



ENGINEERING IMMUNE TOLERANCE

## Year-end report

January–December 2017

## Year-end report, 1 January-31 December 2017

### **FOURTH QUARTER (OCTOBER-DECEMBER 2017)**

- Other operating income amounted to KSEK 0 (0)
- Operating loss totalled KSEK -7,289 (-4,255)
- Loss for the period totalled KSEK -7,315 (-4,255)
- Cash flow from operating activities was KSEK -8,250 (-3,035)
- Loss per share before dilution was SEK 0.35 (-0.36). Loss per share after dilution was SEK 0.19 (-0.36)
- The proposed dividend is SEK 0.00/share (0.00)
- This fourth quarter/year-end report has been prepared in accordance with RFR 2, Accounting for Legal Entities. The report has been prepared in accordance with IAS 34, with consideration for the exceptions and additions to IFRS specified in RFR 2. The company is not included in any group, which is why IFRS-compliant financial statements are not applicable. The transition to presentation in accordance with RFR 2 has not had any effect on the balance sheet at the beginning of 2016, nor on comparative periods.

### **FULL-YEAR PERIOD (1 JANUARY-31 DECEMBER 2017)**

- Other operating income amounted to KSEK 0 (53)  
Operating loss totalled KSEK -21,299 (-12,583)
- Loss for the period totalled KSEK -21,322 (- 12,599)
- Cash flow from operating activities was a negative KSEK -19,906 (-11,407)
- Loss per share before dilution was SEK 1.32 (-1.22) Loss per share after dilution was SEK 0.88 (-1.03)
- The equity/assets ratio was 90% (90).
- At the end of the period, cash and bank balances amounted to MSEK 36.9. In addition, research funding of approximately MSEK 28 will be paid out over the next three years.

### **SIGNIFICANT EVENTS IN THE FOURTH QUARTER**

- The company began working with quality assurance to obtain accreditation for the manufacture of cell therapy products for clinical trials.
- The adaptation of Idogen's manufacturing production facilities was completed as planned in November and the facilities are compliant with clean room requirements.
- In December, a patent was granted in the US for Idogen's tolerogenic cell therapy technology. The new US patent provides broad protection for the company's technology in a key strategic market.
- At the end of 2017, Idogen's cash and bank balances amounted to MSEK 36.9. Immediately after year-end, the EU paid out MEUR 1.2, the first portion of research funding granted by Horizon 2020 (the EU Framework Programme for Research and Innovation). This brought Idogen's cash and cash balances to MSEK 49 at the beginning of 2018. Additional funding of MEUR 1.7 will be paid out over the next 30 months.

## SIGNIFICANT EVENTS AFTER THE END OF THE PERIOD

No other significant events occurred after the end of the financial year.

## CONDENSED EARNINGS AND CASH FLOW

(Amounts in KSEK, unless otherwise stated)	2017	2016	2017	2016
	3 months Oct-Dec	3 months Oct-Dec	12 months Jan-Dec	12 months Jan-Dec
Net sales	0	0	0	53
Operating expenses	-7,289	-4,255	-21,299	-12,636
Operating loss	-7,289	-4,255	-21,299	-12,583
Loss for the period	-7,315	-4,255	-21,322	-12,599
Average number of shares	20,778,467	11,852,419	16,207,516	10,308,456
Average number of warrants	17,111,766	0	7,969,864	1,871,585
Loss per share before dilution (SEK)	-0.35	-0.36	-1.32	-1.22
Loss per share after dilution (SEK)	-0.19	-0.36	-0.88	-1.03
Cash flow from operating activities	-8,250	-3,035	-19,906	-11,407
<b>KEY FIGURES</b>				
Working capital	33,894	16,794	33,894	16,794
Acid-test ratio (%)	895	911	895	911
Equity/assets ratio (%)	90	90	90	90
Loss per share before dilution	-0.35	-0.35	-1.32	-1.22
Average number of shares	20,778,467	12,222,589	16,207,516	10,308,456

## CEO comment

Idogen develops cell therapies to prevent the patient's immune system from attacking biological drugs, transplanted organs or the body's own cells or tissue. In 2017, we received several clear confirmations of the high level of innovation in our technology platform – in the face of intense competition, we were granted research funding of MEUR 2.9 from the EU, and new patents in the US, Europe and Japan.

