Immunovia interim report January-September 2018

Immunovia's IMMray™ platform for blood-based biomarker signatures offers exciting new opportunities to develop accurate diagnostic tests that can detect diseases at an early stage. During the period we presented new results and identified no fewer than two new areas for strategic focus in our ongoing development activities – non-small cell lung cancer and Rheumatoid Arthritis (RA).

In August we presented the results from our first collaboration trial with a global, top-ten pharmaceutical business. The results showed that Immunovia's blood-based IMMray™ biomarker array produced very high accuracy in the diagnosis of non-small cell lung cancer. Later in August we presented the results from the latest of three completed studies within autoimmune testing. The studies represented a breakthrough, showing that IMMray™ can also have significance in the diagnosis of autoimmune rheumatoid diseases. As a consequence of the trial's exceptionally good results, we have decided to make Rheumatoid Arthritis (RA) a strategic focus area within autoimmunity.

These results for new applications clearly indicate the broad usability of the IMMray™ platform for addressing a large amount of unsolved problems within the fields of cancer, autoimmunity and other complex diseases. This means there is an opening for IMMray™ becoming a significant platform in global diagnostics for the future.

As reported at the start of the quarter, new data has emerged showing that optimization of IMMray™ PanCan –d is required before the product can be launched on the market. This means a delay in the sales start until the latter part of 2019. Work on IMMray™ PanCan –d has continued during the quarter with undiminished intensity in the face of these new circumstances.

Immunovia's financial targets were updated before the previous interim report and remain in place.

Mats Grahn
CEO of Immunovia AB

Key indicators

SEK thousand unless otherwise stated	1 Jul–30 Sep 2018	1 Jul–30 Sep 2017	1 Jan–30 Sep 2018	1 Jan–30 Sep 2017	Full year 2017
Net sales	85	27	241	122	149
Operating earnings	–17,344	–11,641	–61,952	–30,157	–45,520
Earnings before tax	–17,403	–11,589	–60,876	–29,914	–45,232
Net earnings	–17,403	–11,589	–60,883	–29,914	–45,232
Earnings per share before and after dilution (SEK/share)	–0.89	–0.69	–3.34	–1.78	–2.67
Equity ratio, %	97	97	97	97	94
No. of shares at the end of the period	19,531,353	17,318,059	19,531,353	17,318,059	17,318,059
Average no. of shares before and after dilution	19,487,025	16,804,059	18,212,275	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 subsidiaries, Immunovia Inc and Immunovia GmbH.

Outlook

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

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

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

CEO's statement

New results and new opportunities

Dear shareholders,

Immunovia's IMMray™ platform for blood-based biomarker signatures offers exciting new opportunities to develop accurate diagnostic tests that can detect diseases at an early stage. During the period we presented new results and identified no fewer than two new areas for strategic focus in our ongoing development activities – non-small cell lung cancer and Rheumatoid Arthritis (RA).

In August we presented the results from our first collaboration trial with a global, top-ten pharmaceutical company. The results showed that Immunovia's blood-based IMMray™ biomarker array produced very high accuracy in the diagnosis of non-small cell lung cancer. The trial showed that the IMMray™ platform can distinguish healthy samples in the control group from samples of non-small cell lung cancer with 95% accuracy. Since IMMray™ has previously shown similarly high accuracy (98%) in detecting pancreatic cancer, the results from this trial strengthen our belief that IMMray™ has the potential to become the central technology platform for cancer diagnosis based on blood samples. We are now really looking forward to the next phase in this collaboration.

As a consequence of the trial's exceptionally good results, we have decided to make Rheumatoid Arthritis (RA) a strategic focus area within autoimmunity.

Rheumatoid Arthritis now a strategic focus area

Later in August we presented the results from the latest of three completed studies within autoimmune testing. The studies represented a breakthrough, showing that IMMray™ can also have significance in the diagnosis of autoimmune rheumatoid arthritis diseases. As a consequence of the trial's exceptionally good results, we have decided to make Rheumatoid Arthritis (RA) a strategic focus area within autoimmunity.

Our first two studies showed that IMMray™ can identify and distinguish with excellent accuracy a number of overlapping autoimmune rheumatic diseases that have similar symptoms, such as RA, Systemic Lupus Erythematosus (SLE), Sjögren's disease and systematic vasculitis. These results were published at the beginning of 2017 and have since been discussed with a large number of Key Opinion Leaders in the field. All of these leaders emphasized that although there is great interest in a differential diagnosis for these diseases, the greater need is for diagnostic tools that enable diagnosis of early-stage RA.

