

# Immunovia interim report January-June 2018



“On 3 April, trading in Immunovia’s shares started on NASDAQ Stockholm’s main market, where we are listed in the Mid Cap segment. During the second quarter we also completed a directed share issue worth around SEK 324 million to reputable institutions in Sweden and internationally.

Very exciting results have been achieved in two major application areas, lung cancer and rheumatoid arthritis, which show that the general usability of the IMMray™ platform opens up great opportunities for Immunovia.

During the spring and summer we completed a lung cancer study with very good results. This was our first collaboration with a global, top-ten pharmaceutical business and the aim was to assess the technical performance of the IMMray™ platform within lung cancer.

In the autoimmune field we have made significant progress within rheumatoid arthritis. In August we published results that mean we will now continue our efforts aimed at developing a product for patients that are difficult to diagnose in this area.

The main focus, as usual, was on IMMray™ PanCan-d. Work has proceeded according to plan in the second quarter. In August, however, new data emerged showing that the sample-collection procedure, which will be applicable commercially and for our final validation studies, affects our product’s algorithms. We have therefore decided that a necessary stage is to optimize IMMray™ PanCan-d to safeguard the quality of the test results prior to release. This will delay the start of sales to the latter part of 2019.”



Mats Grahn, CEO of Immunovia AB

Key indicators					
SEK thousand unless otherwise stated	1 Apr-30 June 2018	1 Apr -30 June 2017	1 Jan-30 June 2018	1 Jan-30 June 2017	Full year 2017
Net sales	44	68	156	95	149
Operating earnings	-27,232	-10,645	-44,608	-18,515	-45,520
Earnings before tax	-26,147	-10,554	-43,473	-18,325	-45,232
Net earnings	-26,154	-10,554	-43,480	-18,325	-45,232
Earnings per share before and after dilution (SEK/share)	-1.47	-0.63	-2.47	-1.09	-2.67
Equity ratio, %	96	96	96	96	94
No. of shares at the end of the period	19,480,853	16,804,059	19,480,853	16,804,059	17,318,059
Average no. of shares before and after dilution	17,846,742	16,804,059	17,582,400	16,804,059	16,932,559

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 and Immunovia GmbH.

## Outlook

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

The company’s financial targets remain in place, but have been delayed in relation to previous announcements, due to the need to perform optimization studies. The company expects to receive the first revenues from self-pay sales in the latter part of 2019.

The following financial targets have been established:

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

# CEO's statement

Dear shareholders,

On 3 April, Immunovia moved from First North to NASDAQ Stockholm's main market. We are listed in the Mid Cap segment, and great interest has been shown in us by investors. The change in listing strengthened Immunovia's brand as expected, significantly increasing awareness of the company, and in the second quarter we completed a directed share issue worth around SEK 324 million. This share issue generated strong interest from reputable institutions in Sweden as well as internationally, including Swedbank Robur, Handelsbanken Fonder, Alfred Berg Kapitalförvaltning AB, Nyenburgh Investment Partners,

*“Very exciting results have been achieved in two major areas of use, lung cancer and rheumatoid arthritis, which show that the general usability of the IMMray™ platform opens up great opportunities for Immunovia.”*

Apus Capital and Bonit Capital. The purpose of the new share issue is to finance product launch preparations and marketing campaigns, the building up of a commercial organization with the main focus on the US, and to enable investment in the product development portfolio, where we are planning for and implementing a broader effort. We are very pleased and grateful for the confidence shown in us by our investors to now utilize the general potential that exists in our IMMray™ platform.

Very exciting results have been achieved in two major areas of use, lung cancer and rheumatoid arthritis, which show that the general usability of the IMMray™ platform opens up great opportunities for Immunovia.

## **Collaboration on lung cancer with global pharmaceutical company**

During the spring, a dedicated Immunovia team carried out a lung cancer study in our first collaboration with a global top-ten pharmaceutical company. The study

included 100 serum samples - 50 NSCLC (non-small cell lung cancer) and 50 controls - and was performed to assess the technical performance of the IMMray™ platform in tests for lung cancer. The result, that we could differentiate healthy controls from NSCLC samples with a 95% accuracy, give us good opportunities to proceed with larger studies in order to confirm the preliminary findings. There is a need for early detection in the lung cancer field, which in addition to being one of the three largest forms of cancer in terms of numbers affected each year, also has the highest mortality, i.e. numbers of deaths per year. Lung cancer is therefore one of the biggest markets for new and effective diagnostic solutions.

A screening program for high risk groups with a special form of CT (LDCT – Low Dose CT), has been established in the US, but one of the concerns is the high number of false positive tests that are recorded and which cause high costs and certain risks for patients in the follow-up examinations that must be performed for these patients who do not have lung cancer despite their positive LDCT test.

A diagnostic test that can determine who actually has cancer is a large, unsolved problem for patients and doctors, and also for the insurance system, especially in the US.

