

## 2016 Financial Statement for Immunovia



Mats Grahn, CEO of Immunovia AB

#### 2016 in Summary

- Prospective validation study of the hereditary risk group for pancreatic cancer started as planned at the end of 2016.
- IMMray™ PanCan –d validated in an American patient cohort. 96% accuracy confirmed for early detection of pancreatic cancer.
- Collaboration with the US National Center Institute to focus on early onset diabetes patients aged over 50.
- Immunovia Scientific Advisory Board in pancreatic cancer was formed.
- Immunovia Board strengthened with internationally experienced commercial leaders.
- World Pancreatic Cancer Coalition was formed and Immunovia is part of the coalition.
- IMMray™ Autoimmunity Program was started in collaboration with Lund University and a large multinational company with good preliminary results announced at the start of 2017.
- Successful completion of preferential rights issue of SEK 28.7 million, adding to previously completed SEK 189.9 million directed issue to ensure necessary financial strength.
- Immunovia announced as Winner of European Small & Mid Cap Stars of Innovation Award 2016.

Key indicators		
SEK thousand unless otherwise stated	Full year 2016	Full year 2015
Net sales	177	205
Operating earnings	-14,978	-7,424
Earnings before tax	-14,723	-7,384
Net earnings	-14,723	-7,384
Earnings per share before dilution (SEK/share)	-0.98	-0.82
	31 dec 2016	31 dec 2015
Equity ratio, %	98	92
Debt ratio, mutiple	0.02	0.09
No. of shares at the end of the period	16,804,059	14,291,216
Average number of shares before and after dilution	14,985,688	8,992,357

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 in 2018. In coming years Immunovia will address a market that in total is worth around SEK 30 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.
- \* Text has been adjusted compared with Financial Statement dated 24 February 2016.

### **CEO's statement**

Dear shareholders.

2016 was an intensive year for Immunovia. We began implementing our commercialization plan that focuses on obtaining reimbursement from various insurance systems and national guideline-status on each market. The most important step is to perform prospective studies, where the test is performed on risk groups. Achieving the correct accreditation, certification and other approvals from the relevant authorities are also essential if we are to reach our sales targets. Finally it is important to win over key opinion leaders, which was also something we managed to achieve in 2016.

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

In December we announced the start of a prospective study designed to monitor over three years one thousand individuals with a genetic predisposition for pancreatic cancer. In the study, IMMray™ PanCan−d testing will be added to the existing high-risk surveillance in familiar pancreatic cancer programs in the US and Europe. We anticipate that upon achieving successful results we will proceed with regulatory and reimbursement applications worldwide to establish our test as a global standard. A very important milestone will be an interim reading at the half way stage of the study, something we greatly look forward to.

During 2016 we announced the participation of several key centers in our network for the PANFAM-1 study, including Mount Sinai in New York, Liverpool University Hospital in the UK, Knight Cancer Institute in



In 2016 Immunovia signed a memorandum of understanding with NCI, the US National Cancer Institute. Cooperation relates to one of the largest risk groups for pancreatic cancer - diabetic patients newly diagnosed with type II diabetes after the age of 50.

"The study aims to monitor 1,000 people over three years, with the predisposition to pancreatic cancer."

Portland, IRYCIS in Madrid, and from January 2017, Michigan University Hospital. Engaging key centers is also important commercially as they will be the first large customers for  $IMMray^{TM}$  PanCan –d.

### Developing the diabetes connection together with NCI

One of the highest risk groups that has gained a lot of attention during the last year are new onset Type II diabetes patients diagnosed after 50 years of age. In 2016 we were extremely pleased to sign a memorandum of understanding with NCI, the US National Cancer Institute. The ambition is to work within a consortium of 12 major health care systems providing patient samples from up to 10,000 diabetes patients over 3 years. These participating centers will be communicated as NCI's plans progress. In addition to this initiative we are pursuing similar schemes in order set up prospective studies among diabetes risk groups as quickly as possible and eventually receive reimbursement and national guideline status.