Healthcare policy recommendations with this purpose are already established. Comprehensive implementation of these guidelines is currently taking place in order to ensure early diagnosis of autoimmune rheumatic diseases in healthcare systems. There are therefore good opportunities for rapid uptake and market penetration of a new diagnostic test that can help eliminate the bottlenecks that exist, and which are also described in the recommendations.

Our third trial therefore represents a major breakthrough: the IMMray™ biomarker signature can diagnose CCP-negative patients with RA with an accuracy over 90 percent compared to healthy control samples. At present, this important patient group – 25-30%t of all RA cases – are at risk of being wrongly diagnosed due to shortcomings in today's standard methods.

These are the exceptionally good results that have prompted us to lift RA to become a strategic focus area. Our overall strategy is to solve the most important clinical needs, primarily around diagnosis of early RA. Our long-term goal is to provide doctors access to cost-effective testing for the whole patient care process, from initial diagnosis and selection of treatment to patient monitoring and measurement of treatment results. Our first step and our product development within this very large area is, as described above, a test that solves an immediate need for specialist doctors, namely to diagnose patients with advanced RA but who currently test negative in today's standard tests. This will be then followed naturally with a product that can help the healthcare system's ongoing reforms to succeed in their ambition to be able to detect RA at an earlier stage than is currently possible.

Decision to optimize IMMray™ PanCan –d

At the start of the quarter new data emerged that showed that an optimization of IMMray™ PanCan –d was required ahead of the product's market introduction, which meant that the sales start was put back to the latter part of 2019. Work on IMMray™ PanCan –d

continued during the quarter with undiminished intensity in the light of these new circumstances. The background to the delay is a study that showed how sample collection procedures on a commercial basis, as for Immunovia's final validation studies, have an impact on the product's algorithms. Due to the variations in collection procedures from different biobanks, the optimization of the signature must be completed before the product can be commercialized. After the optimization, which is expected to be concluded in Q1 2019, a number of the aforementioned tests and studies must be carried out with the optimized signature, which when taken together will lead to the sales launch in the latter part of 2019. It is important to emphasize that in our own commercial business the collection procedures will be under our full control because we will manage them ourselves.

We are now fully focused on the optimization if IMMray™ PanCan –d and are doing everything necessary to maintain the tempo of the work while retaining high quality.

The prospective studies have only contributed in a small way to the delay. During the period we announced that Karolinska Institutet had decided to participate in Immunovia's PanFAM-1 prospective clinical trial for early detection of pancreatic cancer using a blood-based test.

Important scientific recognition

During the period we received acknowledgements of our technology from across the scientific community. The prestigious Journal of Clinical Oncology published the results of the large retrospective clinical validation studies performed by Immunovia in collaboration with Swedish, Danish and American researchers. These studies show that the IMMray™ PanCan –d test can detect pancreatic cancer with 96% accuracy.

After the end of the period, we also achieved registration of our PanFAM-1 prospective clinical trial at ClinicalTrials.gov, the world's largest database for clinical trials. This is an online register that will make information about the PanFAM-1 trial available for patients, relatives, healthcare staff and the general public.

Immunovia's financial targets were updated prior to the previous interim report and remain in place. The company's goal is 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.

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. Our technology creates great opportunities for Immunovia to expand, and as always, we are grateful for our shareholders' continued support.

Mats Grahn
CEO, Immunovia AB

Important events

Important events in the third quarter of 2018

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

Karolinska Institutet has a very high international reputation within oncology and complements the other clinical centres participating in PanFAM-1.

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

Immunovia announced that a trial 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 95% accuracy.

Journal of Clinical Oncology published 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 trial performed by Swedish, Danish and US researchers, showing that the IMMray™ PanCan-d serum biomarker microarray detects early pancreatic cancer with 96% accuracy.

Immunovia announced 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 had confirmed 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 missed due to a failure in the current standard method.

Important events after the end of the third quarter of 2018

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

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

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

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

Consolidated financial results for January-September 2018

Net sales
Net sales for the third quarter of 2018 were SEK 85 thousand (27 k). For the first nine months of 2018, net sales were SEK 241 thousand (122 k). Net sales principally comprise royalties.