In January, orphan drug designation was granted in the EU for our most advanced project, IDO 8, which aims to restore the effect of factor VIII therapy in haemophilia A patients. Orphan drug designation has several advantages, such as less extensive requirements for clinical trials, scientific guidance from the regulators and an extended period of market exclusivity. In addition, we have previously received valuable scientific advice from the Swedish Medical Products Agency regarding the design of a first clinical trial, which we expect to commence by the end of 2018.

Based on the successful development of our unique cell therapy concept and the positive preclinical results generated for IDO 8, we decided in May to broaden our project portfolio by commencing development of the IDO T project to prevent kidney transplant rejection. The aim is to teach the patient's immune system to recognise and accept the transplanted organ, and reduce the need for current methods of often lifelong treatment with drugs that inhibit the functionality of the immune system. Preclinical development is ongoing with the aim of commencing a Phase I/IIa clinical trial in 2019.

In April, we secured access to adapted clean rooms for the manufacturing of our cell therapy products in accordance with current regulations for pharmaceuticals. This will give us control over all stages of the manufacturing process and may reduce lead times for upcoming clinical trials. We are expecting to receive accreditation for the manufacturing production facilities in 2018.

Like other research-intensive companies that develop new therapies, considerable investment will be required before license agreements or own sales can generate revenue for Idogen. The significant research grant we received from Horizon 2020 (the EU Framework Programme for Research and Innovation) in May and the successful issue of new shares in June have given us the financial resources to drive both IDO 8 and IDO T forward at high speed.

Cell therapy is gaining interest as novel treatment option. One indication of this is Takeda's recent announcement regarding the intention to acquire the stem cell therapy company TiGenix for a total contract value of about SEK 5 billion. Our business model is to enter into collaborations and license agreements based on the clinical trial results in each of our projects, and therefore expect to commence the first clinical trial for IDO 8 by the end of 2018. This will be a transformational step in the development of the company.

Lars Hedbys  
Chief Executive Officer



# Idogen in brief

Idogen (AktieTorget: IDOGEN) is a Swedish biotechnology company based in Lund. Idogen develops tolerogenic cell therapies to prevent the patient's immune system from attacking biological agents, transplanted organs or the body's own cells or tissue. The term "tolerogenic" refers to the immune system's selective tolerance of a specific pathogenic or immune activating antigen following treatment with Idogen's therapy. Idogen's intention is to revolutionise the treatment of several disorders in which the body's immune system does not function as it should, and for which there is a major unmet medical need – such as in autoimmune diseases, organ transplant rejection and in patients who

have developed anti-drug antibodies. Idogen's most advanced product candidate, IDO 8, is designed for patients with severe haemophilia A who have developed anti-drug antibodies against their critical treatment with coagulation factor VIII (factor VIII).

The company also develops IDO T – a tolerogenic cell therapy to prevent organ transplant rejection, primarily kidney transplant rejection. IDO T is expected to reduce the need for immunosuppressive drugs and improve transplant survival, thereby reducing the risk of cancer and infections.



# Tolerogenic cell therapy – individualised treatment for each patient

## WHEN THE IMMUNE SYSTEM HAS BECOME YOUR ENEMY

There are many situations where the body's immune system can hurt us instead of protecting us. One example is when it causes transplant rejection. Another is when the immune system neutralises the activity of biological drugs, in the treatment of haemophilia A with factor VIII, for example. A third example is autoimmune diseases – such as rheumatoid arthritis, inflammatory bowel diseases, type 1 diabetes and multiple sclerosis (MS) – where the immune system attacks the body's own proteins or self-antigens.

## IDOGEN'S TECHNOLOGY

The ability to create a properly functioning immune system that protects and defends the body from invasion by foreign organisms – such as viruses, bacteria and tumours – would revolutionise the treatment of patients with severe chronic illness. Idogen wants to be part of

this revolution. The company contributes by developing cell therapies, which is a different approach to conventional medical therapies. Instead of administering a chemical substance to the body, the patient is treated with their own cells.

Idogen's treatment is based on dendritic cells, types of white blood cells, that play a central role in the immune system, because they control other immune system cells' recognition of what belongs in the body (self) and what is foreign (non-self). When we are exposed to bacteria or viruses, the dendritic cells trigger our immune response. At the same time, they ensure that the immune system does not attack our own body. The dendritic cells that prevent the immune system from attacking the body's own, healthy cells are called tolerogenic. The aim of Idogen's technology is to develop tolerogenic dendritic cells that are programmed for defined molecules or antigens.