### Certifications and accreditations continue

Since the beginning of 2016, Immunovia has worked intensively to industrialize the IMMray $^{TM}$  PanCan –d assay as a major part of the

development process and preparation for ISO 13485 certification and other related accreditations required for market entry. During 2016, the regulatory quality standard ISO 13485 was updated to ISO 13485:2016 that introduces notable changes in risk management, software validation and design and development. The preparation for the market introduction and the CE marking has included developing strategies for scaling up the production of the microarray while maintaining the same robustness and reproducibility as in the retrospective validation studies.

The assay industrialization, software verification and validation according to ISO 13485:2016 and production upscale are being performed in parallel. We are evaluating the impact of this increased workload and an updated time plan for the certifications and accreditations will be communicated at the end of Q1 2017.

### Pancreatic cancer community across the world offers support

A validation study using American blood samples was completed in 2016 in collaboration with Knight Cancer Institute in Portland USA, as part of our long-term collaboration. The results of the study, showing 96% accuracy in detecting asymptomatic stage I and II pancreatic cancer, were reported in May, thereby validating the excellent results previously

"The results of the study, showing 96% accuracy in detecting asymptomatic stage I and II pancreatic cancer."



Employees at Immunovia's laboratory in Lund diagnosing pancreatic cancer using a drop of blood on a microarray.

obtained in the large Scandinavian study. This was a very important milestone and raised interest in Immunovia significantly as these findings were presented at all major pancreatic cancer specialist meetings during 2016.

In 2017 we will participate at the most relevant conferences for pancreatic cancer in US, Europe and Japan. The event plan will be uploaded regularly on Immunovia's website.

# Strong links forged with Scientific Advisory Board and patient organizations

Key opinion makers can influence medical practices and national guidelines. During 2016 we formed a Scientific Advisory Board and invited key opinion makers to join it. They are now actively working with us.

To ensure the introduction of IMMray™ PanCan –d into clinical practice, close collaboration with patient organizations is crucial. We have continued the collaboration with PANCAN USA, the largest US-based patient organization, which during 2016 formed a world coalition of more than 50 pancreatic cancer patient organizations. Immunovia joined World Pancreatic Cancer Coalition in May 2015.

# Another key market identified – the Immunovia Autoimmunity and SLE initiative

In the beginning of 2016, we announced that Immunovia and Lund University had started several retrospective clinical validation studies of Systemic Lupus Erythematosus (SLE) biomarker signatures. In addition, Immunovia engaged in collaboration with a multinational life science company to validate the new SLE diagnostics test.

An important study that will determine our ability to differentiate between SLE and other common autoimmune diseases has been running during the year. The study's excellent preliminary results, showing

that SLE could be differentiated with accuracy above 90% on average, were announced in the beginning of 2017.

### Financial strength and change in listing

In the autumn Immunovia announced a preferential rights issue of SEK 28.7 million and a directed issue of SEK 189.9 million, to raise a total of SEK 218.6 million. New and existing institutional investors participated, including funds from Handelsbanken, Öhmans, Alfred Berg and Ålandsbanken. To better meet the great interest from institutional investors, Immunovia plans to apply for a listing on Nasdaq Stockholm's Main Market during 2017.

### Exciting 2017 ahead

In summary, 2017 is likely to be just as exciting as 2016 with a focus on the groundbreaking PANFAM-1 study and developing our NCI collaboration for the over-50's Type II diabetes risk group. I strongly believe we have the scientific, human and, thanks to your support, financial resources in place to continue our exciting journey towards giving clinicians the tools they need for early detection of pancreatic cancer, and potentially other cancers and autoimmune diseases; thereby enabling successful intervention and saving patients' lives.

Thank you for your continuing support of Immunovia!

Mats Grahn
CEO, Immunovia AB

### Consolidated financial results for January-December 2016

#### Net sales

Net sales for the second half of 2016 were SEK 111 thousand (147 k). For the full year 2016 net sales were SEK 177 thousand (205 k). Net sales principally comprise royalties.