Within pharmaceutical development, lung cancer is a focus area where many new, modern drugs are being developed, not least within immune therapy. Another diagnostic requirement in lung cancer is being able to distinguish between patients for whom these drugs have an effect, and those for whom there is no effect. This is important for pharmaceutical companies for several reasons: the cost of clinical studies can be reduced, the probability rises for achieving good results quicker, etc. The insurance systems that pays for new drugs want to minimize costs for drugs that have no effect, and this coincides with the needs of patients and clinicians to choose a treatment that works right from the start of treatment.

Our next step will be to perform larger studies to confirm the preliminary findings of the first study with the same pharmaceutical partner.

We are very pleased to present this first step in the lung cancer field, partly because it has significant market potential, but also because it confirms that IMMray™ has the potential to be a central technological platform for cancer diagnosis based on blood tests.

### **Autoimmunity studies lead to product strategy**

In the autoimmunity field we have performed studies to establish information for our product strategy. As reported in August, this work primarily centered on a large study of rheumatoid arthritis (RA). Here, one of the biggest clinical problems is that over 25% of those who develop RA test negatively in the two standard tests, thus making them very difficult to diagnose. Health providers want to detect and treat RA as early as possible so they can limit or prevent damage to joints and other parts of the body that result from the disease and which mean sickness leave from work and lower quality of life for patients. In the early stages of RA, over 50% of patients test negative, using the current two standard tests, which is a further strong reason for being able to offer a solution that enables an increase in the share of patients diagnosed at an early stage of RA.

In the study we performed in the first half of the year and finished in August, we were able to report exceptionally good results in the detection of so-called double-negative patients from healthy controls. We will now proceed with further studies aimed at developing an optimized product for early detection of RA in patients who are difficult to diagnose.

### **Market introduction of IMMray™ PanCan-d**

During the second quarter, the main focus of the organization was on performing the activities necessary for the release of IMMray™ PanCan-D. This involves a series of studies where the signature and algorithms are finally determined, then verified by independent known samples and finally validated by blind samples. Parallel to this, a variety of other parameters are tested, particularly related to verifying the robustness of the IMMray™ platform. This includes technical variations, storage times and transport conditions for the product and its components, quality controls and their limits, detailed method instructions and many other activities.

The work proceeded according to plan during the quarter and all IMMray™ platform related results came out positive, specifically regarding low technical variations which confirms the robustness of the IMMray™ platform. However, after the end of the quarter we have obtained results from one of the in-depth studies, where it emerged that due to variations in the collection procedures from different biobanks, optimization of the signature must be

performed before release of the product. This means that after optimization, performed with the IMMray's complete development antibody array (expected to be completed in the first quarter 2019), a number of the tests and studies referred to above must be conducted with the optimized signature, which overall is expected to delay the launch of IMMray™ PanCan-d to the later part of 2019.

The financial targets communicated in March 2018 remain in place and with a corresponding delay in time. The company's goal is thus to achieve SEK 250-300 million in turnover in 2022 based on self-pay sales, and sales of SEK 800-1 000 million in 2024, which includes self-pay and reimbursed sales in Europe and the US.

The prospective studies continue with the collection of samples and patient information for interim results starting as soon as the optimization as described above has been completed. The impact on the prospective studies is in other words small.

We will now fully focus on the optimization of IMMray™ PanCan-d and do all that is possible to minimize the delay while maintaining our high quality, but at the same time we feel strengthened by the fact that all tests of the IMMray™ platform show that IMMray™ is robust and reproducible with low technical variations at all levels while being capable of finding solutions to clinical problems in addition to pancreatic cancer. This has been shown in the results for lung cancer and for the autoimmune disease, rheumatoid arthritis. All of this opens great opportunities for Immunovia. We are always grateful for our shareholders' continued support.

Mats Grahn  
*CEO, Immunovia AB*

# Consolidated financial results for January-June 2018

## Net sales

Net sales for the second quarter of 2018 were SEK 44 thousand (68 k). For the first half of 2018, net sales were SEK 156 thousand (95 k). Net sales principally comprise royalties.

Capitalization of costs for the first half of 2018 amounted to SEK 13,093 thousand (11,080 k). Where capitalized development costs are financed through approved and paid grants, the reported amounts are reduced by a comparable amount. During the first half of 2018, grants for development costs amounting to SEK 73,000 were received. No grants were received in the corresponding period in 2017.

## Earnings

The net loss for the second quarter of 2018 was SEK 26,154 thousand (-10,554 k). The loss for the first half of the year was SEK 43,480 thousand (-18,325 k).

The net loss for the first half of 2018 increased due to higher costs relating to organizational enlargement and increased marketing activity. Other external costs and personnel costs increased by a total of SEK 17,546 thousand compared with last year to reach SEK 33,445 thousand in the second quarter of 2018.

