# **Annual Report 2018**





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## This is Immunovia

Immunovia is a molecular diagnostics company that developed the IMMray $^{\text{TM}}$  platform which uses a simple blood sample to aid in the detection of cancer at an earlier stage.

Early detection is the key to curing pancreatic cancer Pancreatic cancer is one of the deadliest forms of cancer, and the key to increasing survival is to begin treatment at an early stage. IMMray™ PanCan −d, which may become the first blood-based test for early detection of pancreatic cancer in stages I-II when the cancer is still operable. If more patients can be diagnosed in stages I and II, total five-year survival could increase from 5-8 percent to 50 percent.

#### **Operations**

Immunovia is active in the market for diagnostics of different cancer indications and autoimmune diseases. Based on its proprietary IMMray™ platform, Immunovia has developed the IMMray™ PanCan −d test for early diagnosis of pancreatic cancer (hence the name PanCan).

IMMray™ PanCan –d is a blood-based test capable of diagnosing patients with high levels of sensitivity and specificity, enabling the diagnosis of pancreatic cancer in patients before symptoms have occurred (stages I and II). With current diagnostic methods, this is problematic and ineffective.

The company's ambition is for IMMray™ PanCan –d to become the world's first test for early diagnosis of pancreatic cancer.

The company was founded in 2007 by researchers at the Institution of Immunotechnology and CREATE Health—the Strategic Division of Translational Cancer Research at Lund University, Sweden. Immunovia is headquartered in Lund, Southern Sweden, and has two wholly owned subsidiaries: one in the US with an office in Boston, and one in Germany with an office in Frankfurt. The company's shares were listed on Nasdaq Stockholm's main market in April 2018, and were previously listed on Nasdaq First North in December 2015.

Immunovia's ambition is to create a blood-based test for the early diagnosis of pancreatic cancer as the standard for pancreas specialists and diabetes physicians worldwide to detect pancreatic cancer in high-risk groups far earlier than is possible at present.

#### Vision

Immunovia's vision is to significantly increase cancer patient survival rates, expand therapy choices and improve the quality of lives of patients and their families.

#### Market introduction and future prospects

The first test based on Immunovia's IMMray™ platform is undergoing commercialization through several clinical evidence studies, both ongoing and in the planning stage. IMMray™ PanCan –d addresses an estimated potential market exceeding over SEK 35 billion.

The journey to the market will continue during 2019, as Immunovia plans to commence sales of the IMMray™ PanCan –d test to self-paying private individuals and healthcare organizations in 2020. To achieve this, the company worked intensively on commercializing IMMray™ PanCan –d in 2018.

Immunovia sees high potential in developing tests for other unsolved problems in cancer and auto-immunity through its  $IMMray^{TM}$  platform.

# **Important Events 2018**

During 2018, Immunovia continued its goal-oriented work on bringing the company's patented, blood-based pancreatic cancer test IMMray™ PanCan −d to the market. Its main activities focused on prospective clinical studies, certification, accreditation and scaling up production capacity, of the product itself, and laboratory capacity. Selected highlights of the year:

- Listing of Immunovia's shares was approved for Nasdag Stockholm's main list.
- Immunovia carried out a directed new share issue of around SEK 324 million.
- The Journal of Clinical Oncology published the results of the retrospective clinical validation study conducted by Swedish, Danish and American researchers. The study showed that IMMray™ PanCan –d serum biomarker microarray detects early pancreatic cancer with 96 percent accuracy.
- At the beginning of the year, the Spanish University Hospital in Santiago de Compostela joined as a new partner in Immunovia's global prospective validation study PanFAM-1 to validate Immunovia's bloodbased test, IMMray™ PanCan –d. Other collaborating partners that were added during the year were Massachusetts General Hospital, NYU School of Medicine, University Hospital in Linköping, Karolinska Institutet and the Spanish University Hospital Clínica Universidad de Navarra. Another four North American clinics targeting hereditary pancreatic cancer (FPC), McGill, Yale, and the universities of Pennsylvania and Massachusetts, joined Immunovia's prospective PanFAM-1 study.
- Immunovia signed a letter of intent for a collaboration on a pancreatic cancer study of diabetic patients with the Danish Center for Strategic Research in Type 2 Diabetes (DD2). The intention is that the DD2 center will participate in the pioneering prospective study PanDIA-1, which examines type-2 diabetics over the age of 50 and the risk that these will develop pancreatic cancer.
- Immunovia's biomarker signature, IMMray™
   PanCan –d, for the diagnosis of pancreatic cancer received patents in Japan.

- Immunovia announced that the IMMray<sup>™</sup> platform can distinguish non-small cell lung cancer from healthy controls with 95 percent accuracy according to a study conducted in collaboration with a global top 10 pharmaceutical company.
- New data emerged that show that the sampling-collection routine that applies commercially and for Immunovia's final validation studies affects the product's algorithms. Immunovia therefore decided to optimize IMMray™ PanCan –d to ensure the quality of the test response before release.
- Immunovia published a new study confirming that the blood-based IMMray<sup>™</sup> test successfully addresses one of the major challenges of autoimmune testing. The study, which was conducted in collaboration with Linköping University, showed that IMMray<sup>™</sup> technology can identify patients with rheumatoid arthritis (RA), even though these have tested negative for antibodies against cyclic citrated peptides (CCP).
- Immunovia's clinical study PanFAM-1 was registered at ClinicalTrials.gov, the world's largest database for clinical studies.
- Based on the promising results of previous discovery studies, Immunovia decided to add a strategic focus of IMMray™ blood-based biomarker signatures for rheumatoid arthritis.
- Immunovia completed the expansion of the production and sample testing facilities, IMMray™
   Dx Laboratories, at their headquarters in Lund,
   Sweden. This new state-of-the-art facility, working in conjunction with our IMMray™ Dx Laboratories at our subsidiary in Marlborough, MA, USA, allows for the capacity and capability to produce slides to not only meet the current foreseen demands for commercial testing but at the same time meet the demands of the large prospective studies.



24,000 participants in 24 fundraising walks in 15 states in the USA



Up to 20 clinics participated in the PanFam-1 study through early 2019



SEK 37 billion
- estimated yearly total
market potential for
IMMray™ PanCan -d



#### **CEO's statement**

## Focused efforts on sales start

We entered 2018 with the continued mission to develop and validate accurate blood-based diagnostic tests and moved towards the exciting activities to commercialize those efforts. We completed the expansion of our production and sample testing facilities, IMMray™ Dx Laboratories, at our headquarters in Lund, Sweden, we advanced our important clinical collaborations and entered into new ones, our shares began trading on Nasdaq Stockholm's main list and embarked on a new and inspiring initiative to partner with several prominent patient organizations to sponsor fundraising walks to help build awareness of the IMMray™ PanCan −d test and educate about the risk factors and the symptoms for pancreatic cancer.

As we accelerated the preparations for the commercialization of IMMray™ PanCan −d, our lead diagnostic candidate for the early detection of pancreatic cancer, Immunovia completed the expansion of our production and sample testing facilities, IMMray™ Dx Laboratories, at our headquarters in Lund, Sweden. This new state-of-the-art facility, working in conjunction with our IMMray™ Dx Laboratories at our subsidiary in Marlborough, Mass, allows us the capacity and capability to produce slides to not only meet the current foreseen demands for commercial testing, but also meet the demands of the large prospective studies when Immunovia reaches its commercial milestone.

#### **Expanding clinical collaborations**

In 2018, we advanced our important clinical collaborations and entered into new ones, which expanded the utilization of our IMMray™ platform for our product pipeline.

In Q3 2018 we announced the postponement of the launch of IMMray™ PanCan −d as an optimization work of the test was added. The optimization work is now being performed as an important part of the launch preparations.

We worked diligently to establish and expand the world's most comprehensive set of prospective clinical trials within the area of detection of pancreatic cancer for IMMray™ PanCan −d consisting of three large studies, PanSYM-1, PanFAM-1 and PanDIA-1.

PanSYM-1, is a large clinical study in collaboration with University College, London, UK, which has already provided us with several hundred samples from high risk patients with symptoms suggestive of pancreatic

cancer. These samples will now be analyzed with IMMray™ PanCan –d and be included as part of the validation program with results expected during 2019.

Turning to our second clinical study, we worked on obtaining new participants in our PanFAM-1 study, which is a multicenter prospective validation study for early diagnosis of people with a high risk of hereditary or familial pancreatic cancer. The PanFAM-1 study now includes close to 20 leading pancreatic cancer centers across the USA, Canada, UK, Spain and Sweden together covering more than 2,000 persons at risk. The overall objective of the study is to show the overall benefit of testing patients with hereditary pancreatic cancer.

Another key development with the PanFAM-1 clinical trial, it is now listed on ClinicalTrials.gov, the largest clinical trials database in the world, enabling risk individuals and patient organizations easier access to information of PanFAM-1.

The third, groundbreaking, prospective study PanDIA-1 has become the world's largest study of new onset of Type 2 diabetics over 50 and their associated risk of developing pancreatic cancer. Supported by the Swedish Government Program SWElife, the sample collection provides access of up to 6,000 new onset diabetic patients based on a collaboration with two major Swedish universities in Lund and Uppsala, Lund University Diabetic Center, as well as Skåne and Uppsala healthcare regions.

#### Additional strategic focus areas

We also identified two additional strategic focus areas adding to our pipeline activities in 2018 – non-small cell lung cancer (NSLC) and Rheumatoid Arthritis (RA). Both indication areas address very large unmet clinical needs, in focus of the global health-care systems, and thereby represent tremendous commercial opportunities for Immunovia adding to our main focus on earlier detection of pancreatic cancer. We look forward to providing updates as follow up studies are performed during 2019.

The advantage of the IMMray™ platform is that the infrastructure that was built during the development of IMMray™ PanCan –d can, to a very large extent, be repurposed for other products in the pipeline. This leads to very efficient development, production, clinical commercial testing and quality control for products in the pipeline.

#### Moved to Nasdaq Stockholm's Main List

On the corporate side, we rounded out the first quarter of 2018 with the announcement of an important corporate milestone: Immunovia's application to move its shares to the Main List, Mid Cap segment on Nasdaq Stockholm. Our shares commenced trading on April 3, 2018. This move not only reflects that we have matured as a company, but it also strengthens our brand and furthers awareness of our work as we move closer to commencing commercial activities.

#### Rights issue and fully funded

In conjunction with the change of market listing, we launched a new website and adopted financial targets on initial sales of  $IMMray^{TM}$  PanCan –d, the first of several applications with significant market potential for the  $IMMray^{TM}$  platform.

The company has a target of SEK 250-300 million in revenue in 2022 based only on self-pay sales, to penetration of around 5 percent of the inherited risk group for pancreatic cancer, and 1 percent penetration of the market potential for use by patients with early symptoms of pancreatic cancer.

We also announced a second target of achieving total turnover of SEK 800-1,000 million in 2024. This includes self-pay and cost reimbursement from the insurance systems in Europe and the United States. Our target for 2024 corresponds to about 20 percent market penetration in the hereditary category risk for pancreatic cancer and 9 percent market penetration within the category for early symptoms of pancreatic cancer, as well as an initial use within the area of diabetics with increased risk for pancreatic cancer.

Immunovia also completed a directed share issue in June 2018 of around SEK 324 million in gross proceeds. With this share issue, we expanded our shareholder base and generated a strong demand from reputable institutions in Sweden and internationally, such as Swedbank Robur, Handelsbanken Fonder, Alfred Berg Kapitalförvaltning AB, Nyenburgh Investment Partners, Apus Capital and Bonit Capital.

The net proceeds from the share issue are intended to be used to accelerate our commercial launch preparations, help build a US sales and key accounts organization, marketing campaigns and other sales efforts, and contribute to further investments in Immunovia's product development platform,



as the company plans for a broader and deeper development portfolio in the coming years.

#### **Partnering with Key Patient Organizations**

Another new and inspiring initiative that we undertook last year was partnering with several prominent patient organizations to sponsor fundraising walks to help build awareness of the IMMray™ PanCan −d test and educate on the risk factors and the symptoms for pancreatic cancer. We connected with over 24,000 participants in 24 walks in 15 states in the US. We plan to continue to take part in these events in 2019 as one of our marketing activities leading up to our sales launch.

As you can see, we worked intensely throughout the year on the preparations for our sales launch targeted for the beginning of 2020. I am excited to report that we are focusing all our efforts to reach this pivotal milestone in Immunovia's continued development.

As we are half way through the first quarter of 2019, we remain committed to our mission and feel this year is shaping up to be even more promising for the company.

Thank you for your continuing support of Immunovia.

Mats Grahn
CEO, Immunovia

## Market overview

Immunovia expects to generate its first revenues in 2020. The estimated market value for IMMray<sup>TM</sup> PanCan -d is SEK 37 billion.

Introducing IMMray<sup>™</sup> PanCan –d on the US and European markets is planned to commence for self-pay customers once accreditation processes and production upscaling is complete, with revenues expected from 2020. IMMray<sup>™</sup> PanCan –d addresses an estimated market value of 37 billion.

Pancreatic cancer – the deadliest form of cancer
Pancreatic cancer is one of the deadliest and hardestto-diagnose forms of cancer because its signs and
symptoms resemble many other illnesses. Over
40,000 people died from pancreatic cancer in 2018,
and 50,000 new cases were diagnosed in the USA
alone. The current five-year survival level for pancreatic cancer is 5-8 percent. From 2020 onwards,
pancreatic cancer is forecast to become the second
most common cause of cancer death. Early discovery
is critical to significantly improving patient five-year
survival. If achieved, survival could increase from 5-8
percent up to 50 percent.

Current diagnostics inappropriate for early detection All currently available methods are regarded as inadequate for early detection. Due to the low incidence of pancreatic cancer, the costs for screening the whole population are too high. A large number of biomarkers for early diagnosis of pancreatic cancer have also been examined and evaluated. However, no marker has demonstrated sufficient sensitivity and specificity

#### **TRENDS**

Immunovia operates on a market with three main drivers:

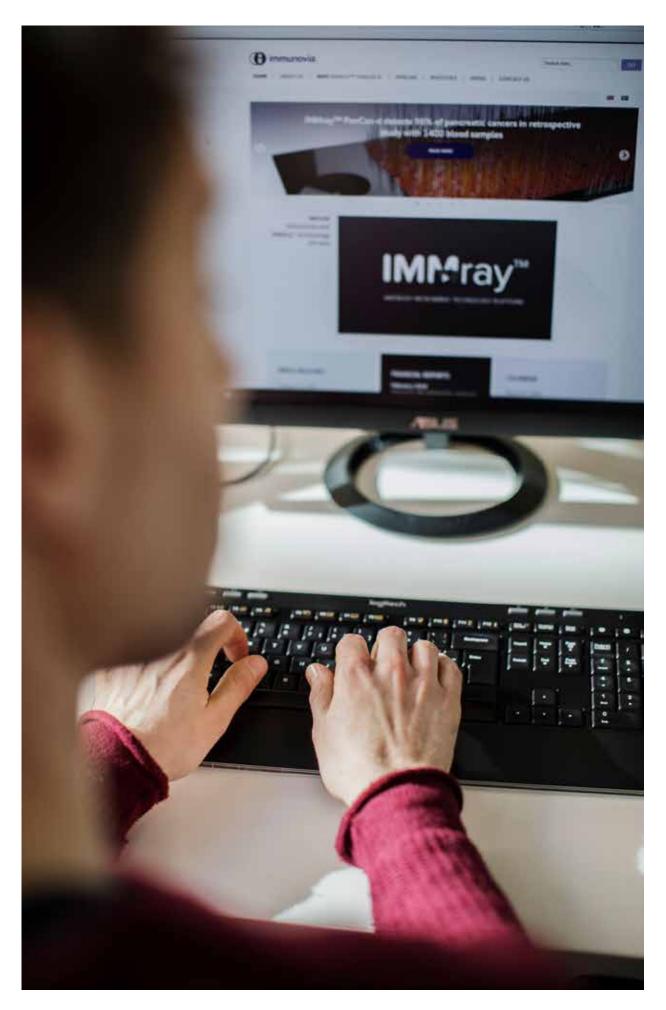
- Early diagnosis is the key to improving the prognosis of cancer patients.
- The cost pressure in the care system is sharpening the focus on early diagnosis.
- Rapidly growing interest in new diagnostic technologies with simultaneous measurement of multiple biomarkers.

to serve as a reliable screening tool to date. The best marker utilized at present is neither fully comprehensive nor sufficiently specific, which reduces its clinical usability as a diagnostic marker.

Three high-risk pancreatic cancer groups
Immunovia's primary market for its core segment of
pancreatic cancer consists of three groups, all of
which are subject to increased risk of developing
pancreatic cancer:

- 1 Patients with previous pancreatic cancer in the family (hereditary pancreatic cancer), or patients with chronic pancreatitis, and patients with certain genetic changes. Immunovia estimates that there are around 200,000 such patients in Europe and the USA. Immunovia believes that these high-risk groups are in need of lifelong screening twice yearly from the age of 40.
- 2 Patients diagnosed with type 2 diabetes, aged 50 and over. The patient group aged 50 or over that have also received their first type 2 diabetes diagnosis have an eight-times-higher risk of contracting pancreatic cancer then the rest of the population, and accordingly should be regularly screened in the first years. If no pancreatic cancer is discovered two to three years after type 2 diabetes is diagnosed, pancreatic cancer can generally be ruled out. In this group, there are an estimated three million new patients each year in Europe and the USA. If they are each tested once a year in the first two years, this would translate to 6,000,000 tests per year on full penetration.
- 3 Patients with early symptoms. The time that passes for patients with pancreatic cancer from their initial primary care visit to accurate diagnosis by a specialist may be six to nine months. This period may involve the patient's condition deteriorating from treatable to untreatable. A blood-based test such as Immunovia's IMMray™ PanCan −d could reduce this lead-time, maximize the number of treatable patients, and increase the chances of improved survival.

The total estimated annual market potential for the three high-risk groups reviewed above is SEK 37 billion at a price of SEK 5,000 per test.



## Immunovia's solution

Immunovia is developing a standard test for the early diagnosis of pancreatic cancer. As far as Immunovia is aware, it is the first company in the world that has developed a cancer diagnosis platform based on a set of specifically selected antibodies to analyze proteins in the blood.

Immunovia's solution is well timed due to three trends:

- Early diagnosis is the key to improving the prognosis of cancer patients.
- The cost pressure in the care system is sharpening focus on early diagnosis.
- Rapidly growing interest in new diagnostic technologies with simultaneous measurement of multiple biomarkers.

Sophisticated analysis enables Immunovia to gather data on the state of the immune system, which is the body's initial reaction to any disease. Unlike other extant tests, this enables the patient's actual condition to be identified accurately in the first test despite the absence of symptoms.

Immunovia's method will be easy to use clinically and patients will need to leave just one blood sample, which will be sent for analysis at a reference laboratory at Immunovia's premises or with collaborative partners. The platform, based on complex biomarker signatures instead of individual markers, improves detection reliability and provides a simple yes/no response. This enables regular testing of high-risk groups before symptoms have expressed, or on vague symptoms that might indicate pancreatic cancer.

Because most pancreatic cancer-related deaths are caused by the cancer being detected too late, Immunovia's solution, which enables early and simple detection, may reduce the number of deaths, and improve patient five-year survival levels from some 5-8 percent up to 50 percent on discovery of the cancer in the earliest stage (stage I).

#### IMMray<sup>™</sup> technology

IMMray™ technology is based on antibodies and utilizes the immune defence as an early, specific and sensitive sensor of diseases such as cancer and autoimmune diseases. Immunovia's technology platform detects high and low-concentration proteins, which means that unlike other technologies, it provides a more complete molecular view of each test. Analyzing the large volume of data generated is only possible thanks to Immunovia's bioinformatics, which quickly and effectively define biomarker signatures that can demonstrate a high degree of specificity and sensitivity.

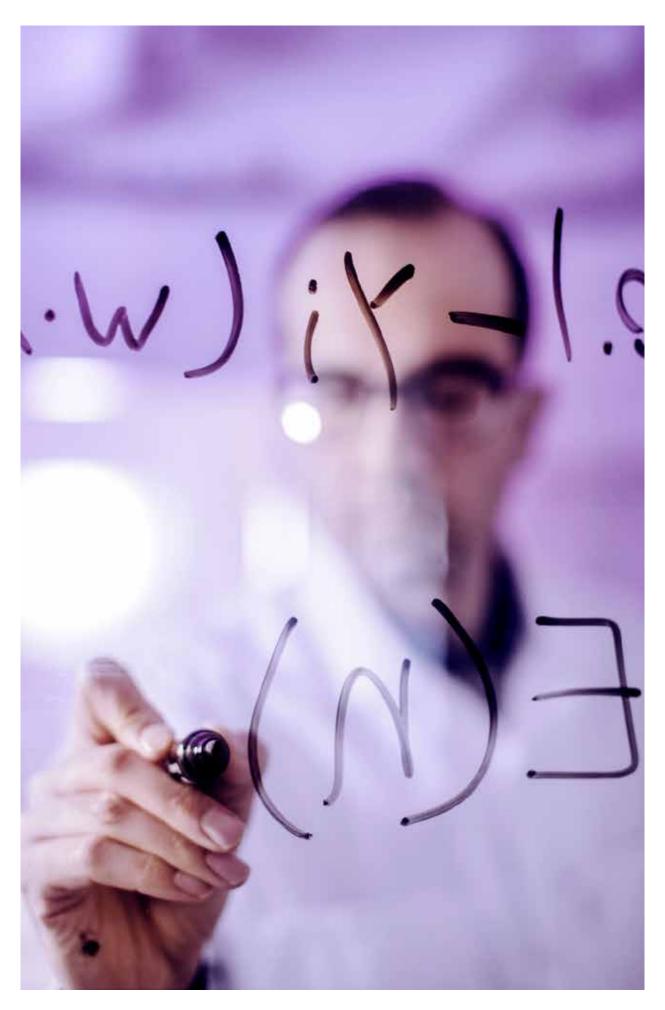
#### IMMray™'s antibody-based micro matrix

Immunovia's concept of antibody-based micromatrixes is based on microscopic droplets (picoliter scale) of individual antibodies in an ordered micromatrix on a plastic surface smaller than a little fingernail. The antibodies specifically bind to unique target proteins present in the blood sample and create a specific pattern. As a result, detailed mapping of the proteins present in blood becomes possible.