Investment in the form of capitalization of development costs amounted to SEK 24,293 thousand (16,791 k). Where capitalized development costs are financed through approved and paid grants, the reported amounts are reduced by a comparable amount. In 2016 grants for development costs were received amounting to SEK 18,451 thousand (14,834 k).

#### **Earnings**

The net loss for the second half of the year was SEK 9,425 thousand (-3,577 k). The loss for the full year was SEK 14,723 (-7,384 k). The net loss rose due to increased activity in product development and organizational enlargement. Other operating costs and personnel costs increased by a total of SEK 14,804 thousand compared with last year to reach SEK 38,930 thousand in 2016. This increase is mainly due to intensified marketing activities and an increase in employees.

### Research and development

Research and development was according to plan. Total costs for R&D during 2016 were 24 293 k (16 791 k), corresponding 62% (69%) of total expenses.

### Financial position and cash flow

Cash flow for 2016 from operating activities amounted to SEK -11,869 thousand (-6,530 k) and total cash flow amounted to SEK 183,327 thousand (43,963 k). Cash and cash equivalents as at 31 December 2016 amounted to SEK 259,094 thousand (75,767 k).

Shareholders' equity at the end of the period was SEK 276,631 thousand (83,801 k) and the equity ratio was 98% (92). During the period the company completed two new share issues that raised SEK 207,107 thousand after costs.

Management believes that there is sufficient working capital to meet working capital needs, given the current business and development plan, for approximately 24 months going forward.

#### Investments

In the second half of 2016 intangible assets were acquired for SEK 14,645 thousand, consisting of capitalized development expenditure for SEK 12,409 thousand, patents for SEK 1,574 thousand and other intangible assets for SEK 662 thousand.

For the full year acquired intangible assets amounted to a total of SEK 28,028 thousand (19,637 k), divided into capitalized expenditure for development work SEK 24,292 thousand (16,791 k), patents SEK 3,074 thousand (2,846 k) and other intangible assets of SEK 662 thousand (0 k).

Investments in tangible assets in the form of inventories were made during the second half of 2016 amounting to SEK 2,366 thousand. For the corresponding period last year the total was SEK 145 thousand.

For the full year tangible assets were acquired in the form of inventories amounting to SEK 2,781 thousand. For the corresponding period last year the total was SEK 145 thousand.

#### **Employees**

The number of employees in the Group during the period averaged 16 (11) and at the end of the period the number of full-time positions was 21, divided across 21 individuals.

### **Key events**

### Important events in the second half of 2016

Immunovia began PANFAM-1, currently the world's largest prospective multi-center study for early detection of pancreatic cancer

The purpose of the study is to validate IMMray™ PanCan –d., the first blood-based test for early detection of pancreatic cancer. The study will run for three years at various sites in the US and Europe that offer screening for familiar pancreatic cancer high-risk patients. The study is a key to achieving reimbursement from healthcare payers and inclusion in national guidelines.

Immunovia began a collaboration with NCI concerning the development and validation of biomarkers for pancreatic cancer among the high-risk group of diabetes patients

Immunovia signed a memorandum of understanding with NCI (the US National Cancer Institute) with the aim of developing and validating biomarkers for cancer, especially regarding early detection of pancreatic cancer among the risk group of newly diagnosed diabetes patients aged over 50. The program aims to discover, develop and validate biomarkers for risk assessment, detection, and molecular diagnosis and forecasting of early-stage cancers. The overall goal is to validate cancer biomarkers so that they can be used in large-scale clinical testing, all with the aim of improving early diagnosis of cancer.

Immunovia arranged World Pancreatic Cancer Day in Lund

World Pancreatic Cancer Day was held on 17 November 2016 in Lund, Sweden, and was organized by Immunovia in collaboration with patient organizations from Sweden, PALEMA, and Denmark, Pancreasnaetverket.