## Research and development

The total cost of research and development in the second quarter of 2018 was SEK 6,881 thousand (5,553 k), which corresponds to 20% (34%) 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 the second quarter of 2018 from operating activities amounted to SEK -17,991 thousand (-9,833 k). Corresponding cash flow for the first half of 2018 was SEK -32,875 thousand (-16,358 k). Cash flow for financing activities in the second quarter of 2018 was SEK 310,714 thousand (474 k).

A new share issue was carried out in the second quarter of 2018, raising SEK 309,733 thousand net after issue costs.

Liquid funds as of 30 June 2018 were SEK 447,212 thousand (228,326 k).

Shareholders' equity at the end of the period was SEK 503,337 thousand (258,779 k) and the equity ratio was 96% (96%).

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

## Investments

In the second quarter of 2018 intangible assets were acquired for SEK 7,719 thousand (6,156 k), consisting of capitalized development expenditure for SEK 6,881 thousand (5,322 k), patents for SEK 309 thousand (834 k), and other intangible assets for SEK 529 thousand (0).

In the first half 2018, intangible assets were acquired for a total of SEK 14,677 thousand (12,332 k), consisting of capitalized development expenditure for SEK 13,093 thousand (11,080 k), patents for SEK 1,054 thousand (1,252 k) and other intangible assets for SEK 529 thousand (0).

Investments in tangible assets in the form of inventories were made during the second quarter of 2018 amounting to SEK 5,653 thousand. For the corresponding period last year the total was SEK 2,520 thousand. In the first half of 2018 investment in tangible assets amounted to SEK 8,473 thousand (2,552 k).

No investment was made in financial assets the first half of 2018. For full year 2017, investments were made in financial assets in the form of blocked bank funds amounting to SEK 2,861 thousand.

## Employees

The number of employees in the Group the second quarter of 2018 averaged 40 (28) and at the end of the period the number of full-time positions was 43.

# Key events in the quarter

## Important events in the second quarter of 2018

*Immunovia's biomarker signature for diagnosis of pancreatic cancer receives patent in Japan*

During the second quarter Immunovia was given approval for a patent by the Japanese patent office for the company's biomarker signature for diagnosis of pancreatic cancer. Japanese patent no. JP 611501 is the first patent awarded to Immunovia in Japan. The patent is for the IMMray™ PanCan-d test.

Immunovia's CEO Mats Grahn commented: "Receiving the patent in Japan is a success for us that provides strong patent protection for our IMMray™ PanCan-d test on an important commercial market."

*Immunovia has completed a directed share issue of approximately SEK 324 million*

Immunovia AB successfully completed a directed share issue which will provide the company with a gross proceed of approximately SEK 324 million.

*NYU School of Medicine joined PanFAM-1, the prospective study for the early detection of pancreatic cancer in familiar risk groups*

Immunovia announced in Q2 that NYU School of Medicine is to participate in PanFAM-1, the largest ever prospective study looking at early diagnosis in high-risk individuals with Familial Pancreatic Cancer (FPC). The study is designed to validate Immunovia's innovative blood test, IMMray™ PanCan-d. The study will analyze more than one thousand individuals over three years across sites in the US and Europe already offering FPC screening programs.

*Clínica Universidad de Navarra, a major Spanish major private hospital, joins world's largest study of familiar risk for pancreatic cancer*

Immunovia announced that Clínica Universidad de Navarra (university hospital) was joining PanFAM-1.

*Linköping University Hospital becomes second Swedish site in largest ever prospective multicenter clinical study for early detection of pancreatic cancer*

Immunovia announced that Linköping University Hospital was joining PanFAM-1.

## Important events after the end of the second quarter of 2018

*Karolinska Institutet participates in Immunovia's PanFAM-1 prospective clinical study for early detection of pancreatic cancer using blood-based test*

Immunovia announced that Karolinska Institutet was joining PanFAM-1.

*Immunovia's blood-based IMMray™ biomarker array provides very high accuracy for diagnosis of non-small cell lung cancer in new collaborative study.*

Immunovia announced that a study carried out in collaboration with a global top-ten pharmaceutical company showed that the IMMray platform could differentiate healthy controls from non-small cell lung cancer samples with a 95% accuracy.

*Journal of Clinical Oncology publishes that IMMray™ PanCan-d serum biomarker test detects early pancreatic cancer with 96% accuracy*

Immunovia AB announced that the prestigious Journal of Clinical Oncology (JCO) was publishing the results of the major retrospective clinical validation study performed by Swedish, Danish and US researchers, showing that the IMMray™ PanCan-d serum biomarker micro-array detects early pancreatic cancer with 96% accuracy.

*Immunovia announces sales launch delay*

Immunovia AB reported that new data had emerged showing that the sample-collection procedure, which will be applicable commercially and for Immunovia's final validation studies, affects the product's algorithms. Immunovia has therefore decided that a necessary stage is to optimize IMMray™ PanCan-d to safeguard the quality of the test results prior to release. This will delay the start of sales to the latter part of 2019.