Capitalization of costs for the third quarter of 2018 amounted to SEK 6,735 thousand (4,479 k). Where capitalized development costs are financed through approved and paid grants, the reported amounts are reduced by a comparable amount. During the first nine months of 2018, grants for development costs amounting to SEK 73,000 were received. Grants worth SEK 164,000 were received in the corresponding period in 2017.

Earnings
The net loss for the third quarter of 2018 was SEK 17,403 thousand (–11,589 k). The loss for the first nine months of the year was SEK 60,883 thousand (–29,914 k).

The net loss for the third quarter 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 7,579 thousand compared with last year. For the January-September 2018 period the corresponding increase was SEK 35,348 thousand.

Research and development
The total cost of research and development in the third quarter of 2018 was SEK 6,863 thousand (4,479 k), which corresponds to 28% (34%) of the Group's total operating costs.

Financial position and cash flow
Cash flow for the third quarter of 2018 from operating activities amounted to SEK –25,656 thousand (–13,467 k). Corresponding cash flow for the first nine months of 2018 was SEK –58,530 thousand (–29,825 k). Cash flow for financing activities in the third quarter of 2018 was SEK 1,619 thousand (5,087 k).

A new share issue was carried out in the third quarter of 2018, raising SEK 1,619 thousand net after issue costs. Liquid funds as of 30 September 2018 were SEK 415,602 thousand (215,300 k).

Shareholders' equity at the end of the period was SEK 487,749 thousand (252,113 k) and the equity ratio was 97% (97).

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

Investments
In the third quarter of 2018 intangible assets were acquired for SEK 7,382 thousand (4,544 k), consisting of capitalized development expenditure for SEK 6,735 thousand (4,479 k), patents for SEK 300 thousand (65 k), and other intangible assets for SEK 347 thousand (0).

In the first nine months 2018, intangible assets were acquired for a total of SEK 22,059 thousand (16,876 k), consisting of capitalized development expenditure for SEK 19,828 thousand (15,559 k), patents for SEK 1,354 thousand (1,317 k) and other intangible assets for SEK 877 thousand (0).

Investments in tangible assets in the form of inventories were made during the third quarter of 2018 amounting to SEK 181 thousand. For the corresponding period last year the total was SEK 102 thousand. In the first nine months of 2018 investment in tangible assets amounted to SEK 8,654 thousand (2,654 k).

No investment was made in financial assets the first nine months of 2018. For full year 2017, investments were made in financial assets in the form of blocked bank funds amounting to SEK 2,759 thousand.

Employees
The number of employees in the Group the third quarter of 2018 averaged 44 (28) and at the end of the period the number of people working in full-time positions was 45.

Share information

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

Subscription warrants scheme
Immunovia has four outstanding warrants schemes covering 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 he warrants, see page 7.

New share capital and number of shares
During September the share capital and number of shares in Immunovia AB (publ) changed following the utilization of subscription warrants. The share capital increased by SEK 2,525.00 to SEK 976,567.65 and the number of shares increased by 50,000 to 19,531,353 shares. The subscription warrants were utilized as part of Immunovia's incentive scheme for leading decision makers, in accordance with resolutions made at the 2015 and 2016 AGMs and subscriptions issues in those years.

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

The ten largest shareholders as of 30 September 2018

Name	No. of shares	Share capital and votes
Carl Borrebaeck	1,709,900	8.75%
Ålandsbanken i ägares ställe	1,363,913	6.98%
Sara Andersson Ek	888,950	4.55%
Christer Wingren	888,950	4.55%
Per Mats Ohlin	888,950	4.55%
Handelsbanken Svenska Småbolag	872,375	4.47%
Vincent Saldell	782,922	4.01%
Catella Småbolagsfond	642,379	3.29%
Försäkringsbolaget Avanza Pension	594,788	3.05%
Swedbank Robur Folksams LO Sverige	500,000	2.56%
10 largest owners	9,133,127	46.76%
Others	10,398,226	53.24%
Total	19,531,353	100.00%

Share capital development

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

Incentive schemes

Warrants

The Annual General Meeting held on 3 May 2018 resolved to offer a warrants scheme (series 2018/2021) to employees and key persons in the company. The warrants (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 7,739.50.

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

The Annual General Meeting held on 30 May 2016 resolved to offer a warrants scheme (series 2016/2019) to employees and key persons in the company. The warrants (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 6,175.