#### Product pipeline

Immunovia's portfolio of products in development can be divided into two main categories:

- 1 Three projects associated with diagnostic tests based on the IMMray™ platform:
  - a Detection of pancreatic cancer IMMray™
     PanCan –d,
  - b Diagnosis of the autoimmune disease
     Rheumatoid Arthritis (RA) based on IMMray technology, and
  - **c** Diagnosis of lung cancer.
- 2 Early-phase research projects based on the IMMray™ platform, and research projects based on other patents held by Immunovia conducted within the academic community, which may eventually transfer to Immunovia for continued research and development.



# Our journey to the market

Immunovia's initial goal is to establish its blood-based test for the early diagnosis of pancreatic cancer – IMMray<sup>TM</sup> PanCan -d-as the standard methodology for pancreatologists worldwide when testing special high-risk groups. This includes the familial hereditary group, and the early symptom group as well as the diabetes risk group.

In the longer term, Immunovia intends to develop, validate and globally commercialize other new diagnostic tools based on IMMray™ technology for patient classification, early detection, as well as monitoring the course of patient disease and response to treatment.

Preparations for commercialization in Scandinavia and the USA are ongoing in 2019. To achieve its established targets, Immunovia must first gain acceptance from KOLs and then start usage by experienced and eminent pancreatologists and diabetes physicians. Successful market adoption usually covers achieving reimbursement from insurance organizations. Immunovia is working to satisfy the necessary criteria to achieve this, simultaneously with executing a controlled launch of the test in selected reference laboratories and private clinics.

The prospective studies and certification, accreditation and production upscaling processes, of the product itself and laboratory capacity, are Immunovia's core activities for achieving the commercial phase.

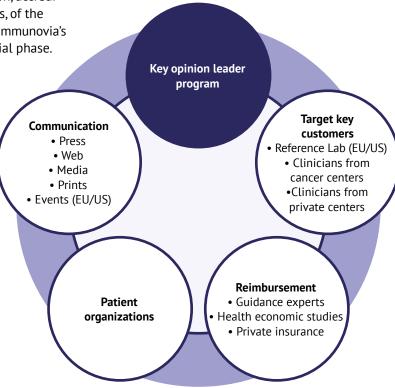
Important goals were achieved in 2018, and Immunovia is working towards starting sales of IMMray™ PanCan –d in early-2020.

#### **Market introduction**

Cost reimbursement from insurance systems is often critical for achieving commercial success. Immunovia is conducting an early market introduction with paying patients and/or care organizations in anticipation of full reimbursement from insurance systems, known as self-pay or out-of-pocket. Work on preparing the market introduction was carried out in 2018, and Immunovia's commercial organization is being gradually increased through 2019. The company anticipates the first revenues from self pay sales in early 2020.

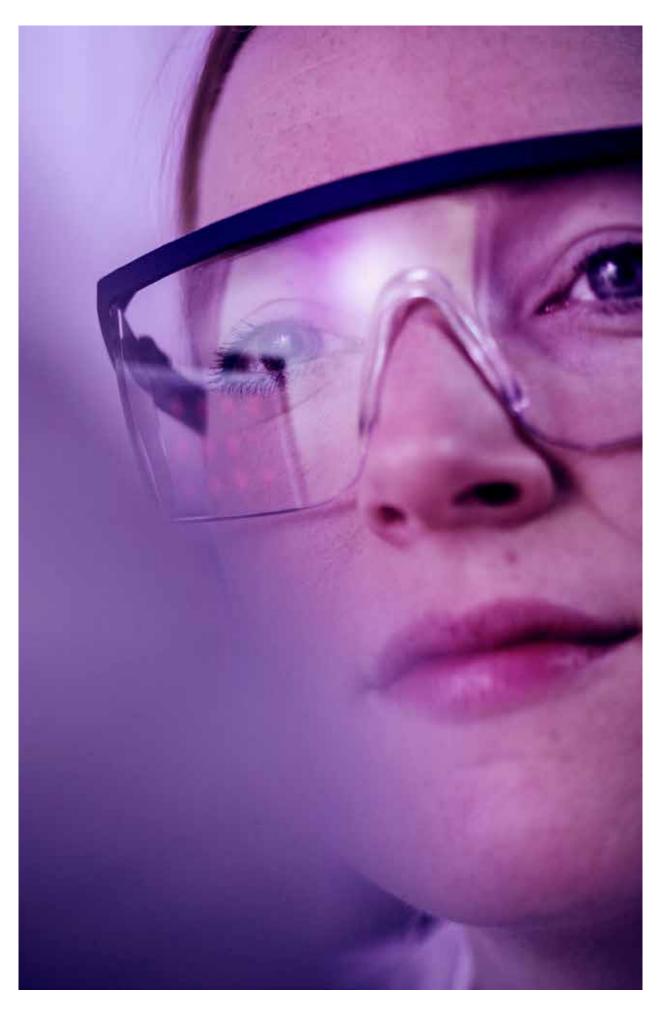
#### National guidelines

Immunovia's goal is for IMMray™ PanCan –d to become part of national and global guidelines for testing special high-risk pancreatic cancer groups. Immunovia's KOL network will enable the company to present the health economic benefits of the test and relevant data from retrospective and prospective studies to the major cancer associations in the USA and Europe.



The key opinion leader program is fundamental for the commercialization strategy .





#### STAGE I

Demonstrate the test's clinical function

Retrospective studies

Building a KOL network on selected geographical markets

#### **STAGES II-III**

Prospective studies designed in partnership with leading cancer centers and verified by reimbursement organizations

Partnerships with leading cancer centers

Out of pocket sales via CLIA-certified or ISA-accredited reference laboratories

Prospective studies consistent with the company's study design in collaboration with KOL network

Facility for early cost reimbursement

STAGE IV

Cost
eimbursement

Full reimbursement per test for risk groups included in the prospective studies STAGE V
Accelerated
market

Expanded market penetration for several patient groups and new geographical regions

#### Distribution

Immunovia's core strategy is to access the whole market by transferring IMMray<sup>™</sup> PanCan −d technology to appropriate partner laboratories and commercial reference laboratories.

#### **Cost reimbursement**

Immunovia needs to demonstrate IMMray™
PanCan –d's clinical benefit and performance, and
health economic advantages, in terms of cost savings
and improved quality of life for patients, in order to
secure cost reimbursement from public and private
insurance systems.

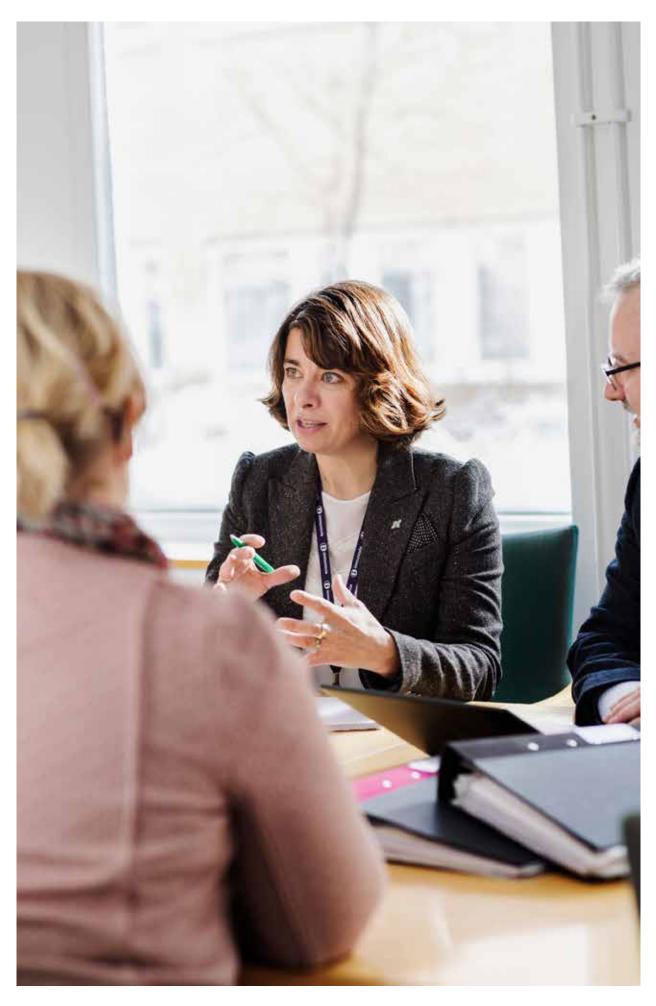
#### Long-term potential

If market adoption for IMMray™ PanCan –d increases, and the test does become subject to cost reimbursement, Immunovia intends to address more patient groups and move into other geographical markets. Expansion will be achieved through collaborations with reference laboratories. As the testing volumes increase, Immunovia will be transferring its IMMray™ technology to these sites. This may require the test being defined as a diagnostic kit in the USA, and gaining approval as an IVD kit for delivery to the reference laboratories. In parallel, Immunovia intends to introduce IMMray™-based diagnostic tools for other forms of cancer and autoimmune disease.

# Organization and network

The company's organization, including its Board of Directors, consists of leading researchers, entrepreneurs, marketers, business developers and specialists in research and diagnostics. Since incorporation, the company has grown progressively, and the group had 45 employees as of December 31, 2018.

In addition to its employees, the company appoints contracted specialists in specific segments. Immunovia's work on validating its blood-based test is conducted through consortia and collaborations with several of the world's well renowned clinics and research institutions. By participating, they contribute with clinical data and patient samples validating the studies. The bredth of collaborations not only provides benefits to studies, but is also an important long-term investment in the market, because the clinics that participate in studies also service important potential customers in the commercial phase.



## Immunovia's shares

#### **Share information**

Immunovia's shares were listed on Nasdaq Stockholm's main list on April 3, 2018, with the ticker IMMNOV.

At the end of the reporting period, there were 19,531,353 shares. The quotient value of shares is SEK 0.05.

#### **Share warrant programs**

The AGM on May 3, 2018 resolved on a share warrant program designated series 2018/2021 for employees and key individuals of the company. The share warrants (150,500 warrants) can be exercised to subscribe for new shares of the company in the exercise period September 7, 2021 until October 7, 2021 inclusive. Each share warrant confers entitlement to subscribe for one share at a subscription price of SEK 271.05 per share. Upon full exercise, the company's share capital would increase by SEK 7,525.

The AGM on April 25, 2017 resolved on a share warrant program designated series 2017/2020 for employees and key individuals of the company. The

share warrants (61,000 warrants) can be exercised to subscribe for new shares of the company in the exercise period September 15, 2020 until October 15, 2020 inclusive. Each share warrant confers entitlement to subscribe for one share at a subscription price of SEK 205.00 per share. Upon full exercise, the company's share capital would increase by SEK 3,050.

The AGM on May 30, 2016 resolved on a share warrant program designated series 2016/2019 to employees and key individuals of the company. The share warrants (137,000 warrants) can be exercised to subscribe for new shares of the company in the exercise period from the present and until October 15, 2019 inclusive. Each share warrant confers entitlement to subscribe for one share at a subscription price of SEK 82.90 per share. Upon full exercise, the company's share capital would increase by SEK 6,850.

The AGM on May 3, 2018 resolved on an alternative cash-based incentive scheme for employees and key individuals based in countries where the share warrant program designated series 2018/2021 was not

#### Share capital development

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

appropriate for various reasons. Such an alternative incentive scheme has been introduced for employees and key personnel and is designed in such a way that it corresponds to the terms of the share warrants program 2018/2021. The total cost for the incentive scheme can not exceed USD 250,000.

The AGM on April 25, 2017 resolved on an alternative cash-based incentive scheme for employees and key individuals based in countries where the share warrant program designated series 2017/2020 was not appropriate for various reasons. Such an alternative incentive scheme has been introduced for 6 key individuals and is designed in such a way that it corresponds to the terms of the share warrant program 2017/2020. The total cost for the incentive scheme may not exceed USD 920,000.

All share warrant programs are subject to customary conversion conditions for share issues etc.

#### **Dividend policy**

Immunovia has not adopted a dividend policy.

#### **Proposed dividend**

The Board of Directors is proposing to the AGM 2019 that no dividend is paid for the financial year 2018.

The ten largest shareholders as of December 31, 2018

		Share capital
Name	No. of shares	and votes
Carl Borrebaeck	1,709,900	8.75 %
Ålandsbanken		
on behalf of owners	1,624,251	8.32 %
Handelsbanken		
Svenska Småbolag	1,000,000	5.12 %
Sara Andersson Ek	888,950	4.55 %
Per Mats Ohlin	888,950	4.55 %
Christer Wingren	883,384	4.52 %
Vincent Saldell	747,319	3.83 %
Försäkringsbolaget		
Avanza Pension	586,170	3.00 %
Catella Småbolagsfond	527,804	2.70 %
Swedbank Robur		
Folksams LO Sverige	500,000	2.56 %
Ten largest shareholders	9,356,728	47.91 %
Other	10,174,625	52.09 %
Total	19,531,353	100.00 %

# Sustainability report 2018

This sustainability report refers to the 2018 financial year and applies to the parent company Immunovia AB (publ) (org. No. 556730-4299) and all entities that are consolidated in Immunovia's consolidated accounts for the same period. These are stated in Note 20 in the 2018 Annual Report. This report has been prepared without Immunovia having any legal mandatory requirement to do so. The report is not based on any specific sustainability standard, but is based on the Annual Accounts Act's regulations. The annual report presents financial aspects regarding Immunovia's operations.

The Board of Directors and CEO have also approved the sustainability report when signing off the annual report and the consolidated accounts.

#### **Public welfare**

Immunovia's value chain

Immunovia's ambition is to create value by being able to diagnose complex diseases such as cancer and autoimmune disorders, considerably earlier and more precisely than is currently possible.

Business model and operation

In our therapeutic core areas – cancer and autoimmune diseases – we address several of society's largest global health challenges and strive to develop more effective diagnostic tools that help improve treatment, quality of life and health economics. Thorough, safe and ethical research is one of the company's cornerstones ensuring both patient safety in clinical trials and that our products are clinically useful with a positive health economic effect.

Immunovia's strategy is to analyze the wealth of information that is in blood and transfer it to clinically useful tools in order to diagnose complex diseases such as cancer and autoimmune disorders considerably earlier and more accurately than is currently possible. Immunovia's Technology Platform − IMMray™ − is an antibody-based multiplex test designed to generate immune defense response snapshots from the information in a single drop of blood.

The IMMray™ platform is a systematic approach, based on the simultaneous measurement of many proteins in the blood with the very latest bioinformatics, aimed at detecting the most clinically relevant changes that may occur in the blood and combining them into a biomarker signature – a kind of "disease fingerprint" – which is specific to each disease.

#### RESEARCH

Basic research is carried out at an academic level

#### PRODUCT DEVELOPMENT

Built on thorough ethical research.
Development takes place in collaboration with leading clinics and research centers in the cancer and autoimmune areas

#### **PURCHASE AND PRODUCTION**

Production of antibodies in accordance with regulatory requirements.

Suppliers undergo Immunovia's approval process

#### DIAGNOSTICS

Diagnosis of cancer and autoimmune diseases in accordance with regulatory requirements. The test is analyzed by Immunovia's IMMray™ platform.

#### CUSTOMER

Early detection of cancer and auto-immune diseases contributes to better treatment and increased survival. Sales of the first test start in early 2020.

#### Social value chain

The prerequisite for sustainable business development and success lies in creating long-term relationships with our employees, customers and suppliers. In order to build up our good reputation, we must maintain high quality and high ethical levels in all our commitments, with a given respect for fundamental human rights.

Collaboration with partners is key to Immunovia's success. Major scientific breakthroughs are often done through collaboration between industry and academia. Working with world-renowned research centers and clinics provides the necessary access to patient samples and data, as well as crucial clinical expertise.

We also value our close relationships with Key Opinion Leaders and patient organizations, as they provide an important insight, knowledge and ability to influence change. Since 2016, Immunovia has been affiliated with the World Pancreatic Cancer Coalition (WPCC), a world coalition between over 50 patient organizations for pancreatic cancer. Our goal is to be a responsible player.

#### Vision and mission

Immunovia's vision is that we shall lead the development of bioinformatic-supported diagnosis so that

all patients are diagnosed in time for effective treatment, resulting in improved quality of life and a significantly higher survival rate.

Against this background, Immunovia has a dual mission:

- Using the IMMray<sup>™</sup> platform discover, develop and establish more precise and reliable tools for early diagnosis of cancer and autoimmune diseases.
- Establishing IMMray™ PanCan –d our blood-based test for early diagnosis of pancreatic cancer – as a global standard for much earlier discovery in highrisk groups.

#### Anti-corruption

Business ethics is important and is an issue that is continuously managed and treated. Anti-corruption guidelines are regulated in Immunovia's Code of Conduct. We have a pronounced zero tolerance to corruption and do not accept bribes or unfair anti-competitive measures. No cases of corruption were detected during the year.

#### Whistle-blowing system

Immunovia strives to have a transparent business environment based on the idea that one should conduct a profitable business while complying with

#### Significant risks and risk management - Public welfare

The company's tests will not be covered by national guidelines for covered by national guidelines for covered by national and medicinal organizational guidelines for testing in high

treatment or by cost compensation programs.

Risk

Risk management

Immunovia works in a competitive environment

risk groups. This work is carried out, amongst others, in the form of lobbying and through the company's network of Key Opinion Leaders.

The market where Immunovia operates in is subject to competition and the company competes with Swedish and international companies which, like

Immunovia, focus on diagnosing cancer and autoimmune diseases. The company

conducts ongoing external monitoring of competitors and technology.

Immunovia is subject to various government regulations and risks not getting the necessary permits for the sale of tests.

Immunovia's operations are, among other things, subject to US, European and local laws, rules and regulations, which, inter alia, concern medical technology products. In order to market and sell medical technology products, permits and/or approvals must be obtained and registered with the relevant authorities.

There is a risk that Immunovia will not receive cooperation and license agreements with different countries' reimbursement systems.

The company conducts work on its own behalf and signs agreements with partners to conduct research, retrospective and prospective studies in various research projects and commercialize their products. The company ensures through cooperation agreements with key partners' insight into different countries' reimbursement systems that make it possible to adapt the company's management of tests for different markets.

ethical rules. It is of the utmost importance for Immunovia that the entire company's operations are conducted with the highest possible sense of responsibility, openness and honesty. Any suspicion of fraudulent behavior, bribery or other similar situations witnessed, must be reported promptly.

In 2019, a whistle blower function will be introduced. This is to enable all employees to feel confident in reporting irregularities, maladministration and serious events without worrying about negative consequences. As the organization grows, more focus will be placed on measures against anti-corruption.

#### Sustainable products and processes

Quality system and registrations

The creation of the quality system forms the basis of the business for obtaining the necessary permits and registrations which then enable future sales. Immunovia works intensively to get product registrations according to EU IVD directive, ISO13485, accreditation of Immunovia's laboratory in Lund according to ISO 17025, and CLI /CAP accreditation of Immunovia Inc's lab in Marlborough, MA, USA will be in place as

soon as possible. Furthermore, we are preparing for future FDA approval of our diagnostic products.

Product development, purchasing and production
Product development and manufacturing procedures
and processes are prepared in accordance with the
regulatory requirements imposed on the business.
The focus is on ensuring the product quality with
systematic work and preserving the quality of
Immunovia's products and services.

#### Chemicals

Risk assessments are made on all chemicals used to produce a product. The waste generated by the business is managed and destroyed according to applicable laws and regulations. Clinical waste (infectious/sharp/cutting waste), GMM waste (genetically modified microorganisms) and solvents, are managed and destroyed in cooperation with certified waste companies.

Minimal environmental impact Immunovia's goal is to lead the Group's the Group's operations with as little negative impact on the

#### Significant risk and risk management - Sustainable products and processes

Risk Risk management

Immunovia's product development does not succeed in meeting market and/or quality requirements.

Through a structured and goal-oriented work in the various areas, the possibility of successful product development increases. Information exchange takes place continuously with the marketing and quality department to meet the market and regulatory requirements that are set.

Risks linked to intellectual property rights.

Immunovia's intellectual property rights, in particular its patents, constitute an important asset in the business and the company's success depends on the company being able to maintain the reputation and value associated with the company's existing patents, brands and other intellectual property rights. In order to ensure that new patents are created, staff are encouraged and given the opportunity to register patents that are then transferred to the company's name. Management of applications and monitoring of existing patents is continuously done by a patent agency engaged by the company.

Risk that accreditation according to ISO 17025 and Clia/Cap accreditation in the US are not received.

Immunovia focuses heavily on the regulatory requirements required to obtain the necessary accreditation of the company's laboratories. Necessary in this is the company's quality system where the company engages in internal and external resources with the experience of building a quality system that enables accreditation. Parallel to this, changes are being made by the registration authorities.

Risk that the necessary product registrations are not received

Immunovia works in a targeted way with the regulatory requirements set for obtaining the necessary registrations. Central to this is the company's quality system, where the company engages both internal and external resources with many years of experience of building quality systems and getting these approved. At the same time, changes are being made by the registration authorities, such as the FDA.

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### Sustainability work's three focus areas







environment as possible while ensuring correct results to the tests being done.

Immunovia strives to improve its environmental performance by:

- Destroying waste complying with Immunovia's waste management policies
- Complying with legal and other relevant requirements
- Minimizing the environmental impact of energy consumption and transport

Our quest to continuously minimize our environmental impact is self-evident. However, Immunovia does not actively measure its environmental impact, in the form of  $\text{CO}_2$  emissions, which the business generates. Management does not consider there are significant risks that can have negative consequences for the business associated with these factors, that require measurement.

Supplier evaluations ensure the sustainability of our value chain

Immunovia conducts supplier evaluations in accordance with the evaluation policy in force at any time. The purpose of the supplier evaluations is to ensure, as far as possible, that Immunovia works with suppliers that provide quality-assured products, which in turn contribute to the reliability of the test responses and thus contribute to safeguarding the sustainability of the value chain. The ambition is to work with our suppliers and regularly review these in order to continuously ensure quality.