*Breakthrough in autoimmune testing*

Immunovia announced that a new study confirms that the IMMray™ blood test successfully addresses one of the major challenges in autoimmune testing. The study, performed in collaboration with Linköping University, showed that IMMray™ technology can identify patients with rheumatoid arthritis (RA), despite testing negative with antibodies against cyclic citrullinated peptides (CCP). Currently, this important group of patients – representing 25-30% of all RA-cases – is risking misdiagnose, because of short-comings of today's gold standard assays.



# Share information

## Share information

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

## Subscription warrants scheme

Immunovia has four outstanding warrants schemes covering 395,500 warrants entitling to subscription of 395,500 shares. There will be no dilution as long as the Group's earnings are negative. For more information about the warrants, see page 8.

## Share data

Immunovia performed a directed share issue worth around SEK 324 million before costs. As a result of the new share issue, the number of shares in Immunovia AB (publ) increased by 2,162,794 shares.

At the end of the reporting period the total number of shares was 19,480,853. The nominal value of each share is SEK 0.05.

## The ten largest shareholders as of 30 June 2018

Name	No. of shares	Share capital and votes
Carl Borrebaeck	1,709,900	8.78%
Ålandsbanken, on behalf of the owner	1,365,653	7.01%
Sara Andersson Ek	888,950	4.56%
Christer Wingren	888,950	4.56%
Per Mats Ohlin	888,950	4.56%
Vincent Saldell	839,715	4.31%
Handelsbanken Svenska Småbolag	787,000	4.04%
Catella Småbolagsfond	598,760	3.07%
Försäkringsbolaget Avanza Pension	573,258	2.94%
Swedbank Robour Folksam LO Sverige	500,000	2.57%
Ten largest	9,041,136	46.41%
Others	10,439,717	53.59%
Total	19,480,853	100.00%

## Share capital development

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

# Risks

## **Risks and uncertainties**

Immunovia's financial risk exposure and risk management are described on page 51 of the 2017 annual report. Business risks are presented on page 33 of the annual report. No significant changes have occurred that affect these reported risks.

## **Market risks**

### ***Currency risks***

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

### ***Interest rate risk in cash flow***

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

### **Credit risk**

Credit risk is the risk that one party to a transaction with a financial instrument fails to meet its obligation. The maximum exposure to credit risk on financial assets as of 30 June 2018 amounted to SEK 454,473 thousand (231 160 k).

### **Liquidity Risk**

Prudent liquidity risk management implies maintaining sufficient cash or agreed credit options to close market positions. Based on the existing business plan, there is enough liquidity for around 24 months.

# Transactions with related parties

In addition to salaries and other remuneration to company managers, and fees to Board members, as decided at the annual general meeting, the company has a consulting agreement with CB Ocean Capital AB regarding services performed by Immunovia's chairman and largest shareholder, Carl Borrebaeck. Services provided do not concern information relating to the

Board role. Instead the services are to provide the company with scientific and strategic support at scientific presentations and conferences, for example. This agreement runs from 1 January 2018 until further notice with three months notice for both parties. The remuneration per quarter amounts to SEK 41,000.

# Incentive schemes

## Warrants

The Annual General Meeting held on 3 May 2018 resolved to offer a warrants scheme (series 2018/2021) to employees and key persons in the company. The warrants (150,500) can be used to subscribe for newly issued shares of the Company during the utilization period from 7 September 2021 to 7 October 2021. Each warrant entitles the holder to subscribe for one share at a subscription price of SEK 271.05 per share. Full utilization would increase the company's share capital by SEK 7,525.

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 Annual General Meeting held on 3 May 2018 resolved to introduce an alternative cash-based incentive scheme for key individuals in countries where allocation of warrants in accordance with the 2018/2021 scheme was not applicable for various reasons. Such an incentive scheme has been introduced for employees and key individuals and is designed so that the economic effects correspond to the terms of the 2018/2021 options scheme. The total cost for the company can be at most USD 250,000.

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

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





# Accounting principles

The Group applies the Swedish annual accounts act and International Financial Reporting Standards (IFRS) as adopted by the EU, and RFR 1 complementary accounting rules for Groups when preparing financial reports. The parent company applies the Swedish annual accounts act and RFR 2 Accounting for legal entities when establishing financial reports. The applied accounting principles are in agreement with the information in the 2017 annual report.

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

This interim report has been prepared in accordance with IAS 34 Interim Financial Reporting. New and amended standards adopted as of 2018 have not had any significant impact on the Group's financial position.

## Financial assets

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

At present, the Group has only financial assets that are not normally sold outside the Group and where the purpose of the holding is to obtain contractual cash flows. Most of the financial assets consist of bank balances. All financial assets are classified as financial assets valued at accrued acquisition value.