*Dendritic cells control other immune system cell's recognition of what is part of us (self) and what is foreign (non-self). The dendritic cells that recognise bacteria or viruses activate our immune system (red) and those that recognise the body's own cells stop the body from attacking its own tissues and create tolerance (green).*

# Idogen's development projects

## IDO 8 – WHEN THE BODY'S IMMUNE SYSTEM ATTACKS FACTOR VIII, A CRITICAL MEDICATION

IDO 8 is Idogen's most advanced project, aimed at developing a tolerogenic cell therapy for patients with severe haemophilia A who have developed inhibitory antibodies against their standard treatment. Idogen's treatment has the potential to restore the original efficacy of factor VIII treatment. The company has chosen haemophilia A as the first indication due to the major unmet medical need of these patients and because the disease has a well-defined antigen, presenting an opportunity to develop an effective treatment for this patient group. Haemophilia A is a rare disease and Idogen has been granted Orphan Drug Designation in Europe for the treatment – a key value-adding step for the company since orphan drug designation provides several advantages, such as less extensive requirements for clinical trials, scientific guidance from the regulator during development and ten-year market exclusivity after launch.

The company expects the first clinical trial to commence at the end of 2018 and have had constructive scientific discussions with the Swedish Medical Products Agency (MPA) regarding the design of the study.

About 50,000 boys and men in the US and Europe are living with haemophilia A, a congenital disease that primarily affects boys and men. The treatment for patients with the severe form of haemophilia A is factor VIII replacement therapy. About 30 percent of the patients treated with factor VIII develop inhibitory antibodies, making the treatment ineffective. This complication can often be managed with regimens to induce immune tolerance, involving frequent injections of a higher doses factor VIII. The treatment is costly and may continue for one or two years. The antibodies remain in about 30 percent of these patients, leaving the patients unable to prevent bleeding. Inhibitor patients are being treated with agents with only short duration of effect, at a cost of as much as SEK 3-8 million per patient a year, to stop acute bleeds.

A new and effective drug for this patient group will soon be launched in the US. One-year treatment costs are believed to be almost SEK 4 million, and analysts estimate that the preparation can reach annual sales of more than SEK 17 billion<sup>1</sup>. However, this drug is associated with the risk of severe side effects, and treatment is lifelong. There are still, therefore, major unmet needs for safer, more cost-effective therapies.



<sup>1</sup> <https://www.fiercepharma.com/regulatory/roche-nabs-pair-blockbuster-fda-approvals-for-hemlibra-gazyva>

## IDO T – WHEN THE BODY'S IMMUNE SYSTEM ATTACKS A TRANSPLANTED ORGAN

The same method that is currently under development for the treatment of haemophilia A can also be used for other indications with only minor adjustments of the production process. The company has therefore made a strategic decision to commence parallel development of a product candidate for kidney transplantation, IDO T. The basic principle is to “teach” the patient’s immune system to recognise and accept the transplanted organ rather than attack it. This could eventually reduce the need for current methods of often lifelong treatment with drugs that inhibit immune system functionality. There is a major unmet need for long-acting, cost-effective and safe treatment to avoid the risk of transplant rejection.

Preclinical development for IDO T is ongoing with the aim of commencing a Phase I/IIa clinical trial in 2019.

Kidney transplants are the most common type of organ transplant and almost 80,000 kidney transplants are performed globally per year, including about 20,000 in Europe<sup>2</sup>. The largest and most serious complication is when the transplant recipient’s immune system attacks, destroys and rejects the donated organ. To prevent this, the transplanted patients – with few exceptions – are given lifelong treatment with a combination of drugs to suppress their immune system. While the proportion of patients who retain a functional transplanted kidney during the first year of transplantation has increased in recent decades, there has not been any improvement in the long-term survival of transplant recipients<sup>3</sup>.

Immunosuppressive therapy also carries a risk of serious infections and cancer. Transplantation is therefore an indication with a major unmet medical need. Idogen’s tolerogenic cell therapy has the opportunity to reduce the need for immunosuppressive drugs and improve transplant survival.



<sup>2</sup> Global Observatory on Donation & Transplantation in collaboration with WHO.

<sup>3</sup> Afzali B, Taylor AL, Goldsmith DJA. What we CAN do about chronic allograft nephropathy: Role of immunosuppressive modulations. *Kidney International*, 2005, 68, 2429-2443.

Wang JH, Skeans MA, Israni AK. Current status of kidney transplant outcomes: dying to survive. *Adv Chronic Kidney Dis*, 2016, 23, 5, 281-286.