#### Sustainable workplace

Our most important asset is our employees Immunovia's employees are an absolute prerequisite for our success. A good corporate culture makes for well-being, low sick leave and good relations, as well as low staff turnover. Immunovia should be a company where responsibility and freedom should be two of its core values and can be summarized as "freedom in responsibility".

Immunovia is a gender equal company and in the Albright Report 2018 entered the green list at 36th place of 329 listed companies regarding gender equality between men and women.

The Albright report annually ranks the listed companies from best to worst in promoting women to the management team. The gender equal companies are listed on Albright's green stock exchange list, the mediocre companies are placed on the yellow stock exchange list and the male-dominated companies end up on the red list.

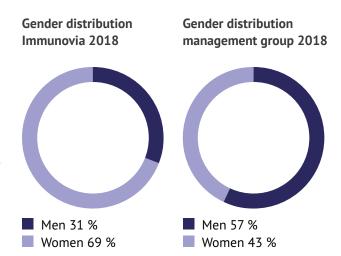
During 2018, the average number of employees in the Group was 39 (30), of which 32 (26) were in the parent company. The average number of women in the Group was 27 (20) and the average number of men in the Group was 12 (10). Immunovia's management group consists of 4 men and 3 women.

#### Education and expertise

A prerequisite for a successful business is to make use of the employees' knowledge, experience and commitment. Immunovia should therefore be a workplace in which all employees' knowledge, skills and expertise are utilized in the best way.

#### Health and safety

Health and safety is a priority area. Immunovia has a zero tolerance regarding work-related accidents,



illnesses and incidents and an ambition to continuously promote improved health and well-being among our employees. The goal is for nobody to suffer from physical or mental illness due to their work situation. No occupational injuries were reported in 2018.

Over the year, measures were taken and adaptations made to the new legislation concerning the GDPR (General Data Protection Regulation).

#### Employee turnover

We strive to make our employees feel comfortable and develop in order to maintain key expertise and recruit new talent. In 2018, 9 new employees started at Immunovia and no employees left. Immunovia is a

#### Significant risk and risk management – Sustainable workplace

Risk	Risk management
Risk that key people leave the organization.	The company's ability to continue to identify and develop opportunities depends on the key employees' knowledge and expertise in the area that Immunovia operates. By creating a good, interesting and challenging workplace where key individuals are given the opportunity to develop within their area, the company ensures that key people want to work at the company.
Work environment risks.	Immunovia works actively for a good work environment where physical, organizational and social aspects are in focus. Examples of preventive activities include the annual health profiles and provision of health insurance and ergonomic reviews of the workplace.
Risk of access to the right skills not being met.	Immunovia is a small, knowledge-intensive company dependent on people with high skill levels and experience to achieve planned success. By being an attractive employer providing market-based and competitive remuneration, this contributes to new employees being recruited and retained.

young company where most of the staff were hired over the last three years.

#### Work environment

Ongoing work on the work environment must be preventive, supportive and encouraging. Preventive – through regular work environment inspections, minimizing risks of accidents/ill-health and ongoing follow-up of activities. Supportive – by regularly carrying out employee surveys on the work climate, job satisfaction and commitment. Encouraging by offering employees opportunities for developing and promoting openness, equality and responsibility. Of course, we have zero tolerance to bullying and harassment.

#### Diversity

We are convinced that diversity - including a mixture of gender, age, ethnic background and sexual orientation - contributes in the long-term to a better working environment, greater creativity and better results. Furthermore, we will never accept prejudice or discrimination in any form, but strive for equal

treatment for all, regardless of background and individual differences.

Immunovia has adopted the following principles to ensure diversity and equal treatment:

- Promote diversity
- Equal treatment regardless of background or individual differences
- Zero tolerance against discrimination
- · Systematic diversity work
- Adapt facilities for accessibility for disabled employees

#### Sustainable development - a summary

Immunovia's ambition is to create value by being able to diagnose complex diseases such as cancer and autoimmune disorders considerably earlier and more precisely than is currently possible.

The concept of *Sustainable Development* was launched by the UN's *Brundtland Commission*, which in 1987 defined it as a development that:

"... meets today's needs without jeopardizing the ability of future generations to meet their needs."

# Auditor's statement on the Sustainability Report 2018

To the general meeting of Immunovia AB (publ), corporate identity number 556730-4299

#### **Engagement and responsibility**

It is the board of directors who is responsible for the statutory sustainability report on pages 20-25 and that it has been prepared in accordance with the Annual Accounts Act.

#### The scope of the audit

Our examination has been conducted in accordance with FARs auditing standard RevR 12 *Auditor's opinion regarding the statutory sustainability report.* This means that our examination of the statutory sustainability report is substantially different and less in scope than an audit conducted in accordance with International

Standards on Auditing and generally accepted auditing standards in Sweden. We believe that the examination has pro-vided us with sufficient basis for our opinion.

#### **Opinion**

A statutory sustainability report has been prepared.

Lund March 3, 2019

Mazars SET Revisionsbyrå AB

Mats-Åke Andersson Authorized public accountant

# **Corporate Governance Report 2017**

This Corporate Governance Report has been prepared in accordance with chap. 6 § 6 of the Swedish Annual Accounts Act and the Swedish Code of Corporate Governance (the 'Code').

The Board of Directors is responsible for this Corporate Governance Report.

The Corporate Governance Report for the financial year has been examined by the company's auditor, as stated in 'the auditor's examination of the corporate governance statement.'

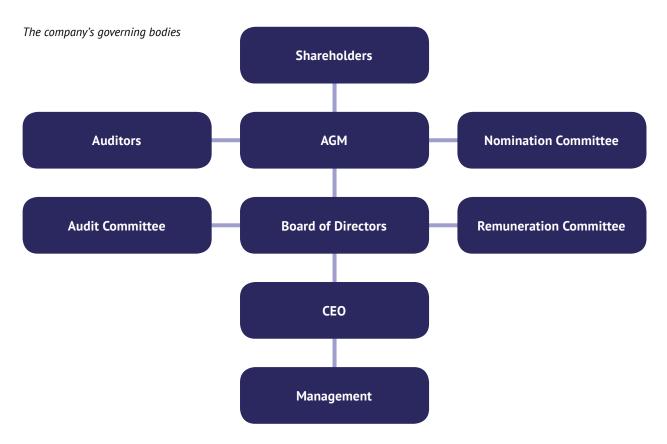
Immunovia is a Swedish public limited company, whose shares are listed for trading on Nasdaq Stockholm's main list. Immunovia complies with the corporate governance guidelines stated in internal and external rules and ordinances. In its capacity as a limited company listed on Nasdaq Stockholm, Immunovia is regulated by the Swedish Companies Act and the Swedish Annual Accounts Act, other applicable

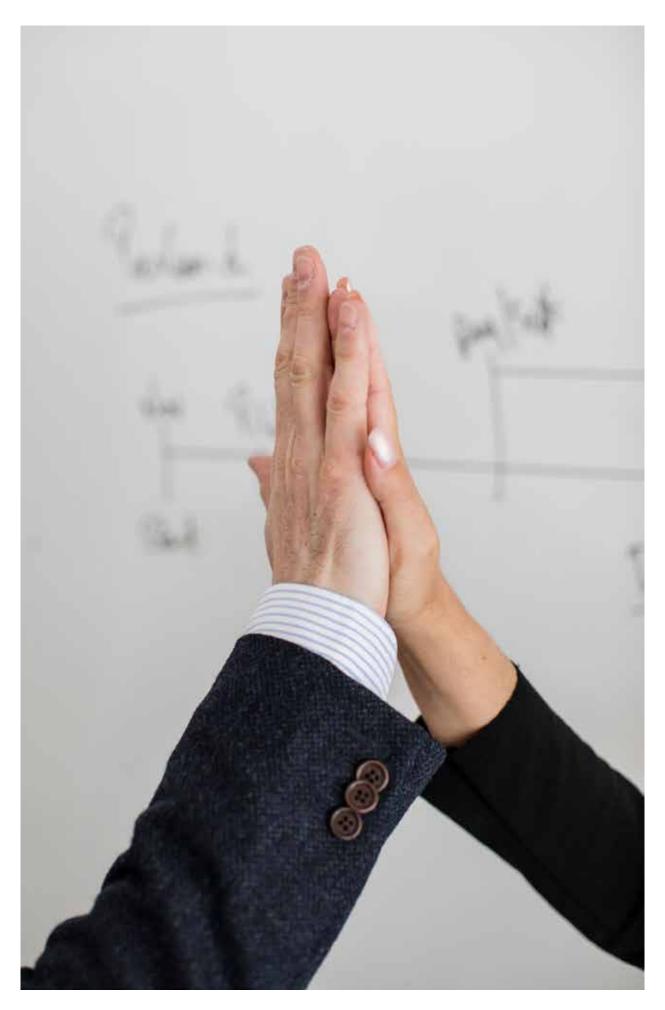
Swedish and foreign laws and regulations, including Nasdaq Stockholm's Rulebook for Issuers.

To ensure compliance with all applicable legal standards, Immunovia has also adopted internal instructions and policies, which are reviewed below. The Board of Directors has also adopted and implemented Rules of Procedure for its work, and adopted instructions for the Chief Executive Officer, with instructions for financial reporting.

## Compliance with the Swedish Code of Corporate Governance

Immunovia's shares are listed for trading on Nasdaq Stockholm, which means that the company is obliged to apply the Swedish Code of Corporate Governance (the 'Code'). The Code is available at the website of the Swedish Corporate Governance Board, which manages the Code (www.corporategovernanceboard. se). The Code is based on the principle of 'follow or explain', which means that companies applying the





Code may depart from individual rules, but if so, must give an explanation for the departure.

#### Corporate governance

The figure on page 26 describes the central organs in Immunovia's corporate governance model and who appoints the central bodies.

#### **Articles of Association**

Immunovia's Articles of Association, which are the basis of governing the company's operations, state the company's name, registered office, the aim of business operations, the company's shares and share capital, and also include rules governing share-holders' meetings. The Articles of Association state no limitations in terms of how many votes each shareholder is entitled to cast at shareholders' meetings, nor any stipulations regarding appointing and dismissing Directors, or amending the Articles of Association. The Articles of Association are stated at https://immunovia.com/governance/articles-of-association/.

#### The shares and shareholders

The total number of shares and votes of the company as of December 31, 2018 was 19,531,353, and the share capital was SEK 976,567.65. Shares of the company are all of the same class, each share carries one vote, and all shares confer equal entitlement to the company's assets and earnings. The company had approximately 3,500 shareholders as of December 31, 2018. The company's largest shareholders as of December 31, 2018 are listed on page 19.

According to the company's knowledge, all other significant relationships between Immunovia and the company's largest shareholders are listed in note 27 titled "Transactions with related parties". The Board of Directors is not aware of any shareholders' agreements or other agreements regarding voting rights or other shareholders' rights.

In June 2018, the Board of Directors exercised its authorization, from the Annual General Meeting (AGM) on May 3, 2018, to resolve on directed share issues of 2,162,794 new shares to Swedish and institutional investors, with discard of shareholders' preferential rights. The new share issue was carried out on June 8, 2018, raising gross proceeds of approximately SEK 324 M.

In September 2018, 50,500 warrants were subscribed, a constituting part of the company's incentive program from resolutions adopted in 2015 and 2016. The number of shares increased by 50,500.

#### **Annual General Meeting**

The AGM is the company's chief decision-making body. The AGM should be held within six months of the end of the financial year. The AGM elects the Board of Directors and auditors. The AGM also adopts the Income Statement and Balance Sheet, and considers matters of the dividend, discharging the Directors and Chief Executive Officer from liability, and approving fees to the Board of Directors and auditors. The AGM also deals with matters that are incumbent on it pursuant to the Swedish Companies Act and the Articles of Association.

The company's ambition is for the AGM to be a satisfactory body for shareholders, and accordingly, its objective is for the whole Board, at least one representative of the Nomination Committee, the Chief Executive Officer and other members of management, as well as the auditor, to always attend the AGM.

Extraordinary General Meetings (EGM) are convened when the Board of Directors or auditors consider this appropriate.

Pursuant to Immunovia's Articles of Association, notices convening AGMs and EGMs are through an announcement in the Swedish Official Gazette, and by making the notice available at the company's website. Issuance of the convening notice is announced in Swedish daily newspaper *Dagens Industri*. Resolutions of meetings are published in press releases and are available on the website.

The AGM 2019 will be held at 16.00 p.m. on April 26, at Medicon Village in Lund, Sweden.

#### Entitlement to attend the AGM

All shareholders directly registered in the share register maintained by Euroclear Sweden AB five days prior to the AGM and have notified the company of their intention to attend (with potential assistants) by no later than the date stated in the convening notice of the AGM, are entitled to attend the AGM and vote for the number of shares they hold. Shareholders can attend the AGM personally or by proxy and may also be assisted by a maximum of two people. Normally, shareholders are able to register in several different ways, as stated in the convening notice.

*Initiatives from shareholders* 

Shareholders that wish to have a matter considered at the AGM must submit a written request thereof to the Board. The Board should normally have received such request by no later than seven weeks prior to the AGM.

#### **Nomination Committee**

The company shall have a nomination committee with the task of preparing and submitting proposals for the AGM, and in certain cases, extraordinary general meetings, resolutions in election and remuneration issues, and, where applicable, procedural issues for the next election committee.

The nomination committee shall propose:

- the chairman of the AGM;
- candidates for the post of chairman and other members of the board;
- fees and other remuneration for board assignments to each of the board members;
- remuneration to members of committees within the board:
- election and remuneration of the company's auditor;
   and
- principles for the Nomination Committee.

The Nomination Committee shall, when assessing the Board's evaluation and in its proposals, take into account the requirement on the versatility and breadth of the board and the requirement to strive for an even gender balance. Nomination Committee members, regardless of how they have been appointed, shall exercise all of the company's shareholders' interests.

Any changes in the composition of the Nomination Committee shall be released immediately.

The Nomination Committee, which will be appointed for the period until a new Nomination Committee has been appointed, should consist of four members, three of whom should be appointed by the company's largest shareholders in terms of the votes, and the fourth should be the Chairman of the Board. When evaluating which shareholder should be considered the largest shareholder of the company, calculations of participating interest should include ownership based on groups of shareholders that collaborate in the company's administration.

As soon as possible after the end of the third quarter each year, the Chairman of the Board should contact the three largest shareholders at this date in an appropriate manner and encourage them to designate the individual such shareholder wishes to appoint as a member of the Nomination Committee in writing within a reasonable time that does not exceed 30 days. If one of the three largest shareholders does not exercise its right to appoint a member of the Nomination Committee, the next shareholder in turn will be offered the right to appoint a member of the Nomination Committee. In cases where several shareholders decline the entitlement to appoint members of the Nomination Committee, the Chairman of the Board should not need to contact more than eight shareholders, providing this is not necessary to compose a Nomination Committee with at least three members. Unless otherwise agreed between members, the Chairman of the Nomination Committee should represent the largest shareholder.

The Chairman of the Board or other Directors may not serve as Chairman of the Nomination Committee

Employees of the Group may not be members of the Nomination Committee.

If a shareholder that has appointed a member of the Nomination Committee is no longer one of the company's three largest shareholders in the year, the member selected by such a shareholder should leave the Nomination Committee. Instead a new shareholder from amongst the three largest shareholders will be entitled, independently and at their own discretion, to appoint a member of the Nomination Committee. However, no marginal differences in shareholdings and changes to shareholdings arising later than three months prior to the AGM should cause any changes to the composition of the Nomination Committee, unless in special circumstances. If a member of the Nomination Committee leaves before the Nomination Committee has completed its assignment due to reasons other than those stated in the preceding paragraph, that shareholder that appointed such member shall be entitled, independently and at their own discretion, to appoint a replacement. If the Chairman of the Board leaves the Board of Directors, his/her replacement should also replace the Chairman of the Board on the Nomination Committee.

No fees are payable to members of the Nomination Committee. However, the company will meet expenses that the Nomination Committee considers necessary to complete its assignment. The current Nomination Committee members are:

- Sara Ek, appointed by Sara Ek, chairman of the nomination committee
- Carl Borrebaeck appointed by Carl Borrebaeck, Chairman of the Board
- · Mikael Löfman appointed by Mikael Löfman; and
- Astrid Samuelsson appointed by Handelsbanken Fonder

The composition of the Nomination Committee must be published on the company's website no later than six months before the AGM.

#### **AGM 2018**

The most recent AGM was held on May 3, 2018 at Medicon Village in Lund. The AGM resolved to re-elect the Directors Carl Borrebaeck, Hans Johansson, Åsa Hedin and Ann-Christine Sundell. The meeting also resolved to elect Mimmi Ekberg and Christofer Sjögren as new Directors. It resolved that a total remuneration of SEK 1,270,000 be paid to the Board of Directors, of which SEK 400,000 to the Chairman of the Board, SEK 150,000 to each other Member of the Board and SEK 40,000 to the Chairman of the Audit Committee, SEK 40,000 to the Chairman of the Remuneration Committee and SEK 20,000 to each other member of these committees.

The proposal that no dividend be paid for the financial year 2017 was approved.

The AGM elected Mazars SET Revisionsbyrå AB as the Company's auditor, with Authorized Public Accountant Mats Åke Andersson as Auditor in Charge, for the period until the end of the AGM 2019.

Furthermore, the Meeting resolved to appoint a Nomination Committee for the next AGM, in accordance with the above section "Nomination Committee".

A decision was made by the AGM to issue a maximum of 226,000 options with deviation from the shareholders' preferential rights.

The options are one of Immunovia's incentive schemes for senior executives and employees and are described in more detail on page 18.

The Meeting also resolved to grant the Board of Directors the right to introduce an alternative cashbased incentive scheme for key individuals based in countries where the allocation of warrants is not appropriate for various reasons. Such an alternative incentive scheme has been introduced for 11 key people and is designed in such a way that its economic

effect for the key person, corresponds to the terms of the above-mentioned incentive scheme based on warrants and are described in more detail on page 18. The total cost for the Company for such alternative incentive schemes must not exceed USD 250,000. The AGM further resolved that, to make it possible for the Board to add working capital to the company and/or new owners of strategic importance for the company, and/or acquisition of other companies or businesses, to authorize the Board during the period until the next Annual General Meeting on one or more occasions, to decide on new share issue so that an increase in the share capital will be no more than twenty (20) percent based on the company's total share capital at the AGM 2018, with or without deviation from shareholders' preferential rights and with or without a provision for a capital contribution.

#### **Board of Directors**

The Board of Directors is the chief decision-making body after the AGM. The responsibilities of the Board of Directors are regulated through means including the Swedish Companies Act, the company's Articles of Association and other laws and ordinances, as well as the Board of Directors' Rules of Procedure and other internal policies.

Pursuant to the Swedish Companies Act, the Board of Directors is responsible for the company's administration and organization, which means that the Board is responsible for matters including setting goals and strategies, ensuring procedures and systems for evaluating established goals, continuously evaluating Immunovia's financial position and results of operations, as well as appraising executive management. The Board of Directors is also responsible for ensuring that the Annual Accounts and Consolidated Accounts, as well as interim reports, are prepared on time. The Board also appoints the CEO.

The Directors are elected by the AGM each year, or where appropriate, by an EGM, for the period until the end of the next AGM. The Chairman is elected by the AGM, or where appropriate, an EGM, and has a special responsibility to lead the work of the Board of Directors and for the work of the Board being well organized and conducted effectively.

The Board of Directors follows written Rules of Procedure, which are reviewed yearly and adopted at the Board meeting following election each year, or as necessary. The Rules of Procedure divide responsibilities

for the work of the Board between the Board and its Committees, and between the Board and the Chief Executive Officer. Pursuant to the Articles of Association, the Board should decide on strategies and budgets, adopt the Annual Accounts and other financial statements, important policies and authorization lists, appoint the CEO and appraise the work of the CEO, adopt rules governing internal controls and monitoring how internal controls are functioning, decide on major investments and far-reaching agreements, decide on the direction of the work of the Board of Directors, appoint the Audit and Remuneration Committees, and appraise the work of the Board's Committees.

The Chairman of the Board leads the work of the Board. The Chairman of the Board should monitor the company's progress and ensure that the Board receives the information necessary for the Board to perform its duties.

The Board meets in accordance with an annual schedule that is approved in advance. In addition to these meetings, further meetings can be arranged to deal with issues that cannot be considered at a scheduled meeting. In addition to Board meetings, the Chairman and CEO maintain an ongoing dialogue regarding management of the company.

#### The work of the Board of Directors

Board meetings are prepared by the Chairman of the Board jointly with the company's Chief Executive Officer. Written material is provided to the Board for each meeting. Certain matters are consulted within the audit committee, whose members are Åsa Hedin (Chairman) and Hans Johansson. Regular issues for Board meetings include reviews of business conditions and financial reporting. The minutes of Board meetings are recorded by the company's CFO.

#### Appraising the work of the Board

Pursuant to the Articles of Association, the Board appraises its work each year. The work of the Board is evaluated yearly through a systematic and structured process that is designed to produce good supporting data for improvements of the Board's own work. The appraisal is conducted partly individually, and partly through discussions at Board meetings. The aim of the appraisal is to provide the Chairman of the Board with information on how Directors perceive the efficiency and aggregatecompetence of the Board, and if there is a need for changes within the Board.

Directors and their independence							
Name	Assignment for the company and other material assignments	Elected to the Board	Atten- dance Board meetings	Attendance Remune- ration Committee	Attendance Audit Committee	Dependent on the company and man- agement	Dependent on major share- holders
Carl Borrebaeck (born 1948)	Chairman	2007	20/20	4/4	-	Yes	No
Åsa Hedin (born 1962) Ann-Christin Malmborg Hager (born 1965)	Member Member	2015 2015 (Resigned	16/20 9/10	- -	5/5 -	No No	No No
Ann-Christine Sundell (born 1964)	Member	2018) 2017	18/20	4/4	-	No	No
Hans Johansson (born 1954)	Member	2017	19/20	_	5/5	No	No
Mimmi Ekberg (born 1959)	Member (elected 2018)	2018	10/10	-	-	No	No
Christofer Sjögren (born 1966)	Member (elected 2018)	2018	10/10	-	-	No	No

The other Directors appraise the Chairman of the Board. The Chairman of the Board informs the Nomination Committee of the outcome of these appraisals.