These financial assets are included in current assets with the exception of items expired for more than 12 months after the end of the reporting period, which are classified as non-current assets. Valuation is made at accrued acquisition value using the effective interest rate method. A depreciation reserve is made when there is objective evidence that the company will not be able to receive all amounts due on the initial conditions of the receivable. The reserved amount is the difference between the asset's reported value and the present value of estimated future cash flows.

An impairment loss is recognized in the income statement as an additional external cost.

## Financial liabilities

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

## Revenues from agreements with customers

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

## Financial instruments

The Group currently has no financial instruments that are valued at fair value. Instead, all financial assets and liabilities are valued at accrued acquisition cost. It is estimated that there are no significant differences between fair value and book value relating to financial assets and liabilities. The reported value of financial assets on the balance sheet date amounted to SEK 454,473 thousand (231,160).

*This quarterly report has not been reviewed by the company's auditor.*



# Board assurance

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

Lund, 24 August 2018.

Carl Borrebaeck  
*Chairman*

Hans Johansson  
*Board member*

Åsa Hedin  
*Board member*

Christofer Sjögren  
*Board member*

Mimmi Ekberg  
*Board member*

Ann-Christine Sundell  
*Board member*

Mats Grahn  
*CEO*

# Other information

## Contact information

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

## Financial reports

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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### Financial calendar

7 November 2018	Q3 2018 interim report
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### Telephone conference

24 August 2018 at 16.00 CET

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# Consolidated income statement, summary

SEK thousand	1 Apr-30 June 2018	1 Apr-30 June 2017	1 Jan-30 June 2018	1 Jan-30 June 2017	Full year 2017
Operating income, etc.					
Net sales	44	68	156	95	149
Capitalized work for own account	6,881	5,553	13,093	11,080	24,041
Other income	145	8	465	24	59
<b>Total</b>	<b>7,070</b>	<b>5,629</b>	<b>13,714</b>	<b>11,199</b>	<b>24,249</b>
Operating costs					
Other external costs	-21,342	-8,253	-35,873	-15,513	-39,113
Personnel costs	-12,103	-7,646	-20,982	-13,572	-29,138
Depreciation and amortization of tangible and intangible assets	-692	-267	-1,228	-507	-1,264
Other operating expenses	-165	-108	-239	-122	-254
<b>Total operating expenses</b>	<b>-34,302</b>	<b>-16,274</b>	<b>-58,322</b>	<b>-29,714</b>	<b>-69,769</b>
<b>Operating profit/loss</b>	<b>-27,232</b>	<b>-10,645</b>	<b>-44,608</b>	<b>-18,515</b>	<b>-45,520</b>
Financial items					
Financial income	1,085	92	1,135	191	298
Financial costs	0	-1	0	-1	-10
<b>Total financial items</b>	<b>1,085</b>	<b>91</b>	<b>1,135</b>	<b>190</b>	<b>288</b>
<b>Profit/loss after financial items</b>	<b>-26,147</b>	<b>-10,554</b>	<b>-43,473</b>	<b>-18,325</b>	<b>-45,232</b>
Tax	-7	0	-7	0	0
<b>Profit/loss for the period</b>	<b>-26,154</b>	<b>-10,554</b>	<b>-43,480</b>	<b>-18,325</b>	<b>-45,232</b>
Earnings per share before and after dilution (SEK)	-1.47	-0.63	-2.47	-1.09	-2.67
Average number of shares before and after dilution	17,846,742	16,804,059	17,582,400	16,804,059	16,932,559
No. of shares at the end of the period	19,480,853	16,804,059	19,480,853	16,804,059	17,318,059

# Consolidated comprehensive income, summary

SEK thousand	1 Apr-30 June 2018	1 Apr-30 June 2017	1 Jan-30 June 2018	1 Jan-30 June 2017	Full year 2017
<b>Profit/loss for the period</b>	<b>-26,154</b>	<b>-10,554</b>	<b>-43,480</b>	<b>-18,325</b>	<b>-45,232</b>
<i>Items that may be later reclassified in the income statement</i>					
Exchange rate differences for foreign net investment	-515	0	-619	0	0
Other comprehensive income for the period	-515	0	-619	0	0
<b>Comprehensive income for the period</b>	<b>-26,669</b>	<b>-10,554</b>	<b>-44,099</b>	<b>-18,325</b>	<b>-45,232</b>