# Future and strategy

Idogen's intention is to enter into collaboration and license agreements based on the clinical trial results in each project, and several large pharmaceutical companies have already shown a major interest. In recent years, a number of smaller cell therapy companies have signed collaboration and license agreements with global pharmaceutical companies, with attractive terms. These include Pfizer's agreement with Sangamo Therapeutics for a haemophilia A project, with a total contract value of USD 545 million, including an upfront payment of USD 70 million and double-digit royalties on net sales. As a strategic option, Idogen may bring IDO 8 to market without a partner.

Cell therapies are a recent addition to treatments for severe diseases and only a handful of products have reached the market. In Europe and in the US, a highly promising cell therapy was recently approved for the treatment of cancer, developed by Novartis – one of the largest pharmaceutical companies in the world. The approval is considered an historic step in the establishment of cell therapies, reducing uncertainty among those investors who were previously doubtful about taking a position in this area.

Idogen's method can be adapted to various medical conditions by making minor changes. In close collaboration with a prominent team of researchers at Oxford University, Idogen has conducted testing in an animal model, which showed that Idogen's therapy concept has the potential to be used to relieve the clinical symptoms of rheumatism. In autoimmune diseases, the body's immune system attacks self-

antigens, but this can be prevented by reprogramming the immune system with Idogen's technology. There are currently more than 100 autoimmune disorders without any cure, where most patients have to endure lifelong medication and often major suffering. These include rheumatoid arthritis, type 1 diabetes and multiple sclerosis (MS). In the eight largest markets – the US, France, Germany, Italy, Spain, the UK, Japan and Australia – an estimated 4.4 million patients have been diagnosed and are being treated for rheumatoid arthritis, and about 200,000 new cases are reported every year<sup>4</sup>. The market potential for a rheumatoid arthritis treatment is an estimated SEK 10-20 billion per year for a penetration rate corresponding to 10% of new cases or 1% of existing patients in these markets.

Idogen's new discoveries have expanded the portfolio to a total of five compounds that independently hold potential for the development of proprietary cell therapies. This increases opportunities for out-licensing parts of the project portfolio, which may become a key element of the marketing strategy. Having our own manufacturing competence may facilitate such agreements and the company has therefore made a strategic decision to build up competence and facilities in Lund for manufacturing tolerogenic cell therapies for clinical trials for the indications presented above.

The strong cash position will move both IDO 8 and IDO T forward at high speed. Idogen is also expecting to secure additional financial resources through two warrant conversion programmes that expire in spring 2018 and spring 2019, respectively.

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*Idogen's vision is to develop the first tolerogenic cell therapy with long-term effect for the treatment of patients with large unmet medical needs*

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<sup>4</sup> Global Data, PharmaPoint. Rheumatoid Arthritis – Global Drug Forecast and Market Analysis to 2025. January 2017.

# Financial information

## FINANCIAL PERFORMANCE FOR THE FOURTH QUARTER, 1 OCTOBER-31 DECEMBER 2017

### Other operating income

Other operating income for the quarter amounted to KSEK 0 (0).

### Operating profit/loss

Operating loss for the quarter totalled KSEK 7,289 (-4,255), a change of KSEK 3,034 compared with the year-on-year quarter. During the quarter, additional internal and external resources were allocated to both projects.

### Profit/loss for the period

Loss for the period totalled KSEK 7,315 (-4,255) Loss per share before dilution was SEK 0.35 (-0.36) and loss per share after dilution was SEK 0.19 (-0.36).

### Liquidity and cash flow

- Cash flow from operating activities was KSEK -8,250 (-3,035)
- Cash flow from investing activities was KSEK -2,703 (-163). During the quarter, investments were made in manufacturing equipment.
- Cash flow from financing activities was KSEK 0 (19,095).
- Cash flow for the quarter was KSEK -10,953 (15,898).
- At the end of the period, the Group's cash and cash equivalents amounted to KSEK 36,943 (18,502).

### Financial position

At 31 December 2017, the equity/assets ratio was 90% (90) and equity amounted to KSEK 39,888 (18,597). On the same date, total assets amounted to KSEK 44,152 (20,668).

## FINANCIAL PERFORMANCE FOR THE FULL-YEAR PERIOD, 1 JANUARY-31 DECEMBER 2017

### Other operating income

Other operating income for the full-year period was KSEK 0 (53).