Immunovia begins collaboration with Ramon y Cajal Institute for Health Research (IRYCIS) in Madrid

Working closely with several leading pancreatic cancer authorities, Immunovia identified three main criteria for the enrolment of the sites participating in the multisite prospective study. IRYCIS meets all three: broad patient reach, world-renowned clinical expertise in oncology and specifically in pancreatic cancer. Hospital Universitario Ramón y Cajal (HURyC), the core of IRYCIS, is a 1,200 bed university hospital located in Madrid and one of the largest in Spain with over 8,000 employees of which 1,312 are physicians.

Immunovia awarded 2016 Stars of Innovation Prize in European Smalland Mid-Cap Awards 2016

Immunovia was nominated by the European exchanges as one of the three most innovative small to medium-sized enterprises in Europe in 2016. In November 2016 the jury selected Immunovia as the most innovative company in Europe.

Immunovia performed a preferential rights issue worth SEK 28.7 million and a directed issue worth SEK 189.9 million

The preferential rights issue was oversubscribed and the directed issue attracted several Swedish and institutional investors, including Handelsbanken Fonder, Ålandsbanken Fondbolag (which has been an investor in Immunovia since the company's stock market launch in December 2015), E. Öhman Jr Fonder and Banque Internationale á Luxembourg.

Immunovia announced its attention to seek a listing on the main Nasdaq-Stockholm market

In August 2016 the Board of Immunovia announced its intention during the first half of 2017 to apply for a listing of the company's shares on the main Nasdaq-Stockholm market.

Professors Diane Simeone and Aldo Scarpa joined Immunovia's Advisory Board Immunovia appointed Professor Diane Simeone, Greenfield Endowed Professor of Surgery and Physiology at the University of Michigan Medical Center and the Director of the Pancreatic Cancer Center and a leading authority on the management of solid and cystic pancreatic tumors, to the company's Scientific Advisory Board. This latest appointment is in line with Immunovia's strategy to deliver the first validated test for early diagnosis of pancreatic cancer. Professor Aldo Scarpa was also appointed to the Advisory Board. He leads the Cancer Biobank Network Programme in the Veneto Region of Italy and is Chief of the Diagnostic Molecular Pathology Laboratory, officially recognised by the Veneto Government as one of two referral centers for cancer molecular diagnostics in the region. Professor Scarpa is also leader of the Italian effort in the International Cancer Genome Consortium funded by the Italian Ministry of Research and Ministry of Health.

### Important events after the end of the accounting period

The first data from the study on systemic lupus erythematosus (SLE) showed above 90% accuracy in distinguishing the disease from other autoimmune diseases

This confirmed that the principal aim of the study had been achieved. The data confirmed that IMMray™ biomarker signatures can distinguish Systemic Lupus Erythematosus (SLE) from three other main autoimmune diseases, rheumatoid arthritis, Sjögren's disease and vasculitis with an average accuracy exceeding 90%. These results are extremely encouraging because the symptoms of SLE mimic other rheumatic, autoimmune diseases leading to more than 50% of the patients being initially misdiagnosed, mainly due to ambiguous laboratory test results.

University of Michigan Pancreatic Cancer Center presented as new partner in Immunovia's global PANFAM-1 prospective validation study
Immunovia announced that the University of Michigan Pancreatic Cancer Center became the most recent member of the global network of prominent sites participating in Immunovia's PANFAM-I prospective clinical study for the early diagnosis of pancreatic cancer in high-risk individuals. The University of Michigan Pancreatic Cancer Center is renowned for its unique collaborative approach and has the largest number of dedicated, interdisciplinary pancreatic cancer researchers in the US. The Center was also the first to identify the pancreatic cancer stems cells responsible for disease dissemination. This has led to a longstanding interest in early detection and surveillance.



CEO Mats Grahn at the ceremony held for the European Small & Mid Cap Awards 2016, Stars of Innovation.

