Swedish government's strategic innovation program, for the project "Improved diagnostics and treatment of diabetes-related comorbidities".

Sahlgrenska University Hospital first Swedish site in the largest ever prospective clinical study for early detection of pancreatic cancer
Sahlgrenska University Hospital in Göteborg became the first Swedish clinical centerto participate in PanFAM-1, an international, multicenter prospective validation study for the early diagnosis in familiar pancreatic cancer (FPC) high-risk individuals.

Immunovia expanded the multicenter clinical study for early detection of pancreatic cancer through collaboration with the renowned University of Pittsburgh

The University of Pittsburgh will be part of PanFAM-1, a multicenter prospective validation study for the early diagnosis in familiar pancreatic cancer (FPC) high-risk individuals. The study will analyze one thousand individuals for three years across sites in both the US and Europe offering FPC screening programs, and will open up opportunities for sales to patients with a high risk for hereditary pancreatic cancer.

## **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 reporting period the total number of shares was 17,318,059. 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. There will be no dilution as long as the Group's earnings are negative. For more information about he warrants, see page 7.

The ten largest shareholders as of 31 December 2017.

Name	No. of shares	and votes
Carl Borrebaeck	1,709,900	9.87 %
Vincent Saldell	1,000,000	5.77 %
Sara Andersson Ek	888,950	5.13 %
Christer Wingren	888,950	5.13 %
Per Mats Ohlin	888,950	5.13 %
Handelsbanken Svenska Småbolag	695,425	4.02 %
Michael Löfman	594,731	3.43 %
Försäkringsbolaget Avanza Pension	589,871	3.41 %
Ålandsbanken	543,106	3.14 %
Mats Grahn	413,039	2.39 %
Ten largest	8,212,922	47.42 %
Others	9,105,137	52.58 %
Total	17,318,059	100.00 %

### 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 which 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.

#### Aktiekapitalets utveckling

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
At end of perio	d	865,902.95		17,318,059		0.05

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## Risks and uncertainties

#### 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 flo

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 2017 amounted to SEK 206,090 thousand (259,199 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 18 months.

# **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 206,090 thousand (259,199 k).

## 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. 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 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. Applied accounting principles are consistent with those applied in the 2016 annual report.

This interim report has been prepared in accordance with IAS 34 Interim Financial Reporting. New and amended standards adopted as of 1 January 2017 have not had any significant impact on the Group's financial position.

As of January 1, 2018, the Group applies IFRS 9 Financial instruments and IFRS 15 Income from agreements with customers. The financial reports will not be affected in any significant way. The Group currently holds only financial assets valued at accrued acquisition value and income in form of royalty income.

IFRS 16 enters into force on January 1, 2019 and the work to evaluate the effects of this standard is in progress. The preliminary assessment is that the leases that the Group holds will lead to a right of use and a financial liability as per January 1, 2018 which amounts to approximately 16,483 tkr. The annual depreciation can be estimated at 2,992 tkr, compared with an annual rent cost of approximately 3,316 tkr. The Group does not intend to use the possibility of early application.

#### Significant accounting policies

#### Basis of preparation

The consolidated financial statements have been prepared using the cost method. The balance sheet items are classified as current assets and current liabilities are expected to be recovered and paid within 12 months. All other balance sheet items are expected to be recovered or paid later.

#### Consolidated accounting

Subsidiaries are all entities over which the Group has control. The Group controls a company when it is exposed to or has the right to variable returns from its holdings in the company and has the capability to impact the return, through its influence in the company. Subsidiaries are fully consolidated from the date on which control is transferred to the Group. They are excluded from the consolidated financial statements from the date that control ceases.

The acquisition method is used to report the Group's business acquisitions. The purchase price for the acquisition of a subsidiary is the fair value of transferred assets and liabilities that the Group incurs to former owners of the acquired company and the shares issued by the Group. The purchase price also includes the fair value of all assets or liabilities that are a result of an agreement on contingent consideration. Identifiable assets acquired and liabilities assumed in a business combination are measured initially at their fair values on the acquisition date. Acquisition-related costs are expensed as incurred.

Intercompany transactions, balances and unrealized gains on transactions between Group companies are eliminated. Accounting policies of subsidiaries have been changed where necessary to ensure consistent application of the Group's principles.

### Foreign currency translation

Functional and presentation currency

Items included in the financial statements for the various units in the Group are valued in the currency used in the economic environment in

which the entity operates (its functional currency). Swedish kronor (SEK), which is the Group's reporting currency, is used in the consolidated accounts.

#### Transactions and balances

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the transaction date or the date when the items were revalued. Exchange gains and losses resulting from the settlement of such transactions and from the translation of monetary assets and liabilities denominated in foreign currencies on the balance sheet date are recognized in the income statement. Exceptions are made when the transactions are hedges that qualify for hedge accounting of cash flows or net investments, where gains/losses are recognized in other comprehensive income.