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

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

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

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

Accounting principles

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

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

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

Financial assets

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

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

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

Financial liabilities

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

Revenues from agreements with customers

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

Effects of future accounting principles

IFRS 16 – Leases will be applied from 1 January 2019. Assets and liabilities attributable to leasing agreements, with a few exceptions, will be reported on the balance sheet. The Group considers that IFRS 16 will mean that the premises rented by the Group shall be reported as an asset on the balance sheet. The current value of future rental fees will be recorded as a liability. Utilisable assets and liabilities have been assessed at SEK 14 million as of 1 January 2019, including an option period. The annual amortisation is estimated at SEK 3.0 million per year, compared with the annual rental fee of SEK 3.3 million.

New and amended standards adopted from 2018 are not expected to have a significant impact on the Group's financial position.

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

Other information

Financial instruments
The Group currently has no financial instruments that are valued at fair value. Instead, all financial assets and liabilities are valued at accrued acquisition cost. It is estimated that there are no significant differences between fair value and book value relating to financial assets and liabilities. The reported value of financial assets on the balance sheet date amounted to SEK 423,146 thousand (174,930).

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

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

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

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

Credit risk
Credit risk is the risk that one party to a transaction with a financial instrument fails to meet its obligation. The maximum exposure to credit risk on financial assets as of 30 September 2018 amounted to SEK 423,146 thousand (174,930 k).

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

Financial reports

Contact information:
Immunovia AB (publ)
Medicon Village
Scheelevägen 2
223 81 Lund
SWEDEN

Tel: 00 46 46-2756 000
ir@immunovia.com
www.immunovia.com

For further information, please contact:
Mats Grahn, CEO, Immunovia AB
E-mail: mats.grahn@immunovia.com

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

Financial calendar

14 February 2019	2018 Financial statement
24 April 2019	Q1 2019 interim report
26 April 2019	AGM
23 August 2019	Q2 2019 interim report
7 November 2019	Q3 2019 interim report
14 February 2020	2019 Financial statement

Telephone conference

7 November 2018 at 16.30 CET

SE: +46 856642662
BE: +32 24040635
CH: +41 225675548
DE: +49 69222229046
DK: +45 82333178
FR: +33 170750712
NE: +31 207168416
NO: +47 23500254
UK: +44 2030089803
US: +1 6465025116

Financial reports

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

Consolidated income statement, summary

SEK thousand	1 Jul-30 Sep 2018	1 Jul-30 Sep 2017	1 Jan-30 Sep 2018	1 Jan-30 Sep 2017	Full year 2017
Operating income, etc.					
Net sales	85	27	241	122	149
Capitalized work for own account	6,735	4,479	19,828	15,559	24,041
Other income	22	35	487	59	59
Total	6,842	4,541	20,556	15,740	24,249
Operating costs					
Other external costs	−11,781	−11,959	−47,653	−27,472	−39,113
Personnel costs	−11,459	−3,702	−32,441	−17,274	−29,138
Depreciation and amortization of tangible and intangible assets	−767	−369	−1,996	−876	−1,264
Other operating expenses	−179	−152	−418	−275	−254
Total operating expenses	−24,186	−16,182	−82,508	−45,897	−69,769
Operating profit/loss	−17,344	−11,641	−61,952	−30,157	−45,520
Financial items					
Financial income	118	53	1,253	244	298
Financial costs	−177	−1	−177	−1	−10
Total financial items	−59	52	1,076	243	288
Profit/loss after financial items	−17,403	−11,589	−60,876	−29,914	−45,232
Tax	0	0	−7	0	0
Profit/loss for the period	−17,403	−11,589	−60,883	−29,914	−45,232
Earnings per share before and after dilution (SEK)	−0.89	−0.69	−3.34	−1.78	−2.67
Average number of shares	19,487,025	16,804,059	18,212,275	16,804,059	16,932,559
No. of shares at the end of the period	19,531,353	17,318,059	19,531,353	17,318,059	17,318,059

Consolidated comprehensive income, summary

SEK thousand	1 Jul-30 Sep 2018	1 Jul-30 Sep 2017	1 Jan-30 Sep 2018	1 Jan-30 Sep 2017	Full year 2017
Profit/loss for the period	−17,403	−11,589	−60,883	−29,914	−45,232
Items that may be later reclassified in the income statement					
Exchange rate differences for foreign net investment	196	0	−423	0	0
Other comprehensive income for the period	196	0	−423	0	0
Comprehensive income for the period	−17,207	−11,589	−61,306	−29,914	−45,232