### **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.

Immunovia's shares are issued in a single category and each share entitles the holder to one vote at the Annual General Meeting. As of 31 December 2016 the total number of shares was 16,804,059. The share capital was SEK 840,202.95 and the nominal value of each share is SEK 0.05. The total number of votes is 16,804,059.

#### Subscription warrants scheme

Immunovia has three outstanding warrants schemes covering 688,000 warrants entitling to subscription of 688,000 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 7.

### Proposed dividend

The Board proposes that no dividend be paid for the 2016 financial year.

The ten largest shareholders as of 31 December 2016.

		Share capital
Name	No. of shares	and votes
Carl Borrebaeck	1,909,900	11.37%
Cart Burrebaeck	, ,	
Vincent Saldell	1,000,000	5.95%
Sara Andersson Ek	968,950	5.77%
Christer Wingren	968,950	5.77%
Per Mats Ohlin	968,950	5.77%
Försäkringsbolaget Avanza Pension	776,298	4.62%
Handelsbanken Svenska Småbolag	560,531	3.34%
Michael Löfman	554,000	3.30%
Banque Internationale á Luxembourg	299,484	1.78%
Ålandsbanken AB, W8IMY	286,226	1.70%
Ten largest	8,293,289	49.35%
Others	8,510,770	50.65%
Total	16,804,059	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.

### Share capital development

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

### Financial risks

#### Market risks

#### Currency risks

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

If the Swedish krona had weakened or strengthened by 10%, with all other variables constant, the adjusted profit after tax as of 31 December 2016 would have been SEK 25 (25) thousand lower / higher, mainly as a result of gains and losses on translation of receivables and liabilities.

### 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.

Calculated on interest-bearing assets and liabilities with variable interest rate as of 31 December 2016, a one percentage point change in market rates would have affected the Group's results by SEK 2,591 (757) thousand.

#### 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 2016 amounted to SEK 259,200 (75,846) thousand.

### **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 two years.

## 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 259,200 thousand (75,846).

### Incentive schemes

#### Warrants

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

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. 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 2,350. The warrants are subject to standard recalculation terms in connection with share issues, etc.

The board meeting held on 10 September 2014 utilized the mandate issued by the Annual General Meeting held on 2 May 2014 to issue warrants (series 2014/2017) to employees and key persons in the company. The warrants (504,000) can be used to subscribe for new shares in the Company during the period from registration of the decision until 15 October 2017. Each warrant entitles the holder to subscribe for one share at a subscription price of SEK 9.50 per share. Full utilization would increase the company's share capital by SEK 25,200. The warrants are subject to customary recalculation terms in connection with share issues, etc.

## **Estimates and judgments**

The company's management team makes make estimates about the future. These estimates will seldom match actual results. The estimates and assumptions that may lead to the risk of significant adjustments in the carrying values of assets and liabilities are primarily the valuation of intangible assets.

Tests are made each year to see if there is an indication that the value of an asset is lower than the carrying value. Is there such an indication, a calculation is made of the asset's recoverable value, which is the lower of the asset's fair value minus sales costs and value in use.

If development work is not completed and commercialization has not yet been initiated, depreciation is not performed. Given current business opportunities, the Board believes that there is no need for impairment.

### **Accounting principles**

This is the first year that the Group has prepared consolidated financial statements. The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) as adopted by the EU. The most significant accounting policies are described below. This interim report has been prepared in accordance with IAS 34 Interim Financial Reporting. New and amended standards adopted as of 1 January 2016 have not had any significant impact on the Group's financial position.

### 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 6.7 years
- Equipment, tools and installations 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

### **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, 14 February 2017.

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.

Carl Borrebaeck

Chairman

Hans Johansson

Board member

Åsa Hedin Board member Ann-Christin Malmborg Hager
Board member

Mats Grahn *CEO* 

Ann-Christin Sundell

Board member

### Other information

### Review by auditors

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

#### **Certified Adviser**

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

### For further information, please contact:

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### Telephone conference:

15 February 2017, 16.00 (CET)

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### Financial calendar

24 March 2017	Annual report
20 April 2017	Q1 2017 interim report
25 April 2017	Annual general Meeting
23 August 2017	Q2 2017 interim report
10 November 2017	Q3 2017 interim report
15 February 2018	2017 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 totaled..