# Consolidated financial position, summary

SEK thousand	30-06-2018	30-06-2017	31-12-2017
<b>ASSETS</b>			
Fixed assets			
Intangible fixed assets	51,312	31,720	36,791
Tangible fixed assets	14,956	5,142	7,211
Financial fixed assets	3,005	0	2,759
<b>Total fixed assets</b>	<b>69,273</b>	<b>36,862</b>	<b>46,761</b>
Current assets			
Accounts receivable	90	0	0
Current receivables	9,630	3,359	11,584
Cash and cash equivalents	447,212	228,326	192,425
<b>Total current assets</b>	<b>456,932</b>	<b>231,685</b>	<b>204,009</b>
<b>TOTAL ASSETS</b>	<b>526,205</b>	<b>268,547</b>	<b>250,770</b>
<b>EQUITY AND LIABILITIES</b>			
Shareholders' equity			
Share capital	974	840	866
Other contributed capital	624,703	309,273	314,170
Translation reserve	-619	0	0
Retained earnings including total comprehensive income	-121,721	-51,334	-78,241
<b>Total shareholders' equity</b>	<b>503,337</b>	<b>258,779</b>	<b>236,795</b>
Current liabilities			
Other liabilities	22,868	9,768	13,975
<b>Total current liabilities</b>	<b>22,868</b>	<b>9,768</b>	<b>13,975</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>526,205</b>	<b>268,547</b>	<b>250,770</b>



# Change in consolidated equity, summary

SEK thousand	Share capital	Other contributed equity	Reserves	Retained earnings including total comprehensive income	Total shareholders' equity
Equity, 1 January 2017	840	308,800	0	-33,009	276,631
Comprehensive income for the period			0	-18,325	-18,325
Received subscription warrant premiums		473			473
Equity, 30 June 2017	840	309,273	0	-51,334	258,779
Comprehensive income for the period			0	-26,907	-26,907
New share issue	26	4 897			4,923
Equity, 31 December 2017	866	314 170	0	-78 241	236 795
Comprehensive income for the period			-619	-43,480	-44,099
Received subscription warrant premiums		908			908
New share issue	108	324,311			324,419
Issue costs		-14,686			-14,686
Equity, 30 June 2018	974	624,703	-619	-121,721	503,337

## Consolidated key indicators

	1 Apr-30 June 2018	1 Apr-30 June 2017	1 Jan-30 June 2018	1 Jan-30 June 2017	Full year 2017	Full year 2016
Operating profit/loss (SEK thousand)	-27,232	-10,645	-44,608	-18,515	-45,520	-14,978
Profit/loss for the period (SEK thousand)	-26,154	-10,554	-43,480	-18,325	-45,232	-14,723
Earnings per share before and after dilution (SEK)	-1.47	-0.63	-2.47	-1.09	-2.67	-0.98
R&D costs (SEK thousand)	-6,881	-5,553	-13,093	-11,080	-24,041	-24,293
R&D costs as percentage of operating costs (%)	20	34	22	37	34	62
Cash and cash equivalents at end of period (SEK thousand)	447,212	228,326	447,212	228,326	192,425	259,094
Cash flow from operating activities (SEK thousand)	-17,991	-9,833	-32,875	-16,358	-46,318	-11,867
Cash flow for the period (SEK thousand)	279,351	-18,035	254,689	-30,768	-66,661	183,327
Equity (SEK thousand)	503,337	258,779	503,337	258,779	236,795	276,631
Equity per share (SEK)	25.84	15.40	25.84	15.40	13.67	16.46
Equity ratio (%)	96	96	96	96	94	98
Average no. of employees	40	28	40	23	30	16
Average no. of employees in R&D	17	16	17	15	16	11

# Consolidated cash flow statement, summary

SEK thousand	1 Apr-30 June 2018	1 Apr-30 June 2017	1 Jan-30 June 2018	1 Jan-30 June 2017	Full year 2017
Operating activities					
Operating profit/loss	-27,232	-10,645	-44,609	-18,515	-45,520
Adjustment for items not included in cash flow	609	267	863	507	1,472
Received interest	67	92	117	191	298
Paid interest	0	-1	0	-1	-10
Paid tax	-7	0	-7	0	0
Cash flow from operating activities before changes in operating capital	-26,563	-10,287	-43,636	-17,818	-43,760
Cash flow from changes in operating capital					
Change in operating receivables	118	-1,733	1,877	-1,527	-9,757
Change in operating liabilities	8,454	2,187	8,884	2,987	7,200
Cash flow from operating activities	-17,991	-9,833	-32,875	-16,358	-46,317
Investment activities					
Investment in intangible assets	-7,719	-6,156	-14,677	-12,332	-25,919
Investment in tangible assets	-5,653	-2,520	-8,473	-2,552	-5,366
Investment in financing assets	0	0	0	0	-2,861
Cash flow from investing activities	-13,372	-8,676	-23,150	-14,884	-34,146
Financing activities					
National and European grants for development costs	73	0	73	0	8,406
New share issue	309,733	0	309,733	0	4,923
Received subscription warrant premiums	908	474	908	474	474
Cash flow from financing activities	310,714	474	310,714	474	13,803
Cash flow for the period	279,351	-18,035	254,689	-30,768	-66,661
Cash and cash equivalents at beginning of period	167,790	246,361	192,425	259,094	259,094
Exchange rate difference in cash and cash equivalents	71	0	98	0	-8
Cash and cash equivalents at end of period	447,212	228,326	447,212	228,326	192,425