Consolidated financial position, summary

SEK thousand	30-09-2018	30-09-2017	31-12-2017
ASSETS			
Fixed assets			
Intangible fixed assets	58,627	36,053	36,791
Tangible fixed assets	14,310	4,922	7,211
Financial fixed assets	2,970	0	2,759
Total fixed assets	75,907	40,975	46,761
Current assets			
Current receivables	9,919	3,927	11,584
Cash and cash equivalents	415,602	215,300	192,425
Total current assets	425,521	219,227	204,009
TOTAL ASSETS	501,428	260,202	250,770
EQUITY AND LIABILITIES			
Shareholders' equity			
Share capital	977	840	866
Unregistered share capital	0	26	0
Other contributed capital	626,320	314,170	314,170
Translation reserve	–423	0	0
Retained earnings including total comprehensive income	–139,125	–62,923	–78,241
Total shareholders' equity	487,749	252,113	236,795
Current liabilities			
Other liabilities	13,679	8,089	13,975
Total current liabilities	13,679	8,089	13,975
TOTAL EQUITY AND LIABILITIES	501,428	260,202	250,770

Change in consolidated equity, summary

SEK thousand	Share capital	Unregistered share capital	Other contributed equity	Reserves	Retained earnings including total comprehensive income	Total shareholders' equity
Equity, 1 January 2017	840	0	308,800	0	−33,009	276,631
Comprehensive income for the period				0	−29,914	−29,914
Received subscription warrant premiums			473			473
New share issue		26	4,897			4,923
Equity, 30 September 2017	840	26	314,170	0	−62,923	252,113
Comprehensive income for the period						
Registration of share capital				0	−15,318	−15,318
Equity, 31 December 2017	26	−26				0
Utgående balans 31 december 2017	866	0	314,170	0	−78,241	236,795
Comprehensive income for the period				−423	−60,883	−61,306
Received subscription warrant premiums			908			908
New share issue	111		325,927			326,038
Issue costs			−14,685			−14,685
Equity, 30 September 2018	977	0	626,320	−423	−139,125	487,749

Consolidated key indicators

	1 Jul-30 Sep 2018	1 Jul-30 Sep 2017	1 Jan-30 Sep 2018	1 Jan-30 Sep 2017	Full year 2017	Full year 2016
Operating profit/loss (SEK thousand)	−17,344	−11,641	−61,952	−30,157	−45,520	−14,978
Profit/loss for the period (SEK thousand)	−17,403	−11,589	−60,883	−29,914	−45,232	−14,723
Earnings per share before and after dilution (SEK)	−0.89	−0.69	−3.34	−1.78	−2.67	−0.98
R&D costs (SEK thousand)	−6,735	−4,479	−19,828	−15,559	−24,041	−24,293
R&D costs as percentage of operating costs (%)	28	28	25	34	34	62
Cash and cash equivalents at end of period (SEK thousand)	415,602	215,300	415,602	215,300	192,425	259,094
Cash flow from operating activities (SEK thousand)	−25,656	−13,467	−58,530	−29,825	−46,317	−11,867
Cash flow for the period (SEK thousand)	−31,600	−13,026	223,090	−43,794	−66,661	183,327
Equity (SEK thousand)	487,749	252,113	487,749	252,113	236,795	276,631
Equity per share (SEK)	24.97	14.56	24.97	14.56	13.67	16.46
Equity ratio (%)	97	97	97	97	94	98
Average no. of employees	44	28	41	28	30	16
Average no. of employees in R&D	17	16	17	16	16	11