Summary of Board meetings in the year In 2018, the Board held 20 meetings, and one strategy day. In the year, the external auditors attended one meeting. Matters considered apart from schedule items included continuous reviews of long-term strategies, review of new product alternatives, and the budget for 2019.

Board composition and independence

Pursuant to the company's Articles of Association, where elected by the AGM, the Board should consist of a minimum of three and a maximum of ten Directors and maximum of ten deputies. Otherwise, there is no stipulation in the Articles of Association regarding appointing or dismissing Directors. Pursuant to the Code, a majority of Directors elected by shareholders' meetings should be independent of the company and its management. At least two should also be

At present, the company's Board of Directors consists of six members elected by shareholders' meetings.

independent of the company's major shareholders.

Immunovia judges that its Board satisfies the

requirements of independence.

The Board's members and their independence are stated in the following table.

#### **Audit Committee**

The Audit Committee members are Åsa Hedin (Chairman) and Hans Johansson. The primary duty of the Committee is to assure the quality of financial reporting, which includes internal controls, reviews of material accounting and measurement issues, and reviews of the company's external reporting. Before the AGM, the Committee should also provide the Nomination Committee with proposals regarding audit fees. The Audit Committee also determines which other services apart from auditing the company may purchase from the company's auditors.

The auditors meet the Board of Directors and Audit Committee each year, both with and without management in attendance.

Minutes are taken at all Audit Committee meetings and distributed to all Directors. The Committee also provides regular reports to the Board on its work through the Chairman of the Committee verbally reporting at the following Board meeting.

The Audit Committee monitors the company's internal controls through continuous feedback and maintains regular contact with the external auditors. Business and control processes will be subject to further documentation and evaluation in 2019, through self-assessment and external appraisal.

The AGM 2018 resolved that the Chairman of the Audit Committee would receive a fee of SEK 40,000 and that other members should each receive SEK 20,000.

#### **Remuneration Committee**

Ann-Christine Sundell is Chairman of the Remuneration Committee, and Carl Borrebaeck is a member of the Remuneration Committee. Its primary duty is to consult on salary, other benefits and employment terms for the Chief Executive Officer and other senior executives, as well as incentive schemes for each group. The Remuneration Committee should ensure compliance with the established guidelines for remunerating senior executives.

Minutes are taken at all Remuneration Committee meetings and distributed to all Directors. The Committee also provides regular reports to the Board on its work through the Chairman of the Committee verbally reporting at the following Board meeting.

The AGM 2018 resolved that the Chairman of the Remuneration Committee would receive a fee of SEK 40,000 and that other members should each receive SEK 20,000.

#### **Auditors**

The AGM 2018 appointed audit firm Mazars Set Revisionsbyrå AB as auditor, with Authorized Public Accountant Mats-Åke Andersson as Auditor in Charge. In addition to auditing, the company has appointed Mazars Set Revisionsbyrå AB for guidance related to the audit on accounting issues. Information on remuneration to the auditing company is provided in Note 9.

#### **CEO** and management

The CEO was appointed by the Board and has the primary responsibility for the company's ongoing administration and daily operations. The segregation of duties between the Board and CEO is stated in the Rules of Procedure of the Board of Directors and instructions for the CEO. The CEO and group manage-

# **Board of Directors**



CARL BORREBAECK (1948), Chairman of the Board since 2007.

**Education/background:** Professor Carl Borrebaeck is the founder of Immunovia AB (publ). He was a co-founder of Senzagen AB (publ), BioInvent International AB (publ) and Alligator BioScience AB (publ). Nominated as Biotech Builder of the Year for his entrepreneurship in 2017. He is a life member of the IVA (Royal Swedish Academy of Engineering Sciences), a Director of CREATE Health—the Strategic Division of Translational Cancer Research (TCR) and former Deputy Vice Chancellor of Lund University (heading up its innovation systems and industrial partnerships), and Head of the Immunotechnology Department. He is also a Founding Mentor of NOME (Nordic Mentor Network for Entrepreneurship).

**Current assignments:** Chairman of SenzaGen AB and CB Ocean Capital AB. Director of Alligator Bioscience AB, Pain Drainer AB, Qlycore AB and Scandion A/S. Managing partner of Immunova Handelsbolag.

**Previous assignments (past five years):** Chairman of LU Innovation System AB. Director of Atlas Therapeutics AB, BioInvent International Aktiebolag, LU Holding AB, Medicon Village Fastighets AB, Clinical Laserthermia Systems AB and Wntresearch AB. Deputy Director of Endo Medical AB.

Holdings in the company as of Dec 31, 2018: 1,709,900 shares and 0 share warrants.



#### ANN-CHRISTINE SUNDELL (1964), Director since 2017.

**Education/background:** Ann-Christine Sundell holds an M.Sc. in biochemistry and has over 30 years' experience of global commercial positions in the diagnostics sector. She was EVP of Genetic Screening at PerkinElmer, one of the world's largest life science companies, for ten years, where she led one of the company's five strategic business areas with over 1,500 employees worldwide. She has rigorous strategic and operational experience in all segments significant to Immunovia Including Sales & Marketing, R&D, Production, Quality and regulatory issues.

**Current assignments:** Chairman of Medix Biochemica Group Oy and Serres Oy. Director of Revenio Group Oyj, Raisio Oyj, Ledil Group Oy, Ledil Oy, Blueprint Genetics Oy and Biocartis Group NV. Member of the Remuneration Committee of Raisio Oyj and Biocartis Group NV. Delegation member of Raisio Oyj's research foundation and shareholder of AConsult.

**Previous assignments (past five years):** Chairman of Oy Medix Biochemica Ab. Director of Minervastiftelsen, Oy Medix Ab, Vanadis Ab and Zymonostics ApS.

Holdings in the company as of Dec 31, 2018: 0 shares or share warrants.



#### HANS JOHANSSON (1954), Director since 2017.

**Education/background:** Hans Johansson holds an M.Sc. (Eng.) in chemical engineering and has long-term experience and a broad-based contact network from previous roles in the life science and diagnostic industries, most recently as Vice President of Companion Diagnostics in Thermo Fisher's Specialty Diagnostics Group. Prior to that, his positions included serving as Global VP and Head of Marketing & Commercial Development for Thermo Fisher's ImmunoDiagnostics Division and VP of Pharmacia Biotechnology AB's Laboratory business area. He has also served as the President, Director and entrepreneur of various start-ups in the sector. He has over 30 years' experience of global business development and commercialization of biotech and diagnostic innovations

**Current assignments:** Chairman of Doloradix AB and Myrtila AB. Director of Single Technologies AB and Uppsala Innovation Centre AB.

Previous assignments (past five years): Deputy Director of Duvbo affärskonsult AB.

Holdings in the company as of Dec 31, 2018: 23,460 shares and 0 share warrants.



#### CHRISTOFER SJÖGREN (1966), Director since 2018.

**Education/background:** Christofer Sjögren has 15 years of experience from the finance industry as equity analysts at companies such as Carnegie, Danske Bank (publ) and Deutsche Bank (publ) based in Stockholm. He has also been an Investor Relations consultant at Citigate Stockholm (previously part of Huntsworth plc), and was Vice President of Trelleborg AB (publ) for seven years, and head of Trelleborg Investor Relations.

**Previous assignments (past five years):** Director of Trelleborg Treasury AB. Deputy Director of Duvbo affärskonsult AB.

 $\textbf{Holdings in the company as of Dec 31, 2018: } 37{,}332 \text{ shares or share warrants.}$ 



#### **ÅSA HEDIN** (1962), Director since 2015.

**Education/background:** Åsa Hedin holds an M.Sc. (Eng.) in biophysics from the University of Minnesota and a B.Sc. in physics from Gustavus Adolphus College. She also holds a Pro Board Work Diploma, M Berglund Roard value

Current assignments: Director of CellaVision AB, C-Rad AB, E. Öhman J:or Fonder AB, Fingerprint Cards AB, HerMed Group Holding AB, Nolato Aktiebolag and Tobii AB.

**Previous assignments (past five years):** Chairman of Elekta Oy. Director of Sensavis AB, Fingerprint Cards AB and Svenska rymdaktiebolaget. Director and President of Elekta Instrument AB.

Holdings in the company as of Dec 31, 2018: 4,600 shares and 0 share warrants.



MIMMI EKBERG (1959), Director since 2018.

**Education/background:** Mimmi Ekberg has about 30 years' experience from the pharmaceutical industry and 25 years' experience within oncology. She has had various positions at both national and Nordic level with experience of successfully launching specialist pharmaceutical. She has extensive strategic and operational experience in Sales & Marketing in the field of oncology. She has over 10 years experience as business area manager from E. Merck, Amgen and today serves as business area manager at Oncology Nordic on Celgene, with focus on pancreatic cancer. She is a trained nurse with an academic background within medical oncology from Lund University, clinical trials at Karolinska University Hospital's oncology department and an Executive MBA from Stockholm University.

**Previous assignments (past five years):** Founder and Director of Anhörigfonden. **Holdings in the company as of Dec 31, 2018:** 0 shares or share warrants.

ment are also responsible for preparing reports and compiling information for group management for Board meetings and present this material at Board meetings. The CEO is responsible for the company's financial reporting, and accordingly, should ensure that the Board gathers sufficient information to enable continuous evaluation the company's financial position. Accordingly, and jointly with the rest of group management, the CEO is responsible for compliance with the group's overall strategy, financial and business controls, capital structure, risk management and acquisitions. This includes preparing financial statements and communication with the capital markets.

In 2018, the CEO and six people in the management team made up group management.

#### Remuneration of group management

Total compensation and other benefits granted directly or indirectly by the company to members of group management are stated in note 10. The company has not issued any loans to members of group management.

## Board of Directors' proposed guidelines for remunerating senior executives

The AGM on May 3, 2018 adopted the following guidelines for remunerating senior executives:

Remuneration of senior executives of the company should consist of basic salary, potential variable compensation, other customary benefits and pensions. Total annual remuneration should be on market terms and competitive on the labour market where the executive is stationed, and consider individual qualifications and experience, as well as reflecting exceptional performance in overall compensation.

Basic salary should be subject to annual review. Senior executives means the CEO and other members of the company's management.

Basic salary and variable compensation should relate to the executive's responsibilities and authority. Variable compensation should be payable in cash and/ or in shares/share warrants/convertible instruments or other share-based instruments such as synthetic options or staff stock options and based on outcomes in relation to established targets, and structured to promote shared interests between the executive and the company's shareholders. The vesting period or period from entering an agreement until a share may be acquired should not be less than three years. Variable cash compensation should not exceed basic salary. The terms and conditions governing variable compensation should be structured so that in especially severe financial conditions, the Board is able to limit or refrain from paying variable compensation if such payment is considered unreasonable and irreconcilable with the company's other responsibilities to shareholders. The annual bonus should have a capability for limitation or refraining from paying variable compensation if the Board considers that this is justified for other reasons.

If a Director renders services on behalf of the company in addition to service on the Board, consulting fees and other compensation for such work should be payable subsequent to a special decision by the Board.

As far as possible, pension benefits should be defined contribution. The CEO and other senior executives should have maximum notice periods of 18 months. Basic salary during the notice period and severance pay should not exceed an aggregate maximum amount corresponding to two years' basic salary.

## Management



MATS GRAHN (1962), Chief Executive Officer since 2013.

**Education/background:** Mats Grahn holds an M.Sc. (Eng.) in engineering physics from Lund University. He has over 25 years' experience of executive positions in the life science and diagnostic sectors, as well as extensive knowledge of business development, strategic development, marketing, product management, product development and accessing markets. He has headed up multinational and commercial operational organizations, restructured marketing organizations, integrated acquired companies and managed new start-ups. Much of his experience has been gathered from the leadership of multinational management teams and organizations in Scandinavia, Europe, the USA and Asia. Previous positions include: CVP of Marketing for Dako A/S, VP of Product Management for GE Healthcare, VP of Marketing for Amersham Biosciences, VP of Laboratory Separations for Pharmacia Biotech and VP of Prevas Bioinformatics.

Current assignments: Chairman & President of Gusmo AB. Deputy Director of Utas Glassmakeri AB.

**Previous assignments (past five years):** Chairman of Alligator Bioscience AB, Atlas Therapeutics AB and Bmatrix AB. Executive positions with Spiber Technologies AB and Biocrine AB.

**Holdings in the company as of Dec 31, 2018:** 413,039 shares and 2,000 share warrants, conferring entitlement to subscribe for 2,000 new shares.



**Education/background:** Rolf Ehrnström holds an M.Sc. (Eng.) in biochemistry and biotechnology from the Royal Institute of Technology, Stockholm. He is the proprietor of Reomics AB and an Independent Partner of Ventac-Partners. He has long-term experience of managing research and has served as Chief Scientific Officer of Dako/Agilent and Gyros AB. He also has experience as Science Director of Amersham Bioscience and Pharmacia Biotech.

Current assignments: Director of Reomics AB and Fluimedix A/S Danmark. Member of the Nomination Committee of Idogen AB.

Previous assignments (past five years): Director of Biomonitor A/S.

**Holdings in the company as of Dec 31, 2018:** 60,750 shares and 2,000 share warrants, conferring entitlement to subscribe for 2,000 new shares.



#### HANS LILJENBORG (1958). CFO since 2013.

**Education/background:** Hans Liljenborg is a graduate of specialist education in business administration and mathematics from Lund University. He has long-term experience as a Finance Director of growing, global medical device companies. He has served as Finance Director of Physio Control Inc./Jolife AB and Finance Manager of Vivoline Medical AB, which was listed on Nasdaq First North in March 2015. He is also proprietor of his own accounting firm.

**Current assignments:** Director of ADAYS AB. Deputy Director of Entreprenörskompetens i Lund AB, Gantus Training AB and IES Interactive Executive Search AB. Auditor of cooperative Byns Förskola Ekonomisk förening. Partner of Prosperus.

Previous assignments (past five years): Executive positions with E-vård MinDoktor.se Sverige AB, Jolife AB, Quick-Cool AB and Vivoline Medical AB. Auditor of Bostadsrättsföreningen Långgårdsgatan 17 and Solbacka Trading. Holdings in the company as of Dec 31, 2018: Personally and through companies, 2,040 shares and 52,000 share warrants, conferring entitlement to subscribe for 52,000 new shares.



#### LAURA CHIRICA (1968), CCO since 2015.

Education/background: Laura Chirica holds an M.Sc. in biochemistry from Umeå University and a Ph.D. in biochemistry from Umeå University. With over 15 years' experience of business executive positions in the life science and diagnostics sectors, she brings extensive knowledge of business, organizational and strategic development, as well as sales, tactical marketing, product management and product support. She has led and restructured multinational sales and marketing organizations, managed business development, the integration of acquired companies, and developed brands and marketing communication platforms. Much of her experience has been gathered from leadership of multinational management teams and organizations in Scandinavia, Europe, the US and Asia. Previous positions include: VP of Sales and Marketing for Euro Diagnostica AB, Director of Purification Technologies for Europe Sartorius Stedim, Global Marketing Director of Dako A/S and Global Marketing Program Manager of GE Healthcare.

Current assignments: Director of SenzaGen AB.

**Previous assignments (past five years):** Executive positions with Euro-Diagnostica AB. **Holdings in the company as of Dec 31, 2018:** 32,000 shares and 0 share warrants.



#### HENRIK WINTHER (1966), Senior Vice President of Business Development since 2017.

**Education/background:** Henrik Winther holds a DVM and Ph.D. in cellular biology and histology from Copenhagen University. He has been at the leading edge of companion diagnostics for over ten years, and brings experience of research & development, business development, regulatory issues, production and commercialization of IVD products. From 2006, he was R&D manager of Dako A/S, as well as Design Manager of HercepTest CDx. He was then Head of Dako Business Development and was involved in the acquisition of Dako by Agilent Technologies. Previous positions include serving as Vice President and General Manager of Agilent Technologies in Santa Barbara, US, and Head of the R&D function of the Companion Diagnostics Division. He was previously an associate professor of cellular biology but has been focusing on cancer diagnostics for the past 17 years.

Current assignments: Director of Saga Diagnostics AB.

Previous assignments (past five years): Executive positions with Agilent Technologies and Dako A/S. Holdings in the company as of Dec 31, 2018: 0 shares and 50,000 share warrants, conferring entitlement to subscribe for 50,000 new shares.





LINDA MELLBY (1979), VP Research & Development since 2013.

**Education/background:** Linda Mellby holds an M.Sc. in chemical engineering and a Ph.D. in immunotechnology from the Institution of Immunotechnology at Lund University. She has over ten years' experience of Immunovia's platforms, microarray technologies for recombinant antibodies and in-depth knowledge of the characteristics, technology development and clinical applications of the platform within oncoproteomics and autoimmunity. She has been one of the key researchers dealing with the development of Immunovia's microarray platform for disease proteomics, and has conducted extensive work on process optimization, standardization and clinical studies.

Current assignments: None.

Previous assignments (past five years): None.

Holdings in the company as of Dec 31, 2018: 32,626 shares and 0 share warrants.



LOTTA BLOMGREN (1960), Operations Director since 2016.

**Education/background:** Lotta Blomgren holds an M.Sc. in chemical engineering from Lund University Faculty of Engineering and has over 30 years' experience of the life science and diagnostic industries, 15 of which in executive positions. She brings experience as a manager of production, quality control and logistics teams, as well as project management in the transfer of new products from development to production scale. Her experience includes managing staff and project portfolios in strategic reorganization processes of international production networks, due diligence for potential acquisitions of new businesses and contract manufacturing organizations. Previous positions include VP of Technical Operations for Euro Diagnostica AB, Head of Supply Chain for Bioglan AB, Product & Technology Support Director for Ferring A/S, Head of Process Development for Ferring AB, multifunctional roles within process development and project management with Astra AB, Kabi Pharmacia AB and ACO AB. **Current assignments:** None.

**Previous assignments (past five years):** Executive positions with Bioglan AB and EuroDiagnostica AB. **Holdings in the company as of Dec 31, 2018:** 510 shares and 32,000 share warrants, conferring entitlement to subscribe for 32,000 new shares.

The company's Board of Directors should endeavor for the Group's subsidiaries to apply these principles.

The Board should be entitled to depart from the above guidelines if the Board considers that there are special reasons justifying this in an individual case.

Questions regarding salary and other compensation to the CEO are subject to consultation by the Remuneration Committee, and decided by the Board. Questions regarding salary and other compensation to other senior executives are consulted and decided by the CEO.

#### Internal audit

The group has straightforward legal and operational structure, and established governance and internal control systems. Against this background, the Board has decided not to create a dedicated internal audit.

## The Board's report on internal controls over financial reporting

The Board's responsibility for internal control and governance is regulated by the Swedish Companies Act and the Swedish Annual Accounts Act, and the

Code is also applied. Immunovia endeavours to manage its operations as effectively as possible. Financial reporting should be reliable and reflect the company's operations accurately, and be prepared in accordance with applicable laws and ordinances. The Board determines which reports should be produced for the Board to be able to monitor the company's progress. Initially, the quality of financial reporting to the Board is evaluated by the Audit Committee.

#### Internal controls and control environment

The Board of Directors' responsibility for internal controls is regulated by the Swedish Companies Act and the Swedish Annual Accounts Act, which stipulates that information on the most important elements of the company's systems for internal controls and risk management relating to financial reporting should be included in the Corporate Governance Report, as well as the code. The Board's duties include ensuring that the company has good internal controls and formal procedures that ensure compliance with established principles for financial reporting and internal controls, and that expedient systems

for monitoring and controlling the company's operations and the risks the company and its operations are associated with, are in place. Decision-paths, authorizations and responsibilities being clearly defined and communicated between different levels of the organisation, as well as control documentation such as policies and guidelines covering all material segments, and providing guidance to different executives within the group, is an important component of the control environment.

One significant part of the Board's work is to formulate and approve a number of fundamental policies, guidelines and frameworks. These include the Board's Rules of Procedure, the Instructions for the CEO, Corporate Communication and Finance Policies. The purposes of these policies include providing a foundation for good internal controls. All policies are subject to annual review and approval by management or the Board. Additionally, the Board should endeavor for its organizational culture to provide clearly defined roles, responsibilities and processes that favor efficient management of the operation's risks, and enable targets to be achieved.

The overall purpose of internal controls is to ensure that the company is following up on its operational strategies and goals, and its owners' investments are protected. Additionally, internal controls should ensure that there is reasonable assurance that financial reporting is reliable and prepared consistently with generally accepted accounting practice, compliant with applicable laws and ordinances and the standards applying to listed companies.

#### Financial reporting

The Board bears overall responsibility for internal controls over financial reporting. With the aim of creating and maintaining a functional control environment, the Board has adopted a number of policies and control documents that regulate financial reporting. They mainly consist of the Board's Rules of Procedure, Instructions for the CEO and instructions for financial reporting. The Board has also adopted a dedicated approvals list and Finance Policy. The company has an accounting handbook stating the principles, guidelines and process definitions for accounting and financial reporting. Additionally, the Board has established an Audit Committee whose primary duty is to ensure compliance with established principles for financial reporting and internal controls, and for main-

taining regular contact with the company's auditors. Responsibility for maintaining an effective control environment and ongoing work on internal controls over financial reporting has been delegated to the company's CEO. The CEO provides regular reports to the Board pursuant to the established instructions for the CEO, and instructions for financial reporting. The Board also receives reports from the company's auditor. Based on a control environment perceived as effective and external examination by auditors, the Board judges that there are no special circumstances in the operation, or other conditions, that would justify establishing an internal audit function.

#### Risk assessment

The risk assessment includes identifying risks that may arise if the fundamental standards apply to the company's financial reporting are not satisfied. The company's management has identified and evaluated the risks that are relevant to the company's operations and evaluated how these risks can be managed in a dedicated risk assessment document. Within the Board, the Audit Committee bears primary responsibility for continuously evaluating the company's risk situation, with the Board conducting an annual review of the risk situation subsequently.