### Operating profit/loss

Operating loss for the full-year period totalled KSEK 21,299 (loss: 12,583), a change of KSEK 8,716 compared with the year-earlier period. During the year, considerable resources were allocated to the development projects.

### Profit/loss for the period

Loss for the period totalled KSEK 21,322 (loss: 12,599). Loss per share before dilution was SEK 1.32 (loss: 1.22) and loss per share after dilution was SEK 0.88 (loss: 1.03).

### Liquidity and cash flow

- Cash flow from operating activities was KSEK -19,906 (-11,407)
- Cash flow from investing activities was KSEK -4,266 (-661)
- Cash flow from financing activities was KSEK 42,613 (19,028)  
Cash flow for the full-year period was KSEK 18,441 (6,960).
- At year-end, cash and bank balances amounted to KSEK 36,943 (18,502).

In May 2017, Idogen was granted research funding of MEUR 2.9 (just over MSEK 28) by Horizon 2020 (the EU Framework Programme for Research and Innovation) for development of the company's tolerogenic cell therapy for the treatment of antibodies against factor VIII in patients with severe haemophilia A. The project will continue for 33 months and the full amount of funding will be paid out over the course of the project. In January, MEUR 1.2 had been received and the remaining amount will be paid out over the coming years.

### Financial position

At 31 December 2017, the equity/assets ratio was 90% (90) and equity amounted to KSEK 39,888 (18,597). On the same date, total assets amounted to KSEK 44,152 (20,668).

## NEW SHARE ISSUE AND TWO CLASSES OF SUBSCRIPTION WARRANTS

During May and June of 2017, Idogen conducted a unit's issue comprising shares and two classes of subscription warrants. The issue was registered

and after the end of the second quarter, had raised proceeds of MSEK 42.6 for the company after issue costs. The capital raised by the issue and the conversion of subscription warrants, combined with the research funding of just over MSEK 28 from the EU, is expected to enable the implementation of two Phase I/II clinical trials.

In addition to shares, those who subscribed to the issue also received two classes of warrants. There are 8,555,883 outstanding Class TO2 subscription warrants, and 8,555,883 Class TO3 subscription warrants. The subscription warrants are traded on AktieTorget. Upon full exercise of the subscription warrants, Idogen will raise proceeds ranging from MSEK 48-73 for Class TO2, and from MSEK 48-106 for Class TO3 after issue costs. Upon full subscription of the warrants, Idogen's will raise total proceeds of at least MSEK 96 and no more than MSEK 179 after issue costs.

#### **Summary of the terms of the TO2 subscription warrants**

Holders of the subscription warrants are entitled, for each subscription warrant, to subscribe for one new share at a subscription price corresponding to 70% of a volume-weighted average price for the company's shares during the period of 9-27 April 2018. However, the subscription price must not be less than SEK 6 per share or more than SEK 9 per share. Subscription warrants may be exercised to subscribe for shares during the period of 3-18 May 2018.

#### **Summary of the terms of the TO3 subscription warrants**

Holders of the subscription warrants are entitled, for each subscription warrant, to subscribe for one new share at a subscription price corresponding to 70% of a volume-weighted average price for the company's shares during the period of 25 February-15 March 2019. However, the subscription price must not be less than SEK 6 per share or more than SEK 13 per share. Subscription warrants may be exercised to subscribe for shares during the period of 19 March-1 April 2019

#### **INVESTMENTS**

Idogen's investments have previously comprised costs for patents only. During the period, the facilities were refurbished for manufacturing tolerogenic cell therapies for clinical trials.

Equipment has been purchased for the laboratory

and for production. During the year, MSEK 4.2 (0.6) was invested.

#### **EVENTS AFTER THE BALANCE-SHEET DATE**

No other significant events occurred after the end of the financial year that affect the year-end financial statements.

#### **EMPLOYEES AND ORGANISATION**

At 31 December 2017, the number of employees was nine.

Idogen's organisation comprises all of the competencies and experience required to run the company. Close collaboration has been established with a number of key consultants in patents, preclinical management, clinical trials, cell therapy, pharmaceutical development, manufacturing, documentation, quality-assurance, finance and legal matters.

#### **RISKS AND UNCERTAINTIES**

In addition to general uncertainty related to research and development activities and delays in clinical trials, there are no known trends, uncertainties, potential claims or other demands, commitments or events that are reasonably likely to have a material adverse effect on the company's prospects. A detailed presentation of various risks can be found in the prospectus prepared in conjunction with the new share issue (pages 14-16) and in the most recent Annual Report (page 21).