Consolidated cash flow statement, summary

SEK thousand	1 Jul-30 Sep 2018	1 Jul-30 Sep 2017	1 Jan-30 Sep 2018	1 Jan-30 Sep 2017	Full year 2017
Operating activities					
Operating profit/loss	−17,344	−11,641	−61,953	−30,157	−45,520
Adjustment for items not included in cash flow	1,136	369	1,999	876	1,472
Received interest	118	53	235	244	298
Paid interest	−177	−1	−177	−1	−10
Paid tax	0	0	−7	0	0
Cash flow from operating activities before changes in operating capital	−16,267	−11,220	−59,903	−29,038	−43,760
Cash flow from changes in operating capital					
Change in operating receivables	−204	−568	1,675	−2,096	−9,757
Change in operating liabilities	−9,185	−1,679	−302	1,309	7,200
Cash flow from operating activities	−25,656	−13,467	−58,530	−29,825	−46,317
Investment activities					
Investment in intangible assets	−7,382	−4,544	−22,059	−16,876	−25,919
Investment in tangible assets	−181	−102	−8,654	−2,654	−5,366
Investment in financing assets	0	0	0	0	−2,861
Cash flow from investing activities	−7,563	−4,646	−30,713	−19,530	−34,146
Financing activities					
National and European grants for development costs	0	164	73	164	8,406
New share issue	1,619	4,923	311,352	4,923	4,923
Received subscription warrant premiums	0	0	908	474	474
Cash flow from financing activities	1,619	5,087	312,333	5,561	13,803
Cash flow for the period	−31,600	−13,026	223,090	−43,794	−66,661
Cash and cash equivalents at beginning of period	447,212	228,326	192,425	259,094	259,094
Exchange rate difference in cash and cash equivalents	−10	0	87	0	−8
Cash and cash equivalents at end of period	415,602	215,300	415,602	215,300	192,425

Parent company's income statement, summary

SEK thousand	1 Jul-30 Sep 2018	1 Jul-30 Sep 2017	1 Jan-30 Sep 2018	1 Jan-30 Sep 2017	Full year 2017
Operating income, etc.					
Net sales	85	27	241	122	149
Capitalized work for own account	6,735	4,479	19,828	15,559	24,041
Other income	22	35	487	59	59
Total income	6,842	4,541	20,556	15,740	24,249
Operating costs					
Other external costs	−10,977	−9,897	−43,682	−27,472	−44,984
Personnel costs	−8,106	−5,784	−23,298	−17,274	−23,343
Depreciation and amortization of tangible and intangible assets	−561	−369	−1,432	−876	−1,264
Other operating expenses	−179	−153	−417	−275	−254
Total operating expenses	−19,823	−16,203	−68,829	−45,897	−69,845
Operating profit/loss	−12,981	−11,662	−48,273	−30,157	−45,596
Financial items					
Interest income	289	73	1,612	244	366
Interest costs	−177	0	−177	−1	−2
Total financial items	112	73	1,435	243	364
Profit/loss after financial items	−12,869	−11,589	−46,838	−29,914	−45,232
Tax	0	0	0	0	0
Profit/loss for the period	−12,869	−11,589	−46,838	−29,914	−45,232
Earnings per share before and after dilution (SEK)					
Average number of shares	−0.66	−0.69	−2.57	−1.78	−2.67
No. of shares at the end of the period	19,487,025	16,804,059	18,212,275	16,804,059	16,932,559
Antal aktier vid periodens slut	19,531,353	17,318,059	19,531,353	17,318,059	17,318,059

Consolidated comprehensive income, summary

SEK thousand	1 Jul-30 Sep 2018	1 Jul-30 Sep 2017	1 Jan-30 Sep 2018	1 Jan-30 Sep 2017	Full year 2017
Profit/loss for the period	−12,869	−11,589	−46,838	−29,914	−45,232
Other comprehensive income for the period	0	0	0	0	0
Comprehensive income for the period	−12,869	−11,589	−46,838	−29,914	−45,232

Parent company's financial position, summary

SEK thousand	30-09-2018	30-09-2017	31-12-2017
ASSETS			
Fixed assets			
Intangible fixed assets	57,721	36,053	36,791
Tangible fixed assets	9,124	4,922	4,597
Financial fixed assets	253	0	0
Total fixed assets	67,098	40,975	41,388
Current assets			
Receivables from Group companies	26,216	3,261	5,618
Current receivables	5,899	1,781	9,909
Prepaid costs and accrued income	3,754	1,030	1,533
Cash and cash equivalents	412,861	213,162	192,216
Total current assets	448,730	219,234	209,276
TOTAL ASSETS	515,828	260,209	250,664
EQUITY AND LIABILITIES			
Shareholder's equity			
Restricted equity			
Share capital	977	840	866
Unregistered share capital	0	26	0
Fund for development expenses	36,710	39,381	16,882
	37,687	40,247	17,748
Unrestricted equity			
Premium fund	311,242	5,691	4,897
Retained earnings including total comprehensive income	153,288	206,175	214,150
	464,530	211,866	219,047
Total shareholders' equity	502,217	252,113	236,795
Current liabilities			
Other liabilities	13,611	8,096	13,869
Total current liabilities	13,611	8,096	13,869
TOTAL EQUITY AND LIABILITIES	515,828	260,209	250,664