#### **Control activities**

Control activities limit identified risks and ensure accurate and reliable financial reporting. The Board is responsible for internal controls and monitoring management. This is conducted through internal and external control activities, and by examining and following up on the company's control documents related to risk management.

#### Information and communication

The company has information and communication pathways intended to promote the accuracy of financial reporting and enable reporting and feedback from operations to the Board and management, through means including making control documents in the form of internal policies, guidelines and instructions for financial reporting available and familiar to the affected staff. The Board has also adopted a Corporate Communication Policy that formalizes the company's communication through financial information in the form of interim reports, financial statements, annual accounts and press releases in tandem with significant

events that may be share price sensitive. Corporate communication complies with the standards stated in Nasdaq Stockholm's Rulebook for Issuers. The Board reviews external financial reports prior to publication. The Corporate Communication Policy also stipulates how communication can be affected, and which parties may represent the company. Information distributed through press releases is also available on the company's website, as is other information considered valuable.

#### Monitoring

The compliance with, and effectiveness of, internal controls are subject to regular monitoring. The CEO insures that the Board receives regular reports on the progress of the company's operations, including the process of the company's results of operations and financial position, and information on important events, such as research outcomes and important agreements. The CEO also reports these issues at each Board meeting.

# The auditor's examination of the corporate governance statement

To the general meeting of shareholders of Immunovia AB (publ), corporate ID no. 556730-4299

#### Assignment and segregation of duties

The Board of Directors is responsible for that the corporate governance statement for 2018 on pages 26-38 has been prepared in accordance with the Annual Accounts Act.

#### Orientation and scope of review

Our examination of the corporate governance statement is conducted in accordance with FAR's auditing standard RevU 16 *The auditor's examination of the corporate governance statement*. This means that our examination of the corporate governance statement is different and substantially less in scope than an audit conducted in accordance with International Standards on Auditing and generally accepted auditing standards in Sweden. We believe that the examination has provided us with sufficient basis for our opinions.

#### **Opinion**

A corporate governance statement has been prepared. Disclosures in accordance with chapter 6 section 6 the second paragraph points 2-6 of the Annual Accounts Act and chapter 7 section 31 the second paragraph the same law are consistent with the annual accounts and consolidated accounts and are in accordance with the Annual Accounts Act.

Lund, March 3, 2019

Mazars SET Revisionsbyrå AB

Mats-Åke Andersson

Authorized Public Accountant

# **Statutory Administration Report**

The Board of Directors and Chief Executive Officer of Immunovia AB (publ), corporate identity number 556730-4299, hereby present the Annual Accounts and Consolidated Accounts for the financial year 2018.

Unless otherwise stated, this information is for the Group. Information in brackets is for the previous year. Amounts are in Swedish kronor (SEK) unless otherwise stated. Rounding errors may occur.

Essentially, the parent company's operations in the period were the same as the Group's. Accordingly, comments on the progress of the Group also apply to the parent company.

#### **Operations**

Immunovia AB conducts the development of new and improved methods for diagnosing complex diseases in cancer and autoimmunity. Operations are mainly conducted in the parent company Immunovia AB, and accordingly, the following comments apply to the group and parent company.

## Progress of operations and significant events in the financial year

We worked on a goal-oriented footing in 2018 to bring our patented, blood-based pancreatic cancer test I M-D to the market. The main activities focused on prospective clinical studies, certification, accreditation and scaling up production capacity, both of the product itself and laboratory capacity. Immunovia Inc., with its office and proprietary reference laboratory, was incorporated in the Boston region. The consistent aim is to commence sales in 2020.

In 2018, trading in the company's shares were transfered from Nasdaq First North to Nasdaq Stockholm's main list.

## Prospective clinical trials paving the way for cost reimbursement

In 2018, prospective clinical studies were conducted within all three target groups of IMMray™ PanCan –d usage as planned. These studies, which we have designated PanDIA-1, PanFAM-1 and PanSYM-1, are designed to validate our blood-based test IMMray™ PanCan –d so it satisfies the criteria of health insurance systems' reimbursement programs, as well as national guidelines. PanDIA-1, our prospective study for the diabetes risk group, focuses on patients

recently diagnosed with type 2 diabetes aged over 50 (NOD), which is one of the biggest risk groups for pancreatic cancer.

We started PanDIA-1, the world's most extensive prospective study on this risk group in December, through a consortium including Lund and Uppsala Universities, the LUDC, and the Scania and Uppsala regional health authorities. This consortium has received a SEK 7.6 m grant from Swedish government innovation program Swelife, in the Improved Diagnostics and Treatment of Diabetes-related Comorbidities project. Through this project, Immunovia will get access to up to 6,000 diabetes patients aged over 50, for prospective testing with IMMray™ PanCan −d.

PanSYM-1, our prospective study for the early symptom risk group, began with gathering tests in a pilot study in collaboration with University College London Hospital. This study is led by Professor Steve Pereira, one of the world's key opinion leaders in the segment. This pilot study is enrolling a minimum of 360 patients, and results are expected as early as in 2018, and given positive results, PanSYM-1 will be expanded. Work also continued with our prospective study for the familial and hereditary risk group, PanFAM-1.

We continued our work on enrolling additional cancer centers in the USA and EU. In December, we were able to announce that Sahlgrenska University Hospital in Gothenburg had become a contributor to the trial as the first cancer center in this group, and the University of Pittsburgh, one of the most respected pancreatic cancer institutions in the US, also joined.

By participating, they will be contributing patient data improving the study's breath and legitimacy. The breadth of this collaboration not only confers advantages to the study itself but is also an important long-term market investment because the clinics participating in this study are also important potential customers in the commercial phase. Other US partners collaborating in the study are Mount Sinai in New York, the Knight Cancer Institute at Oregon Health & Sciences University, and the University of Michigan. In Europe, IRYCIS in Madrid and the University of Liverpool in the UK are also contributors.

#### Continued preparations for sales in 2020

To start sales in 2020, we worked intensively on industrializing I M-D in 2018, work that will conclude in 2019. This primarily involves development and

documentation work, as well as all the preparations for ISO 13485 certification of the development and production process, ISO 17025 accreditation of the clinical laboratory in Lund, CLIA/CAP accreditation of the US laboratories, and CE-labelling of the product. Regulatory authorities in the USA and EU are updating these standards continuously, and we have obviously been monitoring this progress, adapting to news as it emerges. Preparations for a market launch also involve us scaling up production and laboratory processes with retained robustness and reproducibility. Even if much of the necessary validation work that is now ongoing remains to be done, we expect to be complete in early-2020. This will put the company in a position to generate its first sales revenues.

IMMray<sup>™</sup> enjoys substantial potential in autoimmunity In the long term, Immunovia sees great potential in developing tests for other unsolved problems in cancer and autoimmunity based on its IMMray<sup>™</sup> technology platform. Next up for us is tests for SLE and RA, based on the very positive results announced in 2017-2018. Our goal is to develop the next generation of diagnostics of autoimmune diseases based on the IMMray<sup>™</sup> platform.

# Transferring to Nasdaq Stockholm's main list In 2018, Nasdaq Stockholm's Corporate Committee

approved Immunovia's application for admission to transfer trading of the Company's shares to the regulated market Nasdaq Stockholm.

The first day of trading on Nasdaq Stockholm was April 3, 2018. The shares are still traded under the same ticker (IMMNOV) and ISIN code (SE0006091997). The shares are now traded on Nasdaq Stockholm's Mid Cap segment.

#### **Share issues**

In June 2018, a directed share issue was carried out, which provided the company with around SEK 324 million before issue costs by issuing 2,162,794 shares. Furthermore, a new share issue was carried out by utilizing 50,500 warrants, which added SEK 1.6 million to the company.

#### Risks and uncertainty factors

Operational risks

Immunovia's operations and market are subject to a number of risks that are wholly or partly outside the company's control, and effect, or may affect, Immunovia's operations, financial position and results of operations. The following risk factors have been reviewed without any internal order of priority, and without any claim as to completeness:

- Immunovia is a development enterprise with a fairly short operational history, which means there may be a delay before the company is able to report sales revenues.
- The company is in a commercialization phase, which involves risks that sales revenues are lower than expected, or do not appear at all.
- Validation studies may generate unforeseen or negative research outcomes.
- Development expenses are difficult to estimate in advance. These expenses may be higher than planned.
- The company is dependent on collaborative and license agreements, and there is a risk that the company is unable to enter collaborations.
- There is a risk that Immunovia does not obtain the registrations necessary to sell and market its products.
- There is a risk that the company does not obtain accreditation pursuant to ISO 17025.
- Immunovia is subject to several government regulations that may be reformed.
- There is a risk that Immunovia is unable to defend granted patents, registered brands and other intellectual property, or registration applications filed are not granted.

#### Financial risks

For a review of the financial risks, please refer to note 3.

#### **Human resources**

The Group had an average of 39 (30) employees in the period, and at the end of the period, there were 45 employees.

#### **Incentive schemes**

Detailed information on the company's outstanding share warrant programs is in note 9 below.

#### Sustainability and Environmental impact

Immunovia does not conduct any operations that are hazardous to the environment that require permits or notification pursuant to the Swedish Environmental Code. Please refer to Sustainability Report on pages 20-25.

#### Dividend

The Board of Directors is proposing that no dividend is paid for the financial year 2018.

#### Post balance sheet events

As Immunovia previously announced in August 2018, the combination of retrospective samples from different biobanks, with varying sample collection procedures and storage time, introduced unforeseen variability in the test algorithm performance. The distorting effect caused by the variability in blood sampling procedures was eliminated by consistent and optimal protocols. It is now concluded that for optimal performance of the test, the samples should be collected within 24 months to avoid potential storage distortions. The steps to acquire these freshly collected samples for the optimization work has pushed out the previously communicated timeline to complete the optimization work by about 8 weeks, which will impact the commencement of sales accordingly. Acquiring the sample collection is a significant improvement for the optimization process and is deemed as an important and positive step towards commercialization.

#### **Prospects for 2019**

Immunovia is focused on fundamentally transforming the diagnosis of complex forms of cancer and auto-immune diseases. The antibody-based platform IMMray™ is the result of 15 years' research at CREATE Health−Strategic Division of Translational Cancer Research (TCR) at Lund University.

IMMray™ is a technology platform for developing diagnostic tests, and the company's primary test I M-D is the world's first for early diagnosis of pancreatic cancer.

Introduction of IMMray™ PanCan –d on the US and European market is planned for self-pay customers, including private individuals and healthcare organizations, commencing when accreditation and upscaling production is completed, and revenues are expected in 2020. Immunovia will address a total market of SEK 37 billion in the coming years.

Immunovia sees high potential in developing tests for other unsolved problems in cancer and autoimmunity using its IMMray™ technology platform. Retrospective studies to develop tests in Rheumatoid Arthritis (RA) are next on the company's agenda, based on the positive results announced in early 2017.

Group financial summary				
	2018	2017	2016	2015
Net sales (SEK 000) Profit/loss after financial items (SEK 000)	333	149	177	205
	-86,531	-45,232	-14,723	-7,384
Total assets (SEK 000)	477,383	250,770	283,409	91,509
Equity/assets ratio (%)	97	94	98	92

Parent company financial summary					
	2018	2017	2016	2015	2014
Net sales (SEK 000) Profit/loss after financial items (SEK 000) Total assets (SEK 000)	333 -66,334 497,951	149 -45,232 250,665	177 -14,723 283,409	205 -7,384 91,509	359 -8,859 38,874
Equity/assets ratio (%)	97	94	98	92	92

#### Proposed appropriation of the company's earnings

## The following funds are at the disposal of the Annual General Meeting:

	442,629,518
Net earnings/loss	-66,333,762
Profit brought forward	196,785,781
Share premium reserve	312,177,499

#### The Board proposes that:

Carried forward	442,629,518
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442,629,518

# **Financial statements**



There has been rounding in certain cases, which means that tables and calculations do not always total exactly.

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# **Group key indicators**

		Parent company			
SEK 000 unless otherwise stated	2018	2017	2016	2015	2014
Operating earnings/loss (SEK 000)	-87,709	-45,520	-14,978	-7,424	-8,959
Earnings/loss for the year (SEK 000)	-86,539	-45,232	-14,723	-7,384	-8,859
Basic and diluted earnings per share (SEK)	-4.67	-2.67	-0.98	-0.65	-0.99
R&D expenses (SEK 000)	-26,048	-24,041	-24,293	-16,791	-3,126
R&D expenses as a percentage of operating expenses (%)	23	34	62	69	33
Cash and cash equivalents at end of period (SEK 000)	386,136	192,426	259,094	75,767	31,804
Cash flow from operating activities (SEK 000)	-84,111	-46,318	-11,867	-6,531	-8,290
Cash flow for the period (SEK 000)	193,679	-66,661	183,327	43,962	28,197
Equity (SEK 000)	461,952	236,795	276,631	83,801	35,743
Equity per share (SEK)	23.65	13.67	16.46	5.86	3.24
Equity/assets ratio (%)	97	94	98	92	92
Average number of employees	39	30	16	11	3
Average number of employees in R&D	17	16	11	8	2

The Group was created in 2015 with the formation of the subsidiary Immunovia Inc. During the year, a subsidiary was established in Germany, Immunovia GmbH. In order to illustrate the progress of the business, the Group's key ratios are reported from 2015. The business is mainly conducted in the parent company, which is why the Group's key indicators essentially reflect the parent company's key indicators.

#### Alternative key indicators

Of the above key indicators, only the basic and diluted earnings per share metric is obligatory and defined pursuant to IFRS. Of the other key indicators, earnings/loss for the year, cash and cash equivalents at the end of the period, cash flow from operating activities, cash flow for the period and equity are from an IFRS-defined accounting presentation.

The following table indicates the computation of key indicators partly for the IFRS mandatory key indicators basic and diluted

earnings per share, but also the key indicators R&D expenses, R&D expenses as a percentage of operating expenses, equity per share and equity/assets ratio.

The company's business is to conduct research and development (R&D), which is why R&D costs as a percentage of operating expenses, excluding impairment losses, are a key indicator as a measure of efficiency and how much of the costs in the company are used in R&D.

The company's operations are such that it does not have an even flow of revenue, but this comes irregularly in connection with the signing of license agreements and milestones achieved. Therefore, the company complies with the key indicators of equity/assets and equity per share attributable to the parent company's shareholders to be able to assess the company's financial position and stability. Along with these key figures, the various measures of cash flow that follow from the consolidated cash flow report are also followed.

For definitions, see the Definitions section below.

		Parent company			
SEK 000 unless otherwise stated	2018	2017	2016	2015	2014
Earnings/loss for the year (SEK 000)	-86,539	,	,	-7,384	-8,859
Average number of shares before and after dilution  Basic and diluted earnings per share (SEK)	18,545,795 <b>-4.67</b>	16,932,559 <b>-2.67</b>	14,985,688 <b>-0.98</b>	11,424,799 <b>-0.65</b>	8,992,357 <b>-0.99</b>
Operating expenses (SEK 000)	-113,838	-69,768	-39,481	-24,431	-9,493
Administrative expenses (SEK 000)	-85,012	,		•	-6,108
Depreciation and amortization (SEK 000) <b>R&amp;D expenses (SEK 000)</b>	-2,777 <b>-26,048</b>		-549 <b>-24,293</b>	-288 <b>-16.791</b>	-259 <b>-3,126</b>
R&D expenses as a percentage of operating expenses (%)	23	34	62	69	33
operating expenses (%)					
Equity (SEK 000)	461,952	236,795	276,631	83,801	35,743
Registered number of shares on the reporting date	19,531,353	17,318,059	16,804,059	14,291,216	11,046,216
Equity per share (SEK)	23.65	13.67	16.46	5.86	3.24
Equity (SEK 000)	461,952	236,795	276,631	83,801	35,743
Total assets (SEK 000)	477,383	250,770	283,409	91,509	38,874
Equity/assets ratio (%)	97	94	98	92	92

## **Consolidated Income Statement**

SEK Note	Full year 2018	Full year 2017
Operating income, etc.		
Net sales 5	332,595	148,963
Work performed by the company for its own use and capitalized	25,052,105	24,040,810
Other operating revenues 7	744,156	58,662
Total	26,128,856	24,248,435
Operating expenses		
Other external expenses 8, 9	-65,275,019	-39,113,417
Personnel expenses 10	-45,257,263	-29,137,188
Depreciation of property, plant and equipment	-2,777,310	-1,263,509
Other operating expenses	-528,093	-254,085
Total operating expenses	-113,837,685	-69,768,199
Operating earnings/loss	-87,708,829	-45,519,764
Profit/loss from financial items		
Interest income, etc. 11	1,178,230	297,734
Interest expenses, etc. 12	-697	-10,170
Total financial items	1,177,533	287,564
Profit/loss after financial items	-86,531,296	-45,232,200
Tax on earnings for the year 13	-7,345	0
Earnings/loss for the year	-86,538,641	-45,232,200
Earnings per share (SEK)	-4.67	-2.67
Average number of shares before and after dilution	18,545,795	16,932,559
Number of shares at end of year	19,531,353	17,318,059

# **Consolidated Statement of Comprehensive Income**

SEK	Full year 2018	Full year 2017
Earnings/loss for the year	-86,538,641	-45,232,200
Items that are re-classifiable to profit or loss	0	0
Exchange rate differences, foreign net investments	-592,892	0
Other comprehensive income for the year	-592,892	0
Total comprehensive income for the year	-87,131,533	-45,232,200

## **Comments on the Income Statement**

#### **Operating income**

Net sales for 2018 were SEK 333,000 (149,000). Sales consist mainly of royalties.

#### Operating expenses and earnings/loss

The earnings/loss for the year was SEK –86,539,000 (–45,232,000). The net loss for 2018 is largely due to increased expenses resulting from an expanding organization, start-up of prospective studies and increased marketing activities. Other external expenses and personnel costs increased by a total of SEK 42,282,000 on the previous year and amounted to SEK 110,532,000 in 2018.

#### Research & Development work

The total expenses for R&D in 2018 were SEK 26,048,000 (24,041,000), or 23% (34) of the Group's total operating expenses. The decline in the proportion of R&D work is mainly due to other activities relatively increasing such as costs on the marketing side and the construction of the prospective clininical studies.

# **Consolidated Balance Sheet**

SEK Not	te	Dec 31, 2018	Dec 31, 2017
ASSETS			
Non-current assets			
Intangible assets			
Capitalized development expenditure 1	L4	44,788,273	22,526,986
Patents, licenses and similar rights	15	16,997,897	14,264,418
		61,786,170	36,791,404
Property, plant and equipment			
	16	3,304,283	_
	17	10,714,646	7,210,853
- Learnings	. /	14,018,929	
		14,018,929	7,210,853
Financial assets			
Other non-current receivables 1	18	3,008,460	2,758,947
		3,008,460	2,758,947
Total non-current assets		78,813,559	46,761,204
Current assets			
Current receivables			
Accounts receivables		32,424	_
Other receivables		8,473,123	9,986,095
Prepaid expenses and deferred income	19	3,927,964	1,596,607
		12,433,511	11,582,702
Cash and cash equivalents		386,135,825	192,425,655
Total non-current assets		398,569,336	204,008,357
TOTAL ASSETS		477,382,895	250,769,561
EQUITY AND LIABILITIES			
	21		
Share capital		976,568	865,903
Other paid-up capital		626,347,848	314,170,349
Reserves		-592,892	0
Accumulated earnings or loss incl. earnings/loss for the year		-164,779,424	-78,240,783
Total equity		461,952,099	236,795,468
Current liabilities			
Accounts payable		3,031,178	7,470,195
Other liabilities		1,120,705	1,118,995
Accrued expenses and deferred income	22	11,278,913	5,384,903
Total current liabilities		15,430,796	13,974,093
TOTAL EQUITY AND LIABILITIES		477,382,895	250,769,561

## **Comments on the Balance Sheet**

#### Investments

Purchases of intangible assets totaled SEK 28,230,000 (25,919,000), divided between capitalized expenditure for development SEK 25,052,000 (23,329,000), patents SEK 2,288,000 (2,590,000) and other tangible assets of SEK 890,000 (0). Capitalized expenditure for development was partly funded with decided and paid subsidies, less the carrying amount of the corresponding amounts. Of the year's investment in capitalized expenditure for development SEK 2,791,000 (8,406,000) was covered by subsidies.

During the year, tangible fixed assets were acquired in the form of equipment and improvement expenses on another property for SEK 9,056,000, corresponding SEK 5,366,000 in the same period last year.

Investments in financial assets in the form of deposits of SEK 2,000 were made in 2018 compared to SEK 2,861,000 in 2017.

# **Consolidated Statement of Changes in Equity**

				Accumulated	
	<b>-</b>	Other		earnings or loss	
CELL	Share	paid-up	5	incl. earning/loss	
SEK	capital	capital	Reserves	for the year	Total equity
Opening balance, January 1, 2017	840,203	308,799,079	0	-33,008,584	276,630,698
Comprehensive income for the year				-45,232,200	-45,232,200
Transactions with shareholders in their capacity as owners:					
Deposited share warrant premiums		473,970			473,970
New share issue	25,700	4,897,300			4,923,000
Closing balance, December 31, 2017	865,903	314,170,349	0	-78,240,784	236,795,468
Opening balance, January 1, 2018	865,903	314,170,349	0	-78,240,784	236,795,468
Comprehensive income for the year				-86,538,641	-86,538,641
Transactions with shareholders in their capacity as owners:				, ,	, ,
Deposited share warrant premiums		935,880			935,880
New share issue	110,665	325,927,085			326,037,750
Issue costs		-14,685,466			-14,685,466
Transaction differences			-592,892		-592,892
Closing balance, December 31, 2018	976,568	626,347,848	-592,892	-164,779,425	461,952,099

## Consolidated Cash Flow Statement

SEK	Note	Full year 2018	Full year 2017
Operating activities			
Operating earnings/loss		-87,708,830	-45,519,765
Adjustments for non-cash items	23	2,681,744	1,472,205
Interest received		318,591	297,734
Interest paid		-697	-10,170
Tax paid		-7,345	0
Cash flow from operating activities before changes in working capital		-84,716,537	-43,759,996
Cash flow from changes in working capital			
Decrease (+)/increase(-) in operating receivables		-840,302	-9,757,533
Decrease (-)/increase(+) in operating liabilities		1,445,532	7,199,575
Cash flow from operating activities		-84,111,307	-46,317,954
Investing activities			
Investment in intangible assets		-28,229,724	-25,918,983
Investment in property, plant and equipment		-9,056,576	-5,365,672
Investment in financial assets		-2,009	-2,861,433
Cash flow from investing activities		-37,288,309	-34,146,088
Financing activities			
National and European subsidies of development expenses		2,790,818	8,406,360
Share warrant premiums deposited		935,880	473,970
New share issue		311,352,284	4,923,000
Cash flow from financing activities		315,078,982	13,803,330
Cash flow for the year		193,679,366	-66,660,712
Cash and cash equivalents at beginning of year		192,425,655	259,094,216
Exchange rate difference in cash and cash equivalents		30,804	-7,849
Cash and cash equivalents at end of year	24	386,135,825	192,425,655

## Comments on the Cash Flow Statement

The cash flow from operating activities for 2018 was SEK -84,111,000 (-46,318,000) and the total cash flow was SEK 193,679,000 (-66,661,000). The positive cash flow for the year was generated mainly by a large new share issue that contributed SEK 309,736,000 net to the company. Along with option settlements on the issue of new warrants and a new share issue on the redemption of options, SEK 312,288,000 was added net.