# Parent company's income statement, summary

SEK thousand	1 Apr-30 June 2018	1 Apr-30 June 2017	1 Jan-30 June 2018	1 Jan-30 June 2017	Full year 2017
Operating income, etc.					
Net sales	44	68	156	95	149
Capitalized work for own account	6,881	5,553	13,093	11,080	24,041
Other income	145	8	465	24	59
<b>Total income</b>	<b>7,070</b>	<b>5,629</b>	<b>13,714</b>	<b>11,199</b>	<b>24,249</b>
Operating costs					
Other external costs	-19,177	-9,445	-32,705	-17,595	-39,113
Personnel costs	-8,553	-6,454	-15,192	-11,490	-29,138
Depreciation and amortization of tangible and intangible assets	-485	-266	-870	-507	-1,264
Other operating expenses	-163	-109	-238	-122	-254
<b>Total operating expenses</b>	<b>-28,378</b>	<b>-16,274</b>	<b>-49,005</b>	<b>-29,714</b>	<b>-69,769</b>
<b>Operating profit/loss</b>	<b>-21,308</b>	<b>-10,645</b>	<b>-35,291</b>	<b>-18,515</b>	<b>-45,520</b>
Financial items					
Interest income	1,212	92	1,323	191	298
Interest costs	0	-1	0	-1	-10
<b>Total financial items</b>	<b>1,212</b>	<b>91</b>	<b>1,323</b>	<b>190</b>	<b>288</b>
<b>Profit/loss after financial items</b>	<b>-20,096</b>	<b>-10,554</b>	<b>-33,968</b>	<b>-18,325</b>	<b>-45,232</b>
Tax	0	0	0	0	0
<b>Profit/loss for the period</b>	<b>-20,096</b>	<b>-10,554</b>	<b>-33,968</b>	<b>-18,325</b>	<b>-45,232</b>
Earnings per share before and after dilution (SEK)	-1.13	-0.63	-1.93	-1.09	-2.67
Average number of shares	17,846,742	16,804,059	17,582,400	16,804,059	16,932,559
No. of shares at the end of the period	19,480,853	16,804,059	19,480,853	16,804,059	17,318,059

# Consolidated comprehensive income, summary

SEK thousand	1 Apr-30 June 2018	1 Apr-30 June 2017	1 Jan-30 June 2018	1 Jan-30 June 2017	Full year 2017
Profit/loss for the period	-20,096	-10,554	-33,968	-18,325	-45,232
Other comprehensive income for the period	0	0	0	0	0
<b>Comprehensive income for the period</b>	<b>-20,096</b>	<b>-10,554</b>	<b>-33,968</b>	<b>-18,325</b>	<b>-45,232</b>

# Parent company's financial position, summary

SEK thousand	30-06-2018	30-06-2017	31-12-2017
<b>ASSETS</b>			
Fixed assets			
Intangible fixed assets	50,746	31,720	36,791
Tangible fixed assets	9,503	5,142	4,597
Financial fixed assets	253	0	0
<b>Total fixed assets</b>	<b>60,502</b>	<b>36,862</b>	<b>41,388</b>
Current assets			
Accounts receivable	90	0	0
Receivables from Group companies	20,678	1,587	5,618
Current receivables	6,354	1,522	9,909
Prepaid costs and accrued income	3,015	672	1,533
Cash and cash equivalents	445,548	227,903	192,216
<b>Total current assets</b>	<b>475,685</b>	<b>231,684</b>	<b>209,276</b>
<b>TOTAL ASSETS</b>	<b>536,187</b>	<b>268,546</b>	<b>250,664</b>
<b>EQUITY AND LIABILITIES</b>			
Shareholder's equity			
<i>Restricted equity</i>			
Share capital	974	840	866
Fund for development expenses	29,976	35,373	16,882
	30,950	36,213	17,748
<i>Unrestricted equity</i>			
Premium fund	309,625	474	4,897
Retained earnings including total comprehensive income	172,893	222,092	214,150
	482,518	222,566	219,047
<b>Total shareholders' equity</b>	<b>513,468</b>	<b>258,779</b>	<b>236,795</b>
Current liabilities			
Other liabilities	22,719	9,767	13,869
<b>Total current liabilities</b>	<b>22,719</b>	<b>9,767</b>	<b>13,869</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>536,187</b>	<b>268,546</b>	<b>250,664</b>