Parent company's cash flow statement, summary

SEK thousandv	1 Jan-30 Sep 2018	1 Jan-30 Sep 2017	Full year 2017
Operating activities			
Operating profit/loss	−48,273	−30,157	−45,596
Adjustment for items not included in cash flow	2,273	856	1,264
Received interest	227	265	366
Paid interest	0	−1	−2
Paid tax	0	0	0
Cash flow from operating activities before changes in operating capital	−45,773	−29,037	−43,968
Cash flow from changes in operating capital			
Change in operating receivables	−18,443	−4,242	−15,230
Change in operating liabilities	−258	1,317	7,090
Cash flow from operating activities	−64,474	−31,962	−52,108
Investment activities			
Investment in intangible assets	−21,181	−16,876	−25,919
Investment in tangible assets	−5,780	−2,654	−2,654
Investment in financing assets	−253	0	0
Cash flow from investing activities	−27,214	−19,530	−28,573
Financing activities			
National and European grants for development costs	73	164	8,406
New share issue	311,352	4,923	4,923
Received subscription warrant premiums	908	474	474
Cash flow from financing activities	312,333	5,561	13,803
Cash flow for the period	220,645	−45,931	−66,878
Cash and cash equivalents at beginning of period	192,216	259,093	259,094
Cash and cash equivalents at end of period	412,861	213,162	192,216

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, 7 November 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

Auditor's report on the review of the interim report

To the Board of Directors of Immunovia AB (publ) Org. no. 556730-4299

We have conducted a review of the summary of interim financial information (interim report) for Immunovia AB (publ) per 30-09-2018 and the nine-month period ending at that date. The Board of Directors and the Managing Director are responsible for the preparation and fair presentation of this interim report in accordance with IAS 34 and the Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

The scope and focus of the review
We have conducted our review in accordance with the International Standard on Review Engagements ISRE 2410, Review of financial interim information conducted by the company's chosen auditor. A review involves making inquiries, primarily to persons responsible for financial matters and accounting issues, conducting an analytical review and performing other review procedures. A review has a different focus and a significantly smaller scope than the focus and scope of a review in accordance with ISA and with generally accepted auditing practice. The review measures taken in a review do not allow us to obtain such a full understanding that we become aware of all the important circumstances that could have been identified if an audit was carried out. Therefore, the stated conclusion based on a review does not have the assurance that an expressed conclusion based on an audit has.

Conclusion
Based on our review, no circumstances have arisen which give us reason to believe that the interim report has not been prepared in essence for the Group in accordance with IAS 34 and the Annual Accounts Act, as well as for the Parent Company in accordance with the Annual Accounts Act.