Cash, cash equivalents and financial position Cash and cash equivalents on December 31, 2018 amounted to SEK 386,136,000 (192,426,000). Management judges that there is enough working capital to cover working capital requirements for about 2 years with the current business and development plan.

Equity at the end of the period was SEK 461,952,000 (236,795,000) and the equity/assets ratio was 97% (94). During the year a new share issue was carried out of 2,162,794 shares, which contributed SEK 309,736,000 net to the company. Furthermore, 50,500 shares were newly issued through the redemption of options, which increased the company's equity by SEK 1,616,000.

# **Parent Company Income Statement**

SEK	Note	Full year 2018	Full year 2017
Operating revenue, etc.			
Net sales	6	332,595	148,963
Work performed by the company for its own use and capitalized		25,052,105	24,040,810
Other operating revenues	7	744,156	58,662
Total		26,128,856	24,248,435
Operating expenses			
Other external expenses	8,9	-59,679,001	-44,983,657
Personnel expenses	10	-32,003,245	-23,343,351
Amortization and depreciation of intangible assets and			
property, plant and equipment		-1,996,189	-1,263,509
Other operating expenses		-526,674	-254,085
Total operating expenses		-94,205,109	-69,844,602
Operating earnings/loss		-68,076,253	-45,596,167
Profit/loss from financial items			
Interest income, etc.	11	1,743,188	365,581
Interest expenses, etc.	12	-697	-1,630
Total financial items		1,742,491	363,951
Earnings/loss before tax		-66,333,762	-45,232,216
Tax on earnings for the year	13	0	0
Earnings/loss for the year		-66,333,762	-45,232,216

# Parent Company Statement of Comprehensive Income

Total comprehensive income for the year	-66,333,762	-45,232,216
Other comprehensive income for the year	0	0
Other comprehensive income	0	0
Earnings/loss for the year	-66,333,762	-45,232,216
SEK	Full year 2018	Full year 2017

# **Parent Company Balance Sheet**

ASSETS		
Non-current assets		
Intangible assets		
Capitalized development expenditure 14	44,788,273	22,526,986
Patents, licenses and similar rights 15	16,080,126	14,264,418
	60,868,399	36,791,404
Property, plant and equipment		
Improvements on someone else's property 16	2,300,000	0
Equipment, tools, fixtures and fittings 17	6,688,633	4,596,775
	8,988,633	4,596,775
Financial assets		
Participations in group companies 20	253,480	8
	253,480	8
Total non-current assets	70,110,512	41,388,187
Current assets		
Current receivables		
Accounts receivables	32,424	0
Receivables from group companies	29,983,798	5,618,135
Other receivables	8,464,995	9,909,199
Prepaid expenses and deferred income 19	3,843,166	1,533,342
	42,324,383	17,060,676
Cash and bank balances	385,516,553	192,215,779
Total current assets	427,840,936	209,276,455
TOTAL ASSETS	497,951,448	250,664,642
EQUITY AND LIABILITIES		
Equity 21		
Restricted equity		
Share capital	976,568	865,903
Fund for development expenditure	39,143,785	16,882,498
	40,120,353	17,748,401
Non-restricted equity		
Share premium reserve	312,177,499	4,897,300
Accumulated earnings or loss	196,785,781	259,381,983
Earnings/loss for the year	-66,333,762	-45,232,216
	442,629,518	219,047,067
Total equity	482,749,871	236,795,468
Current liabilities		
Accounts payable	3,007,025	7,406,931
Other liabilities	1,120,705	1,077,340
Accrued expenses and deferred income 22	11,073,847	5,384,903
Total current liabilities	15,201,577	13,869,174
TOTAL EQUITY AND LIABILITIES	497,951,448	250,664,642

# Parent Company Statement of Changes in Equity

	Share	Fund for develop- ment	Share premium	Accumulated earnings	Earnings/loss	
SEK	capital	expenditure	reserve	or loss	for the year	Total equity
Opening balance, January 1,2017	840,203	24,292,671	207,107,022	59,114,024	-14,723,206	276,630,714
Transfer of previous year's earnings/loss			-207,107,022	192,383,816	14,723,206	0
Comprehensive income for the year					-45,232,216	-45,232,216
Capitalized development expenditure for the year Transactions with shareholders in		-7,410,173		7,410,173		0
their capacity as owners:						
Deposited share warrant premiums				473,970		473,970
New share issue	25,700		4,897,300	ŕ		4,923,000
Share issue expenses						0
Closing balance, December 31, 2017	865,903	16,882,498	4,897,300	259,381,983	-45,232,216	236,795,468
Opening balance, January 1, 2018	865,903	16,882,498	4,897,300	259,381,983	-45,232,216	236,795,468
Transfer of previous year's						
earnings/loss			-4,897,300	-40,334,916	45,232,216	0
Comprehensive income for the year			, ,	, ,	-66,333,762	-66,333,762
Capitalized development expenditure for the year		22,261,287		-22,261,287		0
Transactions with shareholders in their capacity as owners:						
Deposited share warrant premiums			935,880			935,880
New share issue	110,665		325,927,085			326,037,750
Share issue expenses			-14,685,466			-14,685,466
Closing balance, December 31, 2018	976,568	39,143,785	312,177,499	196,785,781	-66,333,762	482,749,871

# **Parent Company Cash Flow Statement**

SEK	Note	Full year 2018	Full year 2017
Operating activities			
Operating earnings/loss		-68,076,254	-45,596,166
Adjustments for non-cash items	23	2,230,109	1,263,509
Interest received		305,732	365,581
Interest paid		-627	-1,630
Tax paid		0	0
Cash flow from operating activities before changes in working capital		-65,541,040	-43,968,706
Cash flow from changes in working capital			
Decrease (+)/increase(-) in operating receivables		-23,826,318	-15,229,386
Decrease (-)/increase(+) in operating liabilities		1,332,402	7,090,704
Cash flow from operating activities		-88,034,956	-52,107,388
Investing activities			
Investment in intangible assets		-27,340,487	-25,918,983
Investment in tangible assets		-6,149,294	-2,654,489
Investment in subsidiaries		-253,472	0
Cash flow from investing activities		-33,743,253	-28,573,472
Financing activities			
National and European subsidies of development expenses		2,790,819	8,406,360
Share warrant premiums deposited		935,880	473,970
New share issue		311,352,284	4,923,000
Cash flow from financing activities		315,078,983	13,803,330
Cash flow for the year		193,300,774	-66,877,530
Cash and cash equivalents at beginning of year		192,215,779	259,093,309
Cash and cash equivalents at end of year	24	385,516,553	192,215,779

### **Notes**

#### Note 1

#### **GENERAL INFORMATION**

Immunovia AB, with its registered office in Lund, registered in Sweden with corporate identity number 556730-4299, is the parent company of wholly owned subsidiary in Immunovia Inc., file number 350589-6, with registered office in Wilmington, US and Immunovia GmbH corporate identity number HRB 111 597, with registered office in Frankfurt am Main. These companies are collectively termed the group, or Immunovia. The address is Medicon Village, 223 81 Lund, Sweden. The group was formed in December 2015 through the incorporation of Immunovia Inc.

The Group's operations consist of the development of new and improved methods for diagnosing complex diseases within cancer and autoimmunity.

The Board of Directors approved these Consolidated Accounts for publication on March 1, 2019.

#### Note 2 ACCOUNTING POLICIES

The Consolidated Accounts have been prepared in accordance with the Swedish Annual Accounts Act, RFR 1 Supplementary Accounting Rules for Groups, International Financial Reporting Standards (IFRS) and interpretation statements from the IFRS Interpretations Committee (IFRS IC) as endorsed by the EU.

The parent company's Annual Accounts have been prepared in accordance with the Swedish Annual Accounts Act and RFR 2 Accounting for Legal Entities. This recommendation means that the parent company applies the same accounting policies as a group, apart from in those cases where the Swedish Annual Accounts Act or applicable tax regulation limit the scope to apply IFRS. Differences between the parent company's and group's accounting policies are stated under the parent company's accounting policies below.

#### **Basis of preparation**

The Consolidated Accounts have been prepared in accordance with the cost method. The Balance Sheet items entitled current assets and current liabilities are expected to be recovered and paid within 12 months. All other Balance Sheet items are expected to be recovered or paid later. The group's functional reporting currency is Swedish kronor. The Consolidated Accounts and Annual Accounts are issued in Swedish kronor (SEK) unless otherwise stated.

#### New and revised standards applied by the Group

As of January 1, 2018, IFRS 9 Financial Instruments and IFRS 15 Revenue from agreements with customers are applied.

IFRS 15 is an overall framework for determining whether, to a certain extent, the amount, and at what time, income should be reported. The standard replaces IAS 18 for contracts for goods and services. Immunovia applies IFRS 15

with full retroactive effect, but without any differences being identified, no adjustment has been made to the comparative figures.

IFRS 9 has replaced the parts in IAS 39 that are related to the classification and valuation of financial instruments and have introduced a new impairment model for credit losses. Immunovia currently only has financial assets and liabilities where the business model is to collect, alternatively pay, contractual cash flows. This means that there is no change in the valuation compared to IAS 39, but that the category designation has changed. Immunovia applies the simplified method for calculating credit losses, but since the Group's historical loan losses have been largely non-existent, the changed method has not had any effect on the comparative figures.

Otherwise, no standards to be applied by the Group for the first time from January 1, 2018 have had, or are expected to have any impact on the Group's accounts.

#### New standards and interpretation statements that have not vet been applied by the Group

A number of new standards and interpretation statements come into effect for financial years that begin after 1 January 2017 and have not been applied in the preparation of these annual accounts. The new standards and interpretation statements that may have an effect on the consolidated financial statements is IFRS 16 Leasing agreements.

As of January 1, 2019, IFRS 16 Leasing Agreements replaces the current standard IAS 17 Leasing Agreements. When the standard comes into force, Immunovia will apply the simplified transition method, which means that comparative information in previous periods will not be recalculated. The leasing liability consists of the discounted remaining leasing fees as of January 1, 2019.

The used asset rights amounts to an amount corresponding to the leasing liability. The transition to IFRS 16 does not have any effect on equity.

Immunovia will apply the relief rules regarding leasing agreements where the underlying asset has a low value and short-term lease agreements, which also includes agreements that will be terminated in 2019.

The most significant lease agreements consist of agreements for renting office premises. As a result of the introduction of IFRS 16, the Group's total assets will increase through the inclusion of used asset rights and leasing liabilities. Leasing fees that have been reported under IAS 17 as other external expenses in the income statement are replaced by depreciation on the used asset rights which are reported as a cost in the operating profit/loss and interest on the leasing debt, which is reported as a financial expense. The leasing fee is divided between amortization on the lease liability and payment of interest. Upon the transition to IFRS 16, all remaining leasing fees have been presently valued with Immunovia's marginal loan interest. The average loan interest rate as of January 1, 2019 was 4%.

The used asset rights and liability as of January 1, 2019 has been calculated at 35.8, which includes two option periods. The change will affect the balance sheet and income statement and a number of key figures. Immunovia estimates that for 2019, depreciation will increase by SEK 4.6 million, financial expenses will increase by SEK 1.3 million and profit after tax will decrease by SEK 0.5 million. The equity/assets ratio was adversely affected as of January 1, 2019 and amounted to 90% compared to 97% when applying IAS 17.

No other IFRS or IFRS IC interpretations that have not yet come into force are expected to have any significant impact on the Group.

#### **Consolidated Accounts**

Subsidiaries are all companies over which the group exerts a controlling influence. The group controls a company when it is exposed, or has rights, to variable returns from its holding in the company, and has the possibility to affect returns through its influence in the company. Subsidiaries are included in the Consolidated Accounts effective the date when controlling influence is transferred to the group. They are derecognized from the Consolidated Accounts effective the date the controlling influence ceases.

The Acquisition method is used for recognizing the group's business combinations. The purchase price for the acquisition of a subsidiary consists of the fair value of the assets acquired and liabilities the group takes over from previous owners of the acquired company, and the shares issued by the group. The purchase consideration also includes the fair value of all assets or liabilities that are a consequence of an agreement on a conditional purchase consideration. Identifiable acquired assets and liabilities taken over in a business combination are initially measured at fair value on the acquisition date. Acquisition-related costs are expensed as they arise.

Intra-group transactions, Balance Sheet items and unrealized gains and losses on transactions between group companies are eliminated. The accounting policies for subsidiaries have been amended were applicable to ensure consistent application of the group's policies.

#### Translation of foreign currency

Functional currency and presentation currency Items recognized in the financial statements for the different entities of the group are measured in the currency used in the economic environment where each entity is mainly operational (functional currency). In the Consolidated Accounts, Swedish krona (SEK) is utilized, which is the group's presentation currency.

#### Transactions and balance sheet items

Transactions in foreign currency are translated to the functional currency at the rates of exchange ruling on the transaction date, or the date when these items are restated. Exchange rate gains and losses arising on payment of such transactions and on translation of monetary assets and liabilities in foreign currency at closing day rates, are recognized through profit or loss. The exception is when transactions are hedges that satisfy the conditions of hedge accounting of cash flows, or of net investments, when gains/losses are recognized in other comprehensive income.

Exchange rate gains and exchange rate losses from loans and cash and cash equivalents are recognized in profit or loss as financial income or expenses. All other exchange rate gains and exchange rate losses are recognized net in the other operating income or other operating expenses items in the Income Statement.

#### Group companies

The results of operations and financial positions of all group companies that have different functional currencies than the presentation currency are translated to the group's as follows:

- Assets and liabilities for each balance sheet are translated at closing day rates,
- Revenues and expenses for each income statement are translated at average rates of exchange and
- All exchange rate differences arising are recognized in other comprehensive income.

#### Intangible and tangible fixed assets

Intangible and tangible fixed assets are recognized at cost after deductions for amortization and depreciation. The acquisition cost includes expenditure directly related to the acquisition of the asset. Additional expenditure is added to the asset's carrying amount or recognized as a separate asset, whichever is appropriate, only when it is likely that the future financial benefits associated with the asset will benefit the Group and the asset's acquisition value can be measured reliably. Expenditure for repairs and maintenance are reported as expenses in the income statement during the period in which they arise.

Depreciation and amortization is on a straight-line basis as follows:

Patents 16 years
Improvement to another property 20 years
Licenses 5 years
Equipment, tools, fixtures and fittings 5 years

Development expenditure that increases functionality and value is recognized as an intangible asset when the following criteria are satisfied:

- It is technically and economically viable to complete the asset.
- The intention and conditions exist to sell or use the asset,
- It is likely that the asset will generate revenues or lead to cost savings and
- · Expenditure can be measured satisfactorily.

Directly related expenditure capitalized as a portion of an intangible asset includes expenditure for employees and a reasonable share of indirect expenses. Other development expenses that do not satisfy the above criteria are expensed as they arise. Development expenses that had been previously expensed are not recognized as an asset in the subsequent period.

The residual values and useful lives of assets are tested at each reporting date and restated as required. The residual

life of an asset is impaired to its recoverable amount immediately if the asset's carrying amount exceeds its estimated recoverable amount.

#### **Impairment**

Intangible assets that are not ready for use are not impaired, but rather subject to yearly impairment tests. Assets that are depreciated/amortized are subject to impairment tests whenever events or changed circum-stances indicate that the carrying amount may not be recoverable. Impairment is taken at an amount whereby the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the greater of the asset's fair value less selling expenses and value in use. When measuring value in use, estimated future cash flows are discounted to present value by applying a discount rate before tax that reflects the current market assessment of the time value of money, and the risks associated with the asset. When conducting impairment tests, assets are grouped at the lowest level where there are essentially independent cash flows (cash-generating units). For assets that have been previously impaired, a test of reversal is conducted at each reporting date.

#### **Financial assets**

The group classifies its financial assets in the following categories: financial assets measured at fair value through profit or loss, loan receivables and accounts receivable, as well as saleable financial assets. This classification depends on the purpose for which the financial asset was purchased. Management determines the classification of financial assets on first-time recognition. At present, the group only has financial assets in the loan receivables and accounts receivable category.

Financial assets valued at accrued acquisition cost
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. All financial assets are classified as financial assets that are valued at accrued acquisition cost using the effective interest method.

#### Cash and cash equivalents

In the Balance Sheet and Statement of Cash Flows, cash and cash equivalents include cash, bank balances and other investments in securities, etc. with maturities within three months of the acquisition date.

When acquiring financial assets, expected credit losses are reported continuously during the holding period, normally taking into account credit loss risk within the next 12 months. In the event that the credit risk has increased significantly, it is reserved for the credit losses that are expected to occur during the entire term of the asset. Immunovia applies the simplified method for calculating loan losses based on historical data regarding payment patterns and payment ability of the counterparty. Based on historical data, the expected loan losses are judged to be extremely limited.

#### **Equity**

Share capital

Ordinary shares are classified as share capital.

#### Share issue expenses

Transaction expenses that are directly related to the issue of new ordinary shares or options are recognized net of tax in equity, as a deduction from the issue proceeds.

#### Dividend

Dividends to shareholders are reported as a liability in the financial reports in the period in which the dividend is determined by the company's shareholders.

#### Financial liabilities

Financial liabilities valued at accrued cost

The Group only has financial liabilities that are classified and valued at amortized cost using the effective interest method. Accounting is initially made at fair value, net after transaction costs.

#### Income tax

The recognition of income taxes include current tax and deferred tax. Tax is recognized in the Income Statement, apart from those cases where it relates to items recognized directly in equity. In such cases, tax is also recognized in equity. Deferred tax is recognized pursuant to the balance sheet method on all temporary differences. A temporary difference exists when the book value of an asset or liability differs from its value for tax purposes.

Deferred tax is measured by applying the tax rates that are enacted or substantively enacted on the reporting date, and are expected to apply when the affected tax asset is realized or the tax liability is settled.

Deferred tax assets are recognized to the extent it is likely that future taxable surpluses will exist against which the temporary differences can be utilized.

#### Revenue from contracts with customers

Revenue from contracts with customers is reported when the performance commitment is fulfilled and the control of a product or service is transferred to the customer. This assessment should be viewed from the customer's perspective, taking into account indications such as transfer of ownership and risks, customer acceptance, physical access and the right to invoice. Assessment must also be made if the control is transmitted at a certain time or over time.

Net sales relate in their entirety to royalties, which is reported in accordance with the financial substance of each royalty agreement.

Interest income is recognized as revenue over the term by applying the effective interest method.

#### Recognition of public subsidies

Public subsidies are recognized at fair value providing there is reasonable assurance that the terms associated with the subsidy will be satisfied, and that thereby, the subsidy will be received. Subsidies received to cover expenses are recognized

under the heading other income in the same period as the expenses arise. Subsidies relating to an asset reduce the asset's value in the Balance Sheet.

#### Leasing

Leasing arrangements are classified either as finance or operating leases. Finance leases occur when the economic risks and rewards associated with the leased item are essentially transferred to the lessee. Otherwise, the arrangement is an operating lease. The Group has no material finance leases, and accordingly, all leases are recognized as operating leases, which means that lease payments are allocated on a straight-line basis over the lease term.

#### **Employee benefits**

Liabilities for salaries and benefits and paid absence that is expected to be settled within 12 months of the end of the financial year, are recognized as current liabilities at the amount expected to be paid when the liabilities are settled, excluding discounts.

All the group's pension obligations are in defined contribution plans. In a defined contribution plan, the company pays predetermined fees to an independent pension institution. When these contributions are paid, the company has no further obligations. Benefits such as salary and pensions are recognized as an expense in the period when employees have rendered the services that the compensation relates to.

#### Loan expenses

Loan expenses that are directly attributable to the purchase, construction or production of qualified assets are reported as part of the acquisition value of these assets. Qualified assets are assets that necessarily take a considerable amount of time to complete for the intended use or sale. Capitalization ceases when all activities required to complete the asset for its use or sale have been substantially completed. All other loan expenses are expensed as they arise.

#### Cash flow statement

The cash flow statement has been prepared in accordance with the indirect method, which means that net earnings/losses are restated for transactions that do not involve any payments made or received in the period, and for any revenues and expenses relating to cash flow from investing or financing activities. Cash and cash equivalents include cash and immediately available balances with banks.

#### Parent company accounting policies

The parent company applies the same accounting principles as the Group, apart from the respects stated below. The Parent Company's accounting principles are unchanged compared with the previous year.

#### Participations in subsidiaries

Participations in subsidiaries are recognized at cost after deducting for potential impairment. Cost includes acquisition-related expenses and potential additional

purchase considerations. When there is an indication that participations in subsidiaries are impaired, recoverable amount is measured. If the recoverable amount is lower than the carrying amount, an impairment is taken. Impairment is recognized in the earnings/loss from participations in Group companies' items.

#### Financial instruments

The parent company does not apply IAS 39. The parent company measures financial non-current assets at cost less potential impairment and financial current assets at the lower of cost or market, less selling expenses.