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# Consolidated income statement, summary

SEK thousand	1 July-31 Dec 2016	1 July-31 Dec 2015	Full year 2016	Full year 2015
Operating income, etc.				
Net sales	111	147	177	205
Capitalized work for own account	12,409	9,887	24,293	16,791
Other income	25	11	33	11
Total income	12,545	10,044	24,503	17,007
Operating costs				
Other external costs	-13,087	-9,248	-24,115	-17,377
Personnel costs	-8,661	-4,240	-14,815	-6,749
Depreciation and amortization of tangible and intangible				
assets	-373	-144	-549	-288
Other operating expenses	1	0	-2	-17
Total operating expenses	-22,120	-13,632	-39,481	-24,431
Operating profit/loss	-9,575	-3,588	-14,978	-7,424
Financial items				
Financial income	150	12	256	41
Financial costs	0	-1	-1	-1
Total financial items	150	11	255	40
Profit/loss after financial items	-9,425	-3,577	-14,723	-7,384
Tax on income	0	0	0	0
Profit/loss for the period	-9,425	-3,577	-14,723	-7,384
Earnings per share before and after dilution (SEK)	-0.60	-0.30	-0.98	-0.82
Average number of shares before and after dilution	15,680,160	11,803,383	14,985,688	11,424,799
No. of shares at the end of the period	16,804,059	14,291,216	16,804,059	14,291,216

# Consolidated comprehensive income, summary

SEK thousand	1 July-31 Dec 2016	1 July-31 Dec 2015	Full year 2016	Full year 2015
Profit/loss for the year	-9,425	-3,577	-14,723	-7,384
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	-9,425	-3,577	-14,723	-7,384

# Consolidated financial position, summery

SEK thousand	31-12-2016	31-12-2015
ASSETS		
Fixed assets		
Intangible fixed assets	19,483	13,885
Tangible fixed assets	3,002	671
Total fixed assets	22,485	14,556
Current assets		
Current receivables	1,830	1,186
Cash and cash equivalents	259,094	75,767
Total current assets	260,924	76,953
TOTAL ASSETS	283,409	91,509
EQUITY AND LIABILITIES		
Shareholders' equity		
Share capital	840	715
Other contributed capital	308,800	101,372
Retained earnings including total comprehensive income	-33,009	-18,286
Total shareholders' equity	276,631	83,801
Current liabilities		
Other liabilities	6,778	7,708
Total current liabilities	6,778	7,708
TOTAL EQUITY AND LIABILITIES	283,409	91,509

# 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 2015	221	46,424	-10,902	35,743
Comprehensive income for the period			-7,384	-7,384
Transactions with owners in their capacity as owners				
Bonus issue	332	-332		
New share issue	162	59,870		60,032
Costs of share issue		-4,638		-4,638
Received subscription warrant premiums		48		48
Equity, 31 December 2015	715	101,372	-18,286	83,801
Equity, 1 January 2016	715	101,372	-18,286	83,801
Comprehensive income for the period			-14,723	-14,723
Transactions with owners in their capacity as owners  New share issue	125	218,492		218,617
Costs of share issue	123	-11,385		-11,385
Received subscription warrant premiums		321		321
· · · · · · · · · · · · · · · · · · ·	840		77.000	
Equity 31 December 2016	840	308,800	-33,009	276,631