Lund, November 7, 2018

Mazars SET Revisionsbyrå AB

Mats-Åke Andersson
Authorized Public Accountant
Chief Auditor

Martin Gustafsson
Authorized Public Accountant

Definitions

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

Glossary

Actionable information – Information that is sufficiently authoritative and specific to be used in clinical decision making.
Antibodies – Antibodies, or immunoglobulins, are a type of protein used by the body's immune system to detect and identify foreign substances such as viruses, bacteria or parasites.
Antigen – A foreign body substance that elicits a reaction of the immune system in contact with the organism. The substance may be a chemical substance, a protein or a carbohydrate.
Autoimmunity – Autoimmunity is the immune system's harmful attack on the body's own tissue, which can take the form of disease or rejection of organs during transplantation.
Benign – If a tumour is benign it means that the tumour is not dangerous and will not spread.
Bioinformatics – Bioinformatics is an interdisciplinary field in which algorithms are developed for the analysis of biological (especially molecular biology) data.
Biomarker – A biomarker can be defined as a biological response to a change caused by disease or foreign substance. Biomarkers can be used as early warning signs of biological changes in an organism.
Companion Diagnostics – Diagnostics tools aimed at identifying which groups of patients will respond well to a particular treatment and thus ruling out ineffective treatments.
Discovery Trial – Research carried out in order to verify a special hypothesis.
Histology – Histology is the study of biological tissue.
Invasive – Invasive means to penetrate or attack. Invasive medical examinations refer to examinations that include any form of penetration through a hole in the body or surgical operation.
Malignant – Malignant tumours tend to worsen and become mortal. They are termed cancer, and thus differ from benign tumours.
Metastasis – A metastasis is a tumour that has spread to other organs.
Microarray – A microarray is a molecular biology test format for simultaneously measuring the relative concentrations of proteins.
Molecular Diagnosis – A collection of technologies used to analyze biological markers at the genomic and protein levels (ie, the genetic code of individuals and how their cells express their genes as proteins in the body), using molecular biology for medical testing. These technologies are used to diagnose and monitor disease, detect the risk of disease and to determine which treatment is likely to work best for the individual.
NSCLC – Non Small Cell Lung Cancer, the most common type of lung cancer, 80-85% of all lung cancer cases.
Palliative care – Palliative care is administered when the patient's disease is beyond the ability to cure. The purpose of palliative care is to provide support to patients and families using both psychological and medical practices.
PANDIA-1 – Prospective trial for the diabetes risk group of patients aged over 50 recently diagnosed with type-2 diabetes.
PANFAM-1 – Prospective trial for familiar and hereditary risk groups.
Pancreatologist – Doctor specialising in diseases relating to the pancreas.
PANSYM-1 – Prospective trial for early symptom risk groups.
Prospective trial – A trial in which a group of individuals is studied and followed often for a long time to see how a particular disease develops. A prospective trial is used to study the relationship between different risk factors and a certain disease. You follow individuals with and without risk factors going forwards over time. At the end of the trial, the proportion of individuals in the two groups who developed disease is compared.
Proteomics – Proteomics is a branch of biology and includes surveys of large amounts of data about proteins.
RA – Rheumatoid arthritis, one of the most common autoimmune diseases.
RA double negative – Patients who have RA, but test negative for it using the current two single-marker standard tests, RF factor and anti-CCP.
Reproducibility – Within the field of statistics, reproducibility is described as the correlation between results from repeated measurements performed by different observers with different instruments of the same type, which measurements are performed in order to reject any measurement error due to materials and personnel.
Retrospective study – A study in which the focus is on something that has happened in the past, i.e. using historic data. This form of study starts with the answer, i.e. it is known which individuals became ill and which did not.
Screening – Screening refers to medical examinations to identify a disease. It is normally carried out before the patient has exhibited obvious symptoms.
Self-pay customers – Patients or organizations that pay without reimbursement from insurance companies or authorities.
Sensitivity – Sensitivity is a statistical measure of the reliability of a binary diagnostic test and the probability that a generated positive result is correct.
Serum – A serum is a transparent yellowish liquid obtained by allowing the blood to clot, and then removing the blood cells and the coagulation proteins. Serum contains proteins, including antibodies.
SLE (Systemic Lupus Erythematosus) – SLE is an autoimmune inflammatory disease which means that the immune system attacks the body. The symptoms come and go in cycles, sometimes the patient is sick and sometimes has no sickness at all. Usually it is the joints, skin, blood and kidneys which become inflamed, but also the nervous system, lungs and heart can be affected. The disease is currently difficult to diagnose and is often confused with other autoimmune diseases.
Specificity – Specificity is a statistical measure of the reliability of a binary diagnostic test and the probability that the generated negative result is de facto negative.
Vinnova – Vinnova is a Swedish government agency under the Ministry of Industry which aims to promote sustainable growth by improving conditions for innovation and by funding needs-driven research.

Immunovia in brief

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

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

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

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

Pancreatic cancer

Each year about 338,000 patients fall ill with pancreatic cancer. This form of cancer has one of the worst survival forecasts and only about 5% of diagnosed patients live more than five years, making it one of the deadliest cancers in the world. It is estimated that early detection would increase the five-year survival rate by around 50%. The initial addressable market for Immunovia consists of two high-risk pancreatic cancer groups. The market in the US and Europe for diagnosis of these groups is estimated to be worth over SEK 30 billion per year.

Goals

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

Strategy

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

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

Organization. no. 556730-4299

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

Scheelevägen 2, Medicon Village
223 81 Lund
SWEDEN

Tel: 00 46 46-2756 000
ir@immunovia.com
www.immunovia.com

immunovia