Exchange gains and losses that relate to borrowings and cash and cash equivalents are reported in the income statement as financial income or expenses. All other foreign exchange gains and losses are recognized net in Other operating income or Other operating expenses.

#### **Group Companies**

The results and financial position of all group entities that have a functional currency different from the presentation currency are translated into the Group as follows:

- assets and liabilities for each balance sheet are translated at the closing rate,
- income and expenses for each income statement are translated at average exchange rates, and
- all resulting exchange differences are recognized in other comprehensive income.

#### Intangible and tangible assets

Intangible and tangible assets are stated at cost less depreciation. Cost includes expenditure that is directly attributable to the acquisition of the asset. Additional expenses are added to the asset's carrying amount or recognized as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to the Group and the cost of the asset can be measured reliably. Expenses for repairs and maintenance are expensed in the income statement in the period in which they arise. Depreciation is linear as follows:

Patents, contract period
Licences
Equipment, tools and installations
5 years
5 years

Development expenses which add functionality and value are recognized as intangible assets when the following criteria are met:

- it is technically and economically feasible to complete the asset,
- there is an intention and opportunity to sell or use the asset,
- it is probable that the asset will generate revenue or lead to cost savings, and
- expenditure can be calculated in a satisfactory manner.

Directly attributable costs that are capitalized as part of an intangible asset include expenses for employees and a reasonable proportion of indirect costs. Other development costs that do not meet the above criteria, are expensed as incurred. Development costs previously expensed are not capitalized in subsequent periods.

The assets' residual values and useful life cycles are reviewed at each reporting period and adjusted if necessary. An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount exceeds its estimated recoverable amount.

#### Financial assets

The Group classifies its financial assets in the following categories: financial assets at fair value through profit or loss, loans and receivables, and financial assets available for sale. The classification depends on the purpose for which the financial asset was acquired. Management determines the classification of its financial assets at initial recognition. The Group currently has only financial assets in the category loan receivables and trade receivables.

#### Loans and receivables

Loans and receivables are financial assets that are not derivatives, with fixed or determinable payments that are not quoted in an active market. They are included in current assets, except for maturities greater than 12 months after the reporting period, which are classified as fixed assets. Valuation is at amortized cost using the effective interest method. A provision for impairment is established when there is objective evidence that the Group will not be able to collect all amounts due according to the original terms set for the receivables. The size of the provision is the difference between the asset's carrying amount and the present value of estimated future cash flows.

#### Cash and cash equivalents

Liquid assets include, in both the balance sheet and statement of cash flows, cash, bank deposits and other short-term investments with maturities of three months or less.

#### Borrowings and payables

Liabilities to suppliers are recognized at amortized cost using the effective interest method.

#### Revenue recognition

Revenue is measured at the fair value of the consideration received or receivable for goods sold less discounts, returns and value added tax. Net sales relate entirely to royalties which are recognized under the financial implications of the respective royalty agreements. Interest income is recognized over the term using the effective interest method.

#### **Government grants**

Government grants are recognized at fair value as soon as there is reasonable assurance that the conditions attached to the grant will be met and hence that the grant will be received. Contributions received to cover costs are reported under Other income in the same period that the costs are incurred. Contributions that are attributable to an asset reduce the value of the asset in the balance sheet.

#### Dividend

The Board proposes that no dividend be paid for the 2017 financial year.

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

## **Board assurance**

The Board and the CEO certify that the Financial Statement 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, 15 February 2018

Carl Borrebaeck
Chairman

Hans Johansson *Board member* 

Åsa Hedin Board member Ann-Christin Malmborg Hager

Board member

Mats Grahn CEO Ann-Christine Sundell

Board member

## Other information

#### **Certified Adviser**

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

#### **Contact information**

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## For further information, please contact:

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The company's annual report is available at the company's website: www.immunovia.com

### Telephone conference:

15 February 2018, 16.00 (CET)

SE: +46 856642662 CH: +41 225675548 DE: +49 (0) 6922224998 PIN: 89565063# UK: +44 2030089803

### Financial calendar

27 April 2018	Q1 2018 interim report
3 May 2018	Annual general Meeting
24 August 2018	Q2 2018 interim report
7 November 2018	Q3 2018 interim report
14 February 2019	2018 Financial statement

# **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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# Consolidated income statement, summary