#### **EQUITY**

Equity was mainly impacted by the issue, and earnings during the period. At 31 December 2017, equity amounted to MSEK 39.9 (18.6).

#### **THE SHARE**

Profit after tax divided by the number of shares for the period amounted to a loss of SEK 1.32 (-1.22) for the reporting period. At the end of December 2017, Idogen had approximately 2,200 shareholders. The number of shares increased by 8,555,883 during the year, from 12,222,589 to 20,778,472 shares. In addition to the new shares, 8,555,883 Class TO2 and 8,555,883 Class TO3 subscription warrants were issued.

Name	No. of shares	Percentage of votes/capital (%)
HCN Group AB	2,252,234	10.8
Avanza pension	1,017,009	4.9
Ventac Holdings (Cyprus) Ltd	896,527	4.3
Leif G Salford, directly and via companies	751,585	3.6
Others	15,139,117	72.9
<b>Total</b>	<b>20,778,472</b>	<b>100.0</b>

## GENERAL MEETING AND ANNUAL REPORT

The Annual General Meeting (AGM) will be held on 24 April 2018 at 3:00 p.m. in Gamla Gästmatsalen, Medicom Village, Scheelevägen 2, Lund, Sweden. Shareholders will be notified by announcement in *Post- och Inrikes Tidningar* (the Swedish Official Gazette) and on the company's website, as well as by announcement in *Svenska Dagbladet* that notice has been given, no earlier than six weeks and no later than four weeks before the Meeting.

Shareholders who wish to have a matter addressed by the AGM should send a written request to Idogen AB, Att: Board of Directors, Medicom Village, Scheelevägen 2, SE-223 81 Lund, Sweden. Such requests must be received by the Board of Directors no later than seven weeks prior to the AGM, or within sufficient time for the matter to be included, if requested, in the notice of the AGM.

Idogen's 2017 Annual Report is expected to be available for download on the company's website by 15 April 2018.

## NOMINATION COMMITTEE

In accordance with the AGM's decision, the three largest shareholders at the end of the third quarter of 2017 were asked to nominate their representatives for the Nomination Committee. The following representatives – Cecilia Hollerup for HCN Group, Rolf Ehrnström for Ventac Holdings (Cyprus) Ltd and Leif G Salford – were appointed to the Nomination Committee. The Nomination Committee's proposals will be presented in mid-March.

## PROPOSED ALLOCATION OF PROFIT

The Board of Directors and Chief Executive Officer propose that no dividend (SEK 0.0/share, the same as in the preceding year) be paid for the 1 January 2017-31 December 2017 financial year.

## ACCOUNTING POLICIES

This year-end report has been prepared in accordance with RFR 2, Accounting for Legal Entities. The report has been prepared in accordance with IAS 34, with consideration for the exceptions and additions to IFRS specified in RFR 2. The company is not included in any group, which is why IFRS-compliant financial statements are not applicable.

This is the company's first report in accordance with RFR 2. The transition to presentation in accordance with RFR 2 has not had any effect on the balance sheet at the beginning of 2016, nor on comparative periods.

The company has only one reportable segment.

## AUDITOR'S REPORT

This year-end report has not been audited.

## **ASSURANCE BY THE BOARD OF DIRECTORS**

The Board of Directors and Chief Executive Officer certify that this interim report presents a true and fair view of the company's operations, financial position and results and describes the significant risks and uncertainties faced by the company.

Lund, 15 February 2018

The Board of Directors of Idogen AB

Agneta Edberg, Chairman

Ulf Blom

Christina Herder

Karin Hoogendoorn

Leif G. Salford

Lars Hedbys, Chief Executive Officer

## CONDENSED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

(Amounts in KSEK)	2017	2016	2017	2016
	3 months	3 months	12 months	12 months
	Oct-Dec	Oct-Dec	Jan-Dec	Jan-Dec
Net sales				
Other operating income	0	0	0	53
<b>Total income</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>53</b>
<i>Operating expenses</i>				
Other external costs	-5,321	-3,260	-16,452	-9,928
Employee benefit expenses	-1,893	-995	-4,772	-2,708
Depreciation of tangible assets	-75		-75	
<b>Operating profit/loss</b>	<b>-7,289</b>	<b>-4,255</b>	<b>-21,299</b>	<b>-12,583</b>
Interest income and similar