#### Leasing

The parent company reports all lease arrangements as if they were operating leases, which means that lease payments are allocated on a straight-line basis over the lease term.



#### FINANCIAL RISK MANANGEMENT

Through its operations, the Group is exposed to various financial risks such as market risk (extensive currency risk and interest risk in cash flow), credit risk and liquidity risk. The group's overarching risk management policy, which is adopted by the Board of Directors, is intended to minimize unfavorable effects on results of operations and financial position.

#### Market risk

#### Currency risk

The group operates nationally and internationally, which means exposure to fluctuations in various currencies, and then primarily, the USD and EUR. Currency risk arises through future business transactions, and reported assets and liabilities. The scope of the company's operations means that, at present, net exposure in foreign currencies is limited. Accordingly, there is no policy prescribing hedging of this exposure.

If the Swedish krona had depreciated or appreciated by 10%, with all other variables constant, adjusted earnings after tax as of December 31, 2018, would have been SEK 3,481,000 (949,000) lower/higher, mostly as a consequence of gains and losses on the restatement of current receivables and liabilities. The corresponding impact on the parent company would have been SEK 3,490,000 (949,000).

#### Interest risk in cash flow

Interest risk is the risk that the value of financial instruments varies due to fluctuations in market interest rates. At present, the group only has interest-bearing financial assets in the form of bank balances.

On the basis of the financial interest-bearing assets and liabilities that accrue variable interest as of December 31,

2018, a one percentage point change in market interest rates would affect the Group's earnings by SEK 3,891,000 (1,952,000) For the parent company, the corresponding effect would be SEK3,855,000 (1,922,000).

#### Credit risk

Credit risk is the risk that a party in a transaction with a financial instrument is unable to fulfil its obligations. The maximum exposure for credit risks in financial assets as of December 31, 2018 is SEK 397,902,000 (203,419,000). The corresponding figure for the parent company was SEK 392,343,000 (200,374,000).

#### Liquidity risk

Prudence in the management of liquidity risk means holding sufficient cash and cash equivalents or contracted credit facilities to be able to close market positions. Based on the current business plan, liquidity would be sufficient for some 2 years. The maturity structure of the group's financial liabilities is stated below.

## Financial liabilities as of 31 December 2018 become due for payment:

SEK 000	Within 3 mth.		Between 1 yr. and 2 yr.		Later than 5 yr.
Accounts payable Accrued expenses	3,031 5,120	0	0	0	0 0
Total	8,151	0	0	0	0

#### Managing capital risk

The group's goal in terms of capital structure, defined as equity, is to secure the company's ability to continue its operations to enable it to generate returns to shareholders and benefits to other stakeholders, and that its capital structure is optimal considering the cost of capital. Dividends to shareholders, redemption of shares, issuance of new shares or sales of assets are examples of actions the company could use to adjust its capital structure.

The group's debt/equity ratio	
	2018
Total interest- bearing assets (SEK 000))	0
Less interest-bearing assets (SEK 000)	386,136
Net debt (SEK 000)	-386,136
Total equity (SEK 000)	461,952
Net debt/equity ratio (%)	-84

#### Net debt

Interest-bearing liabilities less interest-bearing assets (including cash and cash equivalents).

Net debt/equity ratio
Net debt in relation to equity.



The most important assumptions regarding the future and other sources of uncertainty in estimates as of the report ing date, which involve significant risk of material restatements in the carrying amounts of assets and liabilities inthe following financial years are stated below. The greatest uncertainty is within intangible assets. Intangible assets have not yet started amortization, and accordingly, are subject to annual impairment tests.

Impairment tests are based on a review of recoverable amount, which is estimated on the basis of the value in use of assets. Management makes estimates of future cash flows in accordance with internal business plans and forecasts. Estimates of the discount rate and future growth rates beyond the determined budgets and forecasts are used in this review. The carrying amount of intangible assets is SEK 61,786,000 (36,791,000), of which capitalized development expenditure amounts to SEK 44,788,000 (22,527,000) and SEK 16,998,000 (14,264,000) consists of patents and licenses. Changes to the assumptions management employed in impairment tests could have a material effect on the company's results of operations and financial position. For further information see note 13.

#### Note 5 SEGMENT INFORMATION

Business segments are reported in a manner that is consistent with the internal reporting presented to the chief operating decision maker. The chief operating decision maker is that function responsible for allocating resources and judging the performance of operating segments. In the group, this function has been identified as management, which consists of six individuals including the CEO. Management has determined that the group as a whole is a single segment based on information considered in consultation with the board used as supporting data to allocate resources and evaluate performance. All non-current assets are located in Sweden.

The Group's net sales consist of royalty revenues, which are all invoiced from Sweden. Customers are mostly in the USA.

The Group had one customer representing 10% or more of the company's revenues

#### Note 6 INTRA-GROUP PURCHASES AND SALES

Note 7 OTHER OPERATING INCOME

	Parent co	mpany
	2018	2017
Share of sales relating to group companies	0 %	0 %
Share of purchasing relating to group companies	1 %	10 %

	Gro	up	Parent co	mpany
	2018	2017	2018	2017
Other subsidies	221,224	0	221,224	0
Exchange rate gains	522,932	58,662	522,932	58,662
Total	744,156	58,662	744,156	58,662

#### Note 8 LEASE PAYMENTS

	Gro	up	Parent company	
	2018	2017	2018	2017
Operating leases incl. rent for premises				
Lease payments, expense for the year	3,481,887	1,502,498	2,050,034	1,502,498
Remaining lease payments becomes dye as follows:				
Within 1 yr.	5,307,072	3,271,545	3,540,016	1,944,624
Later than 1 yr. but within 5 yrs.	15,278,688	13,461,404	9,735,044	6,585,540
Later than 5 yrs.	0	0	0	0
Total	20,585,760	16,732,949	13,275,060	8,530,164

#### Note 9 REMUNERATION TO THE AUDITORS

	Gro	up	Parent co	Parent company	
	2018	2018 2017		2017	
Remuneration to the auditors					
Mazars SET Revisionsbyrä					
Audit assignments	241,542	226,813	241,542	226,813	
Other services	115,217	259,998	115,217	259,998	
	356,759	486,811	356,759	486,811	
Other accounting firm					
Other services	60,624	512,200	0	512,200	
	60,624	512,200	0	512,200	
	417,383	999,011	356,759	999,011	

#### Note 10 EMPLOYEES AND PERSONNEL EXPENSES

Average number of employees						
	201	.8	2017			
	No. of employees	Of which men	No. of employees	Of which men		
Parent company						
Sweden	30	13	26	9		
Subsidiary						
USA	8	2	4	1		
Germany	1	0	0	0		
Total subsidiary	9	2	4	1		
Group total	39	15	30	10		

Gender balance, senior executives						
	2018	2018				
	Women	Men	Women	Men		
Board of Directors	3	3	3	2		
CEO and rest of management	3	4	3	4		

Personnel expenses				
	201	18	2017	
	Salary and benefits	Social security contributions	Salary and benefits	Social security contributions
Parent company				
Board and CEO	3,586,604	1,072,356	2,353,426	1,307,448
(of which pension expense)		(720,263)		(464,119)
Other employees	18,336,076	7,509,541	14,065,026	5,485,181
(of which pension expense)		(2,332,617)		(1,750,361)
Subsidiary				
Other employees	10,902,790	0	4,982,899	739,343
(of which pension expense)		(380,427)		(71,594)
Group total	32,825,470	8,581,897	21,401,351	7,531,972
(of which pension expense)		(3,433,307)		(2,286,074)

Senior executives mean the individuals that make up the company's management with the Chief Executive Officer. There are seven people in this group. Fees are payable to the Chairman of the Board and Directors pursuant to AGM resolution. The following table illustrates compensation received. Where Directors' fees are invoiced, social security contributions are included in the carrying amounts.

2018					
Name	Position	Salary & benefits/ directors' fee	Pension expenses	Other benefits	Total
Carl Borrebaeck	Chairman	360,000	0	0	360,000
Hans Johansson	Director	153,334	0	0	153,334
Åsa Hedin	Director	173,334	0	0	173,334
Christofer Sjögren	Director	100,000	0	0	100,000
Mimmi Ekberg	Director	100,000	0	0	100,000
Ann-Christin Malmborg Hager	Director	33,333	0	0	33,333
Ann-Christine Sundell	Director	166,667	0	0	166,667
Total, Board		1,086,668	0	0	1,086,668
Mats Grahn	Chief Executive Officer	2,510,496	720,263	0	3,230,759
Other senior executives		5,235,305	822,241	2,185,853	8,243,399
Total. Chief Executive Officer and senior ex	ecutives	7.745.801	1.542.504	2.185.853	11.474.158

2017					
Name	Position	Salary & benefits/ directors' fee	Pension expenses	Other benefits	Total
Carl Borrebaeck	Chairman	267,135	0	0	267,135
Hans Johansson	Director	105,136	0	0	105,136
Åsa Hedin	Director	119,900	0	0	119,900
Ann-Christin Malmborg Hager	Director	93,300	0	0	93,300
Ann-Christine Sundell	Director	80,000	0	0	80,000
Total, Board		665,471	0	0	665,471
Mats Grahn	Chief Executive Officer	1,731,480	464,119	0	2,195,599
Other senior executives		4,920,311	767,286	2,316,215	8,003,812
Total, Chief Executive Officer and senior executives		6,651,791	1,231,405	2,316,215	10,199,411

The CEO has a notice period of six months on termination by the CEO. A notice period of six months applies to termination by the company. Other compensation to senior executives wholly consists of invoiced fees and compensation for service in management.

The Board of Directors and senior executives are members of share warrant programs, whose terms are stated below.

The group's only pension obligations are in defined contribution plans. In defined contribution plans, the company pays predetermined charges to insurance companies. Retirement age is 65. For CEO Mats Grahn, the company pays a fixed premium of 22% of salary.

#### **Share warrants**

At the Annual General Meeting on May 3, 2018, an option program of series 2018/2021 was approved for employees and key persons in the company. The share warrants (156,150) can be exercised to subscribe for new shares in the company from September 7, 2021 and until October 7, 2021. Each warrant gives the right to subscribe for one share at a subscription price of SEK 271.05 per share. Upon full exercise, the company's share capital increases by SEK 7,739.50.

The AGM on April 25, 2017 resolved on a share warrant program designated series 2017/2020 for employees and key individuals of the company. The share warrants (61,000

warrants) can be exercised to subscribe for new shares of the company in the exercise period September 15, 2020 until October 15, 2020 inclusive. Each share warrant confers entitlement to subscribe for one share at a subscription price of SEK 205.00 per share. Upon full exercise, the company's share capital would increase by SEK 3,050.

The AGM on May 30, 2016 resolved on a share warrant program designated series 2016/2019 to employees and key individuals of the company. The share warrants (123,5000 warrants) can be exercised to subscribe for new shares of the company in the exercise period from the present and until October 15, 2019 inclusive. Each share warrant confers entitlement to subscribe for one share at a subscription price of SEK 82.90 per share. Upon full exercise, the company's share capital would increase by SEK 6,175.

It was resolved at the Annual General Meeting on May 3, 2018 to introduce an alternative cash-based incentive program for key employees in countries where the allocation of warrants under warrants program 2018/2021 was not appropriate for various reasons. Such an alternative incentive program has been introduced for employees and key persons and is designed in such a way that it corresponds to the terms of the warrants program 2018/2021 to its economic effect. The total cost for the Company for the cash-based incentive program cannot exceed USD 250,000.

It was decided at the Annual General Meeting on April 25, 2017 to introduce an alternative cash-based incentive program for key employees in countries where the allocation of warrants under the warrants program 2017/2020 was not appropriate for various reasons. Such an alternative incentive program has been introduced for 6 key persons and is designed in such a way that it corresponds to the terms of the warrants program 2017/2020 to its economic

effect. The total cost for the Company for the cash-based incentive program may not exceed USD 920,000.

All option programs are subject to customary conversion conditions in connection with issues etc.

In addition to what has been stated above, the company has no outstanding warrants, convertibles or other equity-related financial instruments.

#### Note 11 FINANCIAL INCOME/INTEREST INCOME ETC.

	Group		Parent co	Parent company	
	2018	2017	2018	2017	
Interest income, group companies	0	0	577,815	69,347	
Exchange income	859,639	0	859,642	0	
Interest income, other	318,591	297,734	305,731	296,233	
Total	1,178,230	297,734	1,743,188	365,580	

#### Note 12 FINANCIAL EXPENSES/INTEREST EXPENSES ETC.

	Group		Parent co	Parent company	
	2018	2017	2018	2017	
Interest expenses, group companies	0	0	0	0	
Interest expenses, other	-697	-10,170	-697	-1,630	
Total	-697	-10,170	-697	-1,630	

#### Note 13 TAX ON EARNINGS FOR THE YEAR

	Group		Parent company	
	Dec 31, 2018	Dec 31, 2017	Dec 31, 2018	Dec 31, 2017
Current tax	-7,345	0	0	0
Deferred tax total	0	0	0	0
Total	-7,345	0	0	0

	Gro	Group		Parent company	
	Dec 31, 2018	Dec 31, 2017	Dec 31, 2018	Dec 31, 2017	
Theoretical tax					
Reported earnings/loss before tax	-86,531,296	-45,232,000	-66,333,762	-45,232,216	
Tax at applicable tax rate, 22%	19,036,885	9,951,084	14,593,428	9,951,088	
Reconciliation of reported tax					
Effect of non-deductible expenses	-25,090	-1,575,898	-25,590	-1,575,716	
Effect of non-taxable revenues	0	17,010	0	17,010	
Issue expenses recognized in equity	3,230,803	0	3,230,803	0	
Effect of loss carry-forwards that have not been measured	-22,242,598	-8,392,192	-17,798,641	-8,392,382	
Utilization of previously unmeasured loss carry-forwards	-7, 345	0	0	0	
Total	-7.345	0	0	0	

Deductible loss carry-forwards in the group amount to SEK 192,017,000 (90,909,000) as of December 31, 2018. For the parent company, deductible lost carry-forwards amount to SEK 171,812,000 (90,909,000) as of December 31, 2018. All loss carry-forwards have no time limitation. The effect of issue expenses is reported in equity.

#### Note 14 CAPITALIZED DEVELOPMENT EXPENDITURE

	Group		Parent co	mpany
	Dec 31, 2018	Dec 31, 2017	Dec 31, 2018	Dec 31, 2017
Opening cost	64,412,558	41,083,948	64,412,558	41,083,948
Investment	25,052,106	23,328,610	25,052,106	23,328,610
Adjustment	-824,916	0	-824,916	0
Total	88,639,748	64,412,558	88,639,748	64,412,558
National and European subsidies of development expenditure				
Opening balance	-41,885,572	-33,479,213	-41,885,572	-33,479,213
Deducted in the year	-2,790,819	-8,406,359	-2,790,819	-8,406,359
Adjustment	824,916	0	824,916	0
Total	-43,851,475	-41,885,572	-43,851,475	-41,885,572
Carrying amount	44,788,273	22,526,986	44,788,273	22,526,986

Impairment testing has been carried out for capitalized development expenditure. Significant factors in the test have been to assess cash flows for the next five years, assess growth after the forecast period and the weighted capital cost, which is calculated at 10.5%. The forecasts used in the impairment test are approved by the management and are based on the best assessment of the future. The growth rate beyond that forecast period is set at 2%, which is a conservative estimate as it is set at expected long-term inflation.

A sensitivity analysis shows that an impairment requirement arises at an increased weighted capital cost of 16.5 percentage units or at a turnover decrease of about 30% and otherwise unchanged factors. A shift in sales start of about 1 year also means that an impairment need arises.

### Note 15 PATENTS, LICENSES AND SIMILAR RIGHTS

	Grou	ıp	Parent co	mpany
	Dec 31, 2018	Dec 31, 2017	Dec 31, 2018	Dec 31, 2017
Opening cost	15,298,033	12,707,660	15,298,033	12,707,660
Investment	3,177,617	2,590,373	2,288,380	2,590,373
Sales and scrapping	-233,920	0	-233,920	0
Transaction differences of the year	28,534	0	0	0
Closing accumulated cost	18,270,264	15,298,033	17,352,493	15,298,033
Opening amortization	-435,101	-231,699	-435,101	-231,699
Amortization for the year	-238,753	-203,402	-238,753	-203,402
Closing accumulated amortization	-673,854	-435,101	-673,854	-435,101
Opening impairment	-598,513	-598,513	-598,513	-598,513
Closing accumulated impairment	-598,513	-598,513	-598,513	-598,513
Carrying amount	16,997,897	14,264,419	16,080,126	14,264,419

#### Note 16 IMPROVEMENTS IN OTHER PROPERTY

Carrying amount	3,304,283	0	2,300,000	0
Closing accumulated amortization	-48,408	0	0	0
Translation difference for the year	-1,505	0	0	0
Amortization for the year	-46,903	0	0	0
Opening amortization	0	0	0	0
Closing accumulated cost	3,352,690	0	2,300,000	0
Translation difference for the year	32,728	0	0	0
Purchase	3,319,962	0	2,300,000	0
Opening cost	0	0	0	0
	Dec 31, 2018	Dec 31, 2017	Dec 31, 2018	Dec 31, 2017
	Grou	ıρ	Parent company	

### Note 17 EQUIPMENT, TOOLS, FIXTURES AND FITTINGS

	Grou	лb	Parent company	
	Dec 31, 2018	Dec 31, 2017	Dec 31, 2018	Dec 31, 2017
Opening cost	9,119,675	3,851,108	6,505,597	3,851,108
Purchases	5,736,605	5,365,672	3,849,294	2,654,489
Translation difference for the year	280,219	-97,105	0	0
Closing accumulated cost	15,136,499	9,119,675	10,354,891	6,505,597
Opening depreciation	-1,908,822	-848,715	-1,908,822	-848,715
Depreciation in the year	-2,491,654	-1,060,107	-1,757,436	-1,060,107
Translation difference for the year	-21,377	0	0	0
Closing accumulated depreciation	-4,397,021	-1,908,822	-3,666,258	-1,908,822
Carrying amount	10,714,646	7,210,853	6,688,633	4,596,775

#### Note 18 OTHER LONG-TERM RECEIVABLES

	Group		
	Dec 31, 2018	Dec 31, 2017	
Opening acquisition vale	2,758,947	0	
Lending for the year	3,169	2,861,433	
Translation difference for the year	246,344	-102,486	
Carrying amount	3,008,460	2,758,947	

#### Note 19 PREPAID EXPENSES AND ACCRUED INCOME

	Group		Parent company	
	Dec 31, 2018	Dec 31, 2017	Dec 31, 2018	Dec 31, 2017
Prepaid rent	938,824	405,880	935,649	405,880
Prepaid insurance	121,623	71,198	40,000	7,933
Prepaid expenses for prospective studies	1,676,311	0	1,676,311	0
Other prepaid expenses	939,132	1,057,779	939,132	1,057,779
Accrued income	252,074	61,750	252,074	61,750
Carrying amount	3 ,927,964	1,596,607	3,843,166	1,533,342

#### Note 20 PARTICIPATIONS IN GROUP COMPANIES

Moderbolaget						
					Carrying	amount
Company	Corporate ID no.	Reg. office.	No.	Participating interest	Dec 31, 2018	Dec 31, 2017
Immunovia Inc	350589-6	Wilmington, USA	1,000	100 %	8	8
Immunovia GmbH	HRB 111 597	Frankfurt am Main	1	100 %	253,472	0
					253,480	8

### Note 21 EQUITY

There are 19 531 353 shares, each with one vote. The quotient value is SEK 0.05 per share.

#### Note 22 ACCRUED EXPENSES AND PREPAID INCOME

	Group		Parent company	
	Dec 31, 2018	Dec 31, 2017	Dec 31, 2018	Dec 31, 2017
Personnel-related expenses	7,269,986	4,429,392	7,125,544	4,429,392
Accrued study expenses	2,650,758	529,158	2,650,758	529,158
Other accrued expenses	1,358,169	426,353	1,297,545	426,353
Carrying amount	11,278,913	5,384,903	11,073,847	5,384,903

#### Note 23 NON-CASH ITEMS

	Group		Group		Parent company	
	Dec 31, 2018	Dec 31, 2017	Dec 31, 2018	Dec 31, 2017		
Depreciation and amortization	2,777,310	1,263,509	1,996,189	1,263,509		
Disposal of intangible assets	233,920	0	233,920	0		
Translation difference, internal transactions	-329,486	208,696	0	0		
Total	2,681,744	1,472,205	2,230,109	1,263,509		

### Note 24 CASH AND CASH EQUIVALENTS

	Grou	ıp	Parent co	mpany
	Dec 31, 2018	Dec 31, 2017	Dec 31, 2018	Dec 31, 2017
h	0	0	0	0
k balances	386,135,825	192,425,655	385,516,553	192,215,779
al cash and cash equivalents	386,135,825	192,425,655	385,516,553	192,215,779

#### Note 25 FINANCIAL INSTRUMENTS BY CATEGORY

	Group		Parent co	mpany
	Dec 31, 2018	Dec 31, 2017	Dec 31, 2018	Dec 31, 2017
Loan receivables and accounts receivable measured at amortized cost				
Other non-current receivables	3,008,460	2,758,947	0	0
Accounts receivables	32,424	0	32,424	0
Other receivables	8,473,123	8,173,116	6,542,752	8,096,219
Accrued income	252,074	61,750	252,074	61,750
Cash and cash equivalents	386,135,825	192,425,655	385,516,553	192,215,778
	397,901,906	203,419,468	392,343,803	200,373,747
Loan liabilities and accounts payable measured at amortized cost				
Accounts Payable	3,031,178	7,470,195	3,007,025	7,406,931
Accrued expenses	5,119,816	1,751,457	5,059,302	1,751,457
	8,150,994	9,221,652	8,066,327	9,158,388

Financial assets valued at accrued acquisition value
At present, the Group only has financial assets that are not normally sold outside the Group and where the purpose of the holding is to obtain contractual cash flows. All financial assets are classified as financial assets that are valued at amortized cost using the effective interest method.