SEK thousand	1 Oct-31 Dec 2017	1 Oct-31 Dec 2016	Full year 2017	Full year 2016
Operating income, etc.				
Net sales	26	106	149	177
Capitalized work for own account	8,482	7,238	24,041	24,293
Other income	0	25	59	33
Total income	8,508	7,369	24,249	24,503
Operating costs				
Other external costs	-11,640	-7,003	-39,113	-24,115
Personnel costs	-11,863	-5,661	-29,138	-14,815
Depreciation and amortization of tangible and intangible assets	-388	-247	-1,264	-549
Other operating expenses	21	15	-254	-2
Total operating expenses	-23,870	-12,896	-69,769	-39,481
Operating profit/loss	-15,362	-5,527	-45,520	-14,978
Financial items				
Financial income	53	150	298	256
Financial costs	-9	0	-10	-1
Total financial items	44	150	288	255
Profit/loss after financial items	-15,318	-5,377	-45,232	-14,723
Tax on income	0	0	0	0
Profit/loss for the period	-15,318	-5,377	-45,232	-14,723
Earnings per share before and after dilution (SEK)	-0.88	-0.32	-2.67	-0.98
Average number of shares before and after dilution	17,318,059	16,705,212	16,932,559	14,985,688
No. of shares at the end of the period	17,318,059	16,804,059	17,318,059	16,804,059

The profit for the period is entirety attributable to the parent company's shareholders.

# Consolidated comprehensive income, summary

SEK thousand	1 Oct-31 Dec 2017	1 Oct-31 Dec 2016	Full year 2017	Full year 2016
Profit/loss for the year	-15,318	-5,377	-45,232	-14,723
Items that may be later reclassified in the income statement	0	0	0	0
Exchange rate differences for foreign net investment	0	0	0	0
Other comprehensive income for the year	0	0	0	0
Comprehensive income for the period	-15,318	-5,377	-45,232	-14,723

# Consolidated financial position, summary

SEK thousand	31-12-2017	31-12-2016
ASSETS		
Fixed assets		
Intangible fixed assets	36,791	19,483
Tangible fixed assets	7,211	3,002
Financial fixed assets	2,759	0
Total fixed assets	46,761	22,485
Current assets		
Current receivables	11,584	1,830
Cash and cash equivalents	192,425	259,094
Total current assets	204,009	260,924
TOTAL ASSETS	250,770	283,409
EQUITY AND LIABILITIES		
Shareholders' equity		
Share capital	866	840
Other contributed capital	314,170	308,800
Retained earnings including total comprehensive income	-78,241	-33,009
Total shareholders' equity	236,795	276,631
Current liabilities		
Other liabilities	13,975	6,778
Total current liabilities	13,975	6,778
TOTAL EQUITY AND LIABILITIES	250,770	283,409

# Change in consolidated equity, summary

SEK thousand	Share capital	Other contributed equity	Retained earnings including total com- prehensive income	Total shareholders' equity
Equity, 1 January 2016	715	101,372	-18,286	83,801
Comprehensive income for the period			-14,723	-14,723
Received subscription warrant premiums		320		320
New share issue	125	218,493		218,618
Costs of share issue		-11,385		-11,385
Equity 31 December 2016	840	308,800	-33,009	276,631
Equity, 1 January 2017	840	308,800	-33,009	276,631
Comprehensive income for the period			-45,232	-45,232
Received subscription warrant premiums		473		473
New share issue	26	4,897		4,897
Equity 31 December 2017	866	314,170	-78,241	236,795

# Consolidated cash flow statement, summary

SEK thousand	1 Oct-31 Dec 2017	1 Oct-31 Dec 2016	Full year 2017	Full year 2016
Operating activities				
Operating profit/loss	-15,363	-5,527	-45,520	-14,978
Adjustment for items not included in cash flow	388	247	1,264	548
Received interest	53	150	298	256
Paid interest	-9	0	-10	-1
Paid tax	0	0	0	0
Cash flow from operating activities before changes in operating capital	-14,931	-5,130	-43,968	-14,175
Cash flow from changes in operating capital				
Change in operating receivables	-7,655	-455	-9,751	-645
Change in operating liabilities	5,885	-795	7,194	2,951
Cash flow from operating activities	-16,701	-6,380	-46,525	-11,869
Investment activities				
Investment in intangible assets	-9,043	-9,065	-25,919	-28,028
Investment in tangible assets	-2,614	-331	-5,268	-2,781
Investment in financial assets	-2,759	0	-2,759	0
Cash flow from investing activities	-14,416	-9,396	-33,946	-30,809
Financing activities				
National and European grants for development costs	8,242	17,650	8,406	18,451
New share issue	0	25,829	4,923	207,233
Received subscription warrant premiums	0	9	474	321
Cash flow from financing activities	8,242	43,488	13,803	226,005
Cash flow for the period	-22,875	27,712	-66,669	183,327
Cash and cash equivalents at beginning of period	215,300	231,382	259,094	75,767
Cash and cash equivalents at end of period	192,425	259,094	192,425	259,094

# Consolidated key indicators

SEK thousand unless otherwise stated	Full year 2017	Full year 2016
Operating profit /loss (CEV thousand)	-45,520	-14,978
Operating profit/loss (SEK thousand)	· ·	,
Profit/loss for the year (SEK thousand)	-45,232	-14,723
Earnings per share before and after dilution (SEK)	-2.67	-0.98
R&D costs (SEK thousand)	-24,041	-24,293
R&D costs as percentage of operating costs (%)	34	62
Cash and cash equivalents at end of period (SEK thousand)	192,425	259,094
Cash flow from operating activities (SEK thousand)	-46,525	-11,869
Cash flow for the period (SEK thousand)	-66,669	183,327
Equity(SEK thousand)	236,795	276,631
Equity per share (SEK)	13.67	16.46
Equity ratio (%)	94	98
Average no. of employees	30	16
Average no. of employees in R&D	16	11

# Parent company's income statement, summary

SEK thousand	1 Oct-31 Dec 2017	1 Oct-31 Dec 2016	Full year 2017	Full year 2016
Operating income, etc.				
Net sales	26	106	149	177
Capitalized work for own account	8,482	7,238	24,041	24,293
Other income	0	25	59	33
Total income	8,508	7,369	24,249	24,503
Operating costs				
Other external costs	-17,491	-7,002	-44,984	-25,112
Personnel costs	-6,069	-5,662	-23,343	-13,818
Depreciation and amortization of tangible and intangible assets	-388	-247	-1,264	-549
Other operating expenses	21	15	-254	-2
Total operating expenses	-23,927	-12,896	-69,845	-39,481
Operating profit/loss	-15,419	-5,527	-45,596	-14,978
Financial items				
Financial income	101	150	366	256
Financial costs	0	0	-2	-1
Total financial items	101	150	364	255
Profit/loss after financial items	-15,318	-5,377	-45,232	-14,723
Tax on income	0	0	0	0
Profit/loss for the period	-15,318	-5,377	-45,232	-14,723
Earnings per share before and after dilution (SEK)	-0.88	-0.32	-2.67	-0.98
Average number of shares before and after dilution	17,318,059	16,705,212	16,932,559	14,985,688
No. of shares at the end of the period	17,318,059	16,804,059	17,318,059	16,804,059

# **Consolidated comprehensive income, summary**

SEK thousand	1 Oct-31 Dec 2017	1 Oct-31 Dec 2016	Full year 2017	Full year 2016
Profit/loss for the year	-15,318	-5,377	-45,232	-14,723
Items that may be later reclassified in the income statement	0	0	0	0
Exchange rate differences for foreign net investment	0	0	0	0
Other comprehensive income for the year	0	0	0	0
Comprehensive income for the period	-15,318	-5,377	-45,232	-14,723

# Parent company's financial position, summary

SEK thousand	31-12-2017	31-12-2016
ASSETS		
Fixed assets		
Intangible fixed assets	36,791	19,483
Tangible fixed assets	4,597	3,002
Financial fixed assets	2,759	0
Total fixed assets	44,147	22,485
Current assets		
Current receivables	14,301	1,830
Cash and cash equivalents	192,216	259,094
Total current assets	206,517	260,924
TOTAL ASSETS	250,664	283,409
EQUITY AND LIABILITIES		
Shareholders' equity		
Restricted equity		
Share capital	866	840
Fund for development expenses	16,882	24,293
	17,748	25,133
Unrestricted equity		
Premium fund	4,923	207,107
Retained earnings including total comprehensive income	214,124	44,391
	219,047	251,498
Total shareholders' equity	236,795	276,631
Current liabilities		
Other liabilities	13,869	6,778
Total current liabilities	13,869	6,778
TOTAL EQUITY AND LIABILITIES	250,664	283,409

# Parent company's cash flow statement, summary

SEK thousand	Full year 2017	Full year 2016
Cash flow from operating activities	-49,349	-11,869
Cash flow from investing activities	-31,332	-30,809
Cash flow from financing activities	13,803	226,005
Cash flow for the period	-66,877	183,327
Cash and cash equivalents at beginning of period	259,094	75,767
Cash and cash equivalents at end of period	192,216	259,094

# **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.	

## **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.

**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.

**Prospective study** – A study in which a group of individuals is studied and followed often for a long time to see how a particular disease develops. A prospective study 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 study, the proportion of individuals in the two groups who developed disease is compared.

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

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

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

**Selfpay customers** – Patients or organizations that pay for drugs without reimbursement from insurance companies or government agencies.

**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 59%. The initial addressable market for Immunovia consists of three 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

IAs 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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