# Parent company's cash flow statement, summary

SEK thousand	1 Jan-30 June 2018	1 Jan-30 June 2017	Full year 2017
Operating activities			
Operating profit/loss	-35,291	-18,515	-45,596
Adjustment for items not included in cash flow	1,888	507	1,264
Received interest	101	191	366
Paid interest	0	-1	-2
Paid tax	0	0	0
Cash flow from operating activities before changes in operating capital	-33,302	-17,818	-43,968
Cash flow from changes in operating capital			
Change in operating receivables	-12,873	-1,949	-15,230
Change in operating liabilities	8,851	2,987	7,090
Cash flow from operating activities	-37,324	-16,780	-52,108
Investment activities			
Investment in intangible assets	-14,147	-12,332	-25,919
Investment in tangible assets	-5,658	-2,552	-2,654
Investment in financing assets	-253	0	0
Cash flow from investing activities	-20,058	-14,884	-28,573
Financing activities			
National and European grants for development costs	73	0	8,406
New share issue	309,733	0	4,923
Received subscription warrant premiums	908	474	474
Cash flow from financing activities	310,714	474	13,803
Cash flow for the period	253,332	-31,190	-66,878
Cash and cash equivalents at beginning of period	192,216	259,093	259,094
Cash and cash equivalents at end of period	445,548	227,903	192,216



# 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 shareholders 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

- 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.
- Molecular Diagnosis** – A collection of technologies used to analyze biological markers at the genomic and protein levels (ie, the genetic code of individuals and how their cells express their genes as proteins in the body), using molecular biology for medical testing. These technologies are used to diagnose and monitor disease, detect the risk of disease and to determine which treatment is likely to work best for the individual.
- NSCLC** – Non Small Cell Lung Cancer, the most common type of lung cancer, 80-85% of all lung cancer cases.
- Palliative care** – Palliative care is administered when the patient's disease is beyond the ability to cure. The purpose of palliative care is to provide support to patients and families using both psychological and medical practices.
- PANDIA-1** – Prospective study for the diabetes risk group of patients aged over 50 recently diagnosed with type-2 diabetes.
- PANFAM-1** – Prospective study for familiar and hereditary risk groups.
- Pancreatologist** – Doctor specialising in diseases relating to the pancreas.
- PANSYM-1** – Prospective study for early symptom risk groups.
- 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.
- RA** – Rheumatoid arthritis, one of the most common autoimmune diseases.
- RA double negative** – Patients who have RA, but test negative for it using the current two single-marker standard tests, RF factor and anti-CCP.
- Reproducibility** – Within the field of statistics, reproducibility is described as the correlation between results from repeated measurements performed by different observers with different instruments of the same type, which measurements are performed in order to reject any measurement error due to materials and personnel.
- Retrospective study** – A study in which the focus is on something that has happened in the past, i.e. using historic data. This form of study starts with the answer, i.e. it is known which individuals became ill and which did not.
- Screening** – Screening refers to medical examinations to identify a disease. It is normally carried out before the patient has exhibited obvious symptoms.
- Self-pay customers** – Patients or organizations that pay without reimbursement from insurance companies or authorities.
- Sensitivity** – Sensitivity is a statistical measure of the reliability of a binary diagnostic test and the probability that a generated positive result is correct.
- Serum** – A serum is a transparent yellowish liquid obtained by allowing the blood to clot, and then removing the blood cells and the coagulation proteins. Serum contains proteins, including antibodies.
- SLE (Systemic Lupus Erythematosus)** – SLE is an autoimmune inflammatory disease which means that the immune system attacks the body. The symptoms come and go in cycles, sometimes the patient is sick and sometimes has no sickness at all. Usually it is the joints, skin, blood and kidneys which become inflamed, but also the nervous system, lungs and heart can be affected. The disease is currently difficult to diagnose and is often confused with other autoimmune diseases.
- Specificity** – Specificity is a statistical measure of the reliability of a binary diagnostic test and the probability that the generated negative result is de facto negative.
- Vinnova** – Vinnova is a Swedish government agency under the Ministry of Industry which aims to promote sustainable growth by improving conditions for innovation and by funding needs-driven research.

# Immunovia in brief

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

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

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

The antibody-based technology platform, IMMray™, is the result of 15 years of research at CREATE Health, Lund University. It is used to decode mechanisms behind the body's immune system, the first system in the body that reacts to disease. The platform can also be used for the development of diagnostic tests for autoimmune diseases.

## **Pancreatic cancer**

Each year about 338,000 patients fall ill with pancreatic cancer. This form of cancer has one of the worst survival forecasts and only about 5% of diagnosed patients live more than five years, making it one of the deadliest cancers in the world. It is estimated that early detection would increase the five-year survival

rate by around 50%. The initial addressable market for Immunovia consists of two high-risk pancreatic cancer groups. The market in the US and Europe for diagnosis of these groups is estimated to be worth over SEK 30 billion per year.

## **Goals**

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

## **Strategy**

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

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

Organization. no. 556730-4299

*Immunovia has its head office in Lund, Sweden. Immunovia's shares (IMMNOV) are listed on Nasdaq Stockholm First North. The Certified Advisor is Wildeco. For more information, visit [www.immunovia.com](http://www.immunovia.com)*

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