Financial liabilities valued at accrued acquisition value
The Group only has financial liabilities that are classified
and valued at accrued acquisition value using the effective
interest method. Accounting is initially made at fair value,
net after transaction costs.

# Note 26 SIGNIFICANT POST BALANCE SHEET EVENTS

As Immunovia previously announced in August 2018, the combination of retrospective samples from different biobanks, with varying sample collection procedures and storage, introduced unforeseen variability in the test algorithm performance. The distorting effect caused by the variability in blood sampling was eliminated by consistent and optimal protocols. It was also concluded that for optimal performance of the test, the samples should be collected within 24 months of the testing period. The step of gaining these fresh samples has pushed out the previously communicated timeline by about 8 weeks which will impact the start of sales accordingly.

#### Note 28 APPROPRIATION OF EARNINGS/LOSS

#### Proposed appropriation of the company's earnings/loss

The following funds are at the disposal of the AGM:	
Share premium reserve	312,177,499
Earnings brought forward	196,785,781
Earnings/loss for the year	-66,333,762
	442,629,518
The Board of Directors proposes:	
Carried forward	442,629,518
	442,629,518

#### Note 27 TRANSACTIONS WITH RELATED PARTIES

Remuneration to the Board of Directors and senior executives is stated in note 9.

In addition to salaries and other remuneration to the executive management and board fees, according to a resolution by the AGM, the company has also entered into a consultancy agreement with CB Ocean Capital AB for services to be performed by Immunovia's chairman and its largest owner Carl Borrebaeck. The services provided do not include tasks that belong to board assignments, but the services are aimed at providing the company with scientific and strategic support for, for example, scientific presentations and conferences. The agreement applies from January 1, 2018 and runs until further notice with a three-month mutual notice period and provides a quarterly remuneration of SEK 41,000.

# **Board of Directors' and Chief Executive Officer's certification**

The Consolidated Income Statement and Consolidated Balance Sheet will be presented to the Annual General Meeting on April 26, 2019 for adoption.

The Board of Directors and Chief Executive Officer hereby certify that the Consolidated Accounts have been prepared in accordance with International Financial Reporting Standards, IFRS, as endorsed by the EU and give a true and fair view of the group's financial position and results of operations. The financial statements for the parent company have been prepared in accordance with generally accepted accounting practice and give a true and fair view of the parent company's financial position and results of operations.

The Statutory Administration Report of the group and parent company gives a true and fair view of the progress of the group's and parent company's operations, financial position and results of operations, and states the material risks and uncertainty factors facing the parent company and companies in the group.

Lund, Sweden, March 1, 2019

Carl Borrebaeck
Chairman of the Board

Mimmi Ekberg *Director* 

Åsa Hedin *Director*  Hans Johansson *Director* 

Christofer Sjögren *Director*  Ann-Christine Sundell Director

Mats Grahn
Chief Executive Officer

Our Audit Report was presented on March 3, 2019 Mazars SET Revisionsbyrå AB

> Mats-Åke Andersson Authorized Public Accountant Auditor in Charge

The Consolidated Income Statement and Consolidated Balance Sheet, and the Parent Company Income Statement and Parent Company Balance Sheet will be subject to adoption at the Annual General Meeting.

# **Audit Report**

To the general meeting of the shareholders of Immunovia AB (publ), corporate ID no. 556730-4299

## Report on the annual accounts and consolidated accounts

**Opinions** 

We have audited the annual accounts and consolidated accounts of Immunovia AB (publ) for the year 2018. The annual accounts and consolidated accounts of the Company are included on pages 40-71 in this document.

In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the Parent Company as of December 31, 2018 and its financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. The consolidated accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the Group as of December 31, 2018 and their financial performance and cash flow for the year then ended in accordance with International Financial Reporting Standards (IFRS), as adopted by the EU, and the Annual Accounts Act. The statutory administration report is consistent with the other parts of the annual accounts and consolidated accounts.

We therefore recommend that the general meeting of shareholders adopts the income statement and balance sheet for the Parent Company and the Group.

Our opinions in this report on the annual accounts and the consolidated accounts are consistent with the content of the supplementary report submitted to the parent company's audit committee in accordance with Article 11 of the audit regulation (537/2014/EU).

#### Basis for opinions

We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the Parent Company and the Group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements. This includes, based on our best knowledge and beliefs, no prohibited services referred to in Article 5 (1)

(537/2014/EU) of the Auditors Regulations, the audited company or, where applicable, its parent company or its controlled companies within the EU has been provided.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

#### Particularly important areas

Particularly important areas for the audit are the areas that, according to our professional assessment, were the most important for the audit of the annual accounts and consolidated accounts for the current period and include, among other things, the most important assessed risks for material misstatements. These areas were treated within the framework of the audit of, and in our opinion on, the annual accounts and the consolidated accounts as a whole, but we make no separate statements about these areas.

#### Intangible fixed assets

The intangible fixed assets are presented in more detail in notes 2, 4, 14 and 15. As of December 31, 2018, the Group's carrying amount of intangible fixed assets amounts to SEK 61,786,000 and constitutes a significant part of the Group's reported assets. In accordance with applied accounting principles, certain conditions exist for the fact that capitalization of expenses can take place, see also Note 2, and partly the executive management make an annual impairment test regarding the asset. The management has made impairment tests based on discounted cash flow. The calculations include a high degree of assessments and assumptions about future cash flows and conditions that are complex. Notes 4 and 14 contain an account of which parts have been tested, how the assessments have been made, important assumptions and the outcome of sensitivity analyzes.

We have formed an understanding of the company's operations and market, assessed the calculation model used by the management and took note of the estimates and assessments made. The management's assumptions mainly linked to the variables that have the greatest impact on impairment testing, such as growth, margins and the discount factor have been tested by us. We have tested what effect changes in assumptions regarding the above-mentioned variables have on the trials. This is to assess whether an

impairment requirement exists. Assessment has been made of the accuracy of the disclosures in the annual accounts.

Other information than the annual accounts and consolidated accounts

This document also contains other information than the annual accounts and consolidated accounts and is found on pages 2–39 and 76-79. The Board of Directors and the CEO are responsible for this other information

Our opinion on the annual accounts and consolidated accounts does not cover this other information and we do not express any form of assurance conclusion regarding this other information.

In connection with our audit of the annual accounts and consolidated accounts, our responsibility is to read the information identified above and consider whether the information is materially inconsistent with the annual accounts and consolidated accounts.

In this procedure we also take into account our knowledge otherwise obtained in the audit and assess whether the information otherwise appears to be materially misstated.

If we, based on the work performed concerning this information that we have had access to prior the date of this auditor's report, conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Responsibilities of the Board of Directors and the Chief Executive Officer

The Board of Directors and the CEO are responsible for the preparation of the annual accounts and consolidated accounts and that they give a fair presentation in accordance with the Annual Accounts Act and, concerning the consolidated accounts, in accordance with IFRS as adopted by the EU. The Board of Directors and the CEO are also responsible for such internal control as they determine is necessary to enable the preparation of annual accounts and consolidated accounts that are free from material misstatement, whether due to fraud or error.

In preparing the annual accounts and consolidated accounts, The Board of Directors and the CEO are responsible for the assessment of the company's and the group's ability to continue as a going concern.

They disclose, as applicable, matters related to going concern and using the going concern basis of accounting. The going concern basis of accounting is however not applied if the Board of Directors and the CEO intends to liquidate the company, to cease operations, or has no realistic alternative but to do so.

The Board's Audit Committee shall, without prejudice to the Board's responsibilities and tasks in general, monitor, among other things, the Company's financial reporting.

#### Auditors' responsibility

Our objectives are to obtain reasonable assurance about whether the annual accounts and consolidated accounts as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinions. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts and consolidated accounts.

As part of an audit in accordance with ISAs, we exercise professional judgment and maintain professional skepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the annual accounts and consolidated accounts, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinions. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of the company's internal control relevant to our audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates

- and related disclosures made by the Board of Directors and the CEO.
- Conclude on the appropriateness of the Board of Directors' and the CEO's use of the going concern basis of accounting in preparing the annual accounts and consolidated accounts. We also draw a conclusion, based on the audit evidence obtained, as to whether any material uncertainty exists related to events or conditions that may cast significant doubt on the company's and the Group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the annual accounts and consolidated accounts or, if such disclosures are inadequate, to modify our opinion about the annual accounts and consolidated accounts. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause a company and a group to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the annual accounts and consolidated accounts, including the disclosures, and whether the annual accounts and consolidated accounts represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient and appropriate audit evidence regarding the financial information of the entities or business activities within the Group to express an opinion on the consolidated accounts. We are responsible for the direction, supervision and performance of the Group audit. We remain solely responsible for our opinions.

We must inform the Board of Directors of, among other matters, the planned scope and timing of the audit. We must also inform of significant audit findings during our audit, including any significant deficiencies in internal control that we identified.

We must also provide the Board with a statement that we have complied with relevant professional ethical requirements regarding independence, and to address all relations and other conditions that can reasonably affect our independence, and, if applicable, associated countermeasures.

Of the areas communicated with the Board, we determine which of these areas have been the most

important for the audit of the annual accounts and the consolidated accounts, including the most important assessed risks for material misstatements, and which therefore constitute the areas of particular importance to the audit. We describe these areas in the auditor's report unless laws or other regulations prevent information about the issue or when, in extremely rare cases, we consider that an issue should not be communicated in the audit report because the negative consequences of doing so reasonably would be expected to be greater than the public interest of this communication.

#### Report on other legal and regulatory requirements Opinions

In addition to our audit of the annual accounts and consolidated accounts, we have also audited the administration of the Board of Directors and the CEO of Immunovia AB (publ) for the year 2018 and the proposed appropriations of the company's profit or loss.

We recommend to the general meeting of share-holders that the profit be appropriated in accordance with the proposal in the statutory administration report and that the members of the Board of Directors and the CEO be discharged from liability for the financial year.

#### Basis for opinions

We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the Parent Company and the Group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

## Responsibilities of the Board of Directors and the Chief Executive Officer

The Board of Directors is responsible for the proposal for appropriations of the company's profit or loss. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the company's and the Group's type of operations, size and risks place on the size of

the Company's and the Group's equity, consolidation requirements, liquidity and position in general.

The Board of Directors is responsible for the company's organization and the administration of the company's affairs. This includes among other things continuous assessment of the company's and the Group's financial situation and ensuring that the company's organization is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner. The CEO shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are necessary to fulfil the company's accounting in accordance with law and handle the management of assets in a reassuring manner.

#### Auditor's responsibility

Our objective concerning the audit of the administration, and thereby our opinion about discharge from liability, is to obtain audit evidence to assess with a reasonable degree of assurance whether any member of the Board of Directors or the CEO in any material respect:

- has undertaken any action or been guilty of any omission which can give rise to liability to the company, or
- in any other way has acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

Our objective concerning the audit of the proposed appropriations of the company's profit or loss, and thereby our opinion about this, is to assess with reasonable degree of assurance whether the proposal is in accordance with the Companies Act.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give rise to liability to the company, or that the proposed appropriations of the company's profit or loss are not in accordance with the Companies Act.

As part of an audit in accordance with generally accepted auditing standards in Sweden, we exercise professional judgment and maintain professional skepticism throughout the audit. The examination of the administration and the proposed appropriations

of the company's profit or loss is based primarily on the audit of the accounts. Additional audit procedures performed are based on our professional judgment with starting point in risk and materiality. This means that we focus the examination on such actions, areas and relationships that are material for the operations and where deviations and violations would have particular importance for the company's situation. We examine and test decisions undertaken, support for decisions, actions taken and other circumstances that are relevant to our opinion concerning discharge from liability. As a basis for our opinion on the Board of Directors' proposed appropriations of the company's profit or loss, we examined whether the proposal is in accordance with the Companies Act.

Mazars SET Revisionsbyrå AB, Box 1317, 111 83 Stockholm, was appointed Immunovia AB's auditor at the Annual General Meeting in May 2018 and has been the company's auditor since April 2017.

Lund, March 3, 2019 Mazars SET Revisionsbyrå AB

Mats-Åke Andersson

Authorized public accountant

# **Definitions**

Key indicator	Definition	Motivation for using financial key indicator not defined pursuant to IFRS
Net sales	Revenues from goods and services sold, and royalties received relating to the main activity during the relevant period.	
Operating earnings/loss	Earnings/loss before financial items and tax.	Operating earnings/loss provides a view of the earnings that the company's ordinary activities have generated.
Basic and diluted earnings per share	Earnings/loss divided by the weighted number of shares in the period before and after dilution respectively.	
Average number of shares before and after dilution	The average number of outstanding shares in the period before and after dilution respectively. Because the group is generating a loss, there is no dilution, despite the subscription price being lower than the share price.	
R&D expenses	The company's direct expenses for research and development. Expenses for staff, materials and external services.	The company's main activity is research and development. Management considers that R&D expenses are an important parameter to monitor as an indicator of activity levels within the company.
R&D expenses as a percentage of operating expenses	R&D expenses divided by operating expenses, which include other external expenses, personnel expenses, depreciation and amortization.	Management considers that the company's R&D expenses in relation to total expenses are an important indication of the proportion of total expenses that are used for the company's main activity.
Cash and cash equivalents	Cash and bank balances.	
Cash flow from operating activities	Cash flow before cash flow from investing activities and financing activities.	
Cash flow for the period	The change in cash and cash equivalents for the period excluding effective unrealized exchange rate gains and exchange rate losses	5.
Equity per share	Equity divided by the number of shares divided by the number of shares at the end of the period.	Management follows this indicator to monitor the value of equity per share.
Equity/assets ratio	Equity as a percentage of total assets	Management follows this indicator of the company's financial stability.
Average number of employees	The average number of employees is the total of working-hours in the period divided by scheduled working hours for the period.	
Average number of employees in R&D	The average of the number of employees in the company's research and development functions.	

# **Glossary**

**Actionable information**—in this Annual Report, actionable information means information that is sufficiently reliable and specific to serve as the basis for clinical decisions.

**Antigen**—a foreign substance that promotes an immunodefence reaction on contact with the organism. This substance may be a chemical compound, a protein or a carbohydrate.

**Antibodies**—antibodies, or immunoglobulines, are a type of protein used by the body's immune system to detect and identify foreign entities such as viruses, bacteria or parasites. **Autoimmunity**—autoimmunity is the harmful attack of the immune defence on the body's own tissue, which may express as a disease or rejection of organs in transplantation.

**Benign**—a benign tumor means that the tumor is benevolent and will not spread.

**Bioinformatics**—an inter-disciplinary field where algorithms for analyzing biological (especially molecular biological) data are developed.

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

**Companion diagnostics**—a diagnostic tool designed to identify which patient groups will respond positively to a specific treatment, and thus exclude ineffective treatments. **Discovery study**—research conducted to verify a particular hypothesis.

**Histology**—histology is the study of biological tissue **Invasive**—the term invasive means to enter or attack. Invasive medical examinations are examinations that involve some form of entry through a body cavity, or a surgical procedure.

**Sensitivity**—sensitivity is a statistical measure of reliability in a binary diagnostic test and states the likelihood that generating a positive result is correct.

**Malignant** — malignant tumors tend to deteriorate and become terminal, and unlike benign tumors, are termed cancers.

**Metastasis**—a metastasis is a tumor that has spread to other organs.

**Microarray** – a Microarray is a molecular biology test format for simultaneous measurement of the relevant concentration of proteins.

Molecular diagnostics—a collective technology used to analyze biological markers acting at gene and protein level (i.e. an individual's genetic code and how cells express genes as proteins in the body), such techniques are used to diagnose and monitor diseases, discover the risk of disease and determine which therapy will probably be best for the individual.

**Palliative care**—palliative care is administered when a patient's disease is no longer curable. The intention of palliative care is to provide patients and relatives with psychological and medical support.

**PanDIA-1**—prospective study for the diabetes risk group of patients aged over 50 that have been recently diagnosed with type 2 diabetes.

**PanFAM-1**—prospective study for the familiar and inherited risk group.

**Pancreatologist** – pancreatologists are specialists that focus on diseases with a connection to the pancreas.

**PanSYM-1**—prospective study for the early symptom risk group.

**Prospective study**—study where a group of individuals are studied and monitored for a period, often extended, to determine how a specific disease develops. Prospective studies are used to examine connections between different risk factors and a specific disease. Individuals with and without risk factors are monitored over time. At the endpoint of the study, the share of individuals that have contracted the disease is monitored and measured for comparisons between the two groups.

**Proteomics** – proteomics is a of branch of biology and involves examination of large data volumes regarding proteins.

**Reproducibility**—in statistics, reproducibility is defined as the consistency between the result of repeated measures conducted using different measurement devices of the same type, conducted with the aim of being able to eliminate potential measurement errors due to materials and personnel.

**Retrospective study**—a study involving retroactive examination of previous occurrences, i.e. using historical measurement data. A retrospective study proceeds from responses, i.e. when which individuals that have and have not contracted an illness is already known.

**Screening**—screening means medical examinations to identify a disease and is usually conducted before patients have expressed early symptoms.

**Self-paying customers**—patients and organizations that pay without reimbursement from insurance companies or health authorities.

**Serum**—serum is a yellow transparent liquid obtained by allowing blood to coagulate and then separating the blood cells and coagulation proteins. Serum contains proteins including antibodies.

**SLE** (systemic lupus erythematosus)—SLE is an autoimmune inflammatory disease that involves the immune defence attacking the body. This disorder is periodic, with patients experiencing periods of illness, and periods with no symptoms. The inflammation usually affects the joints, skin, blood and kidneys, which become inflamed, although the nervous system, lungs and heart can also 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 states the probability that generating a negative result is de facto negative.

Vinnova—Vinnova is a Swedish government body within the Swedish Ministry of Enterprise, Energy & Communications, whose mission is to promote sustainable growth by improving the potential for innovation and financing needs-based research.

## Shareholder information

#### **Annual General Meeting 2019**

The shareholders of Immunovia AB (publ) are called to the Annual General Meeting on April 26, 2019, at 4 pm at Medicon Village in Lund.

#### Registration

Shareholders who wish to attend the Annual General Meeting must be included in the register of shareholders held by Euroclear Sweden AB no later than Thursday, April 18, 2019, and must register with the company no later than Thursday, April 18, 2019. Registration for attendence is made by mail to Immunovia AB (publ), Medicon Village, 223 81 Lund, Sweden, by phone +46 46 275 60 00, or by e-mail to info@immunovia.com.

The registration must include the name of the person or organization, person or organization number, number of shares, address, daytime telephone number and, if applicable, the number of assistants (maximum two) referred to at the meeting.

Shareholders who have registered their shares with a bank or other nominee must be temporarily registered in their own name in order to participate in the AGM. Such registration must be registered at Euroclear Sweden AB no later than Thursday, April 12, 2019, meaning that the shareholder should notify the nominee well in advance before that date.

#### Financial calendar

April 24, 2019 Interim Report, Jan-Mar 2019

April 26, 2019 AGM

August 23, 2019 Interim Report, Jan-Jun 2019 November 8, 2019 Interim Report, Jan-Sep 2019

February 14, 2020 Year-end Report 2019

### Contact information

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#### For more information, please contact:

Mats Grahn, CEO of Immunovia AB E-mail: mats.grahn@immunovia.com

The company's Annual Report is available for download at the company's website: www.immunovia.com

## Immunovia in brief

Immunovia is a Swedish molecular diagnostics company with a secure financial position in the commercialization phase that is developing and commercialising diagnostic tools for complex forms of cancer and autoimmune disease.

Immunovia AB was founded in 2007 by researchers at the Institution of Immunotechnology and CREATE Health – the Strategic Division of Translational Cancer Research at Lund University, Sweden. The aim was to establish a base for discoveries and patents within human antibodies, biomarkers and antibody matrixes from research to clinical application.

Immunovia's central technology platform, IMMray™, is based on the analysis of micro arrays of biomarker antibodies. IMMray™ PanCan –d is the company's primary diagnostic tool, capable of diagnosing patients with very high sensitivity and specificity. This enables diagnosis of patients with pancreatic cancer before symptoms have expressed (stages I and II), which is not possible with extant diagnostic methods. Immunovia is now conducting clinical validation studies to prepare for commercialisation of IMMray™ PanCan –d, which may become the first blood-based test for early diagnosis of pancreatic cancer.

The antibody-based technology platform IMMray™ is the result of 15 years' research at CREATE Health at Lund University, and is used for decoding the mechanisms underlying immunodefence, which is the body's initial reaction to any disease. The platform is also used for developing diagnostic tests for autoimmune diseases.

#### Pancreatic cancer

Some 338,000 patients contract pancreatic cancer every year. This type of cancer has one of the poorest survival prognoses, with only some 5-8 percent of sufferers surviving for over five years, which makes it one of the world's deadliest forms of cancer. Given early detection, the estimated increase in five-year survival would increase to 50 percent. The initial addressable market for Immunovia consists of the three high-risk groups within pancreatic cancer. The US and European market for diagnosing these patient groups have an estimated annual value of over SEK 37 billion.

#### **Objective**

Immunovia's objective is to provide diagnostic tests and enable earlier, more effective and more accurate diagnosis of patients at risk of contracting cancer or autoimmune disease. The ambition is for Immunovia's tests to be the first choice for specialists and general practitioners worldwide when screening especially high-risk groups, and on general suspicion of the aforementioned diseases.

#### Strategy

Immunovia's strategy is to be the first company to analyse the wealth of information in the blood and translate this into practical tools to diagnose complex diseases earlier and more accurately than has previously been possible. Its focus is on unsolved problems in early diagnostics, monitoring the course of disease, and patient response to therapy. These segments have an especially substantial clinical benefit for patients and the healthcare sector, there are either no, or inadequate, solutions present, while they also offer IMMray™ the greatest competitive edges.

Immunovia's initial main focus is to bring IMMray™ PanCan –d to the market. Because early detection of pancreatic cancer is a major clinical problem, Immunovia judges that there is very good potential to be the first mover and secure strong market positioning.

Corporate identity number: 556730-4299

Immunovia's head office is in Lund, Sweden. Immunovia's shares (IMMNOV) are listed on Nasdaq Stockholm's main list. For more information, go to: www.immunovia.com.



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