## Consolidated cash flow statement, summary

SEK thousand	1 July-31 Dec 2016	1 July-31 Dec 2015	Full year 2016	Full year 2015
Operating activities				
Operating profit/loss	-9,575	-3,588	-14,978	-7,424
Adjustment for items not included in cash flow	373	144	548	288
Received interest	150	12	256	42
Paid interest	0	-1	-1	-1
Paid tax	0	0	0	0
Cash flow from operating activities before changes in operating capital	-9,052	-3,433	-14,175	-7,095
Cash flow from changes in operating capital				
Change in operating receivables	-803	981	-645	-331
Change in operating liabilities	1,222	-3,296	2,951	896
Cash flow from operating activities	-8,633	-5,748	-11,869	-6,530
Investment activities				
Investment in intangible assets	-14,645	-11,473	-28,028	-19,637
Investment in tangible assets	-2,366	0	-2,781	-145
Cash flow from investing activities	-17,011	-11,473	-30,809	-19,782
Financing activities				
National and European grants for development costs	17,651	14,834	18,451	14,834
New share issue	207,233	55,393	207,233	55,393
Received subscription warrant premiums	126	0	321	48
Cash flow from financing activities	225,010	70,227	226,005	70,275
Cash flow for the period	199,366	53,006	183,327	43,963
Cash and cash equivalents at beginning of period	59,728	22,761	75,767	31,804
Cash and cash equivalents at end of period	259,094	75,767	259,094	75,767

The comparative figures in the cash flow analysis classification have been syncronized with current year figures.

# **Consolidated key indicators**

(2014 figures are for parent company)

SEK thousand unless otherwise stated	Full year 2016	Full year 2015	Full year 2014
Operating profit/loss (SEK thousand)	-14,978	-7,424	-8,959
Profit/loss for the year (SEK thousand)	-14,723	-7,384	-8,859
Earnings per share before and after dilution (SEK)	-0.98	-0.82	-1.02
R&D costs (SEK thousand)	-24,293	-16,791	0
R&D costs as percentage of operating costs (%)	62	69	0
Cash and cash equivalents at end of period (SEK thousand)	259,094	75,767	31,804
Cash flow from operating activities (SEK thousand)	-11,869	-6,530	-8,290
Cash flow for the period (SEK thousand)	183,327	43,963	-8,297
Equity(SEK thousand)	276,631	83,801	35,743
Equity per share (SEK)	16.46	5.86	3.24
Equity ratio (%)	98	92	92
Average no. of employees	16	11	3
Average no. of employees in R&D	11	8	2

## **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 tumor is benign it means that the tumor is not dangerous and will not spread.

**Bioinformatics** – Bioinformatics is an interdisciplinary field in which algorithms are developed for the analysis of biological (especially molecular biology) data.

**Biomarker** – A biomarker can be defined as a biological response to a change caused by disease or foreign substance. Biomarkers can be used as early warning signs of biological changes in an organism.

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

**Discovery 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 tumors tend to worsen and become mortal. They are termed cancer, and thus differ from beniqn tumors.

Metastasis - A metastasis is a tumor that has spread to other organs.

**Microarray** – A microarray is a molecular biology test format for simultaneously measuring the relative concentrations of proteins.

**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.

**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.

**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 commercialization phase with a strong financial position. The company develops and commercializes diagnostic tools for complex forms of cancer and autoimmune diseases.

Immunovia AB was founded in 2007 by researchers from the Department of Immunotechnology at Lund University and CREATE Health, the Center for Translational Cancer Research in Lund, Sweden. The purpose was to establish a base from which to make scientific discoveries and gain patents within the fields of human antibodies, biomarkers and antibody arrays, covering the stages from research to clinical application.

Immunovia's core technology platform, IMMray™, is based on microarray analysis of biomarker antibodies. IMMray™ PanCan –d is the company's primary diagnostic tool, capable of diagnosing with a high level of sensitivity and specificity. This enables diagnosis of patients with pancreatic cancer before symptoms are noted (stages I and II), which is not currently possible with existing methods. Immunovia is now performing clinical validation studies to prepare for the commercialization of IMMray™ PanCan –d, which could become the first blood-based test for early diagnosis of pancreatic cancer.

The antibody-based technology platform, IMMray<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

VEach 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 especially 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  $^{\text{TM}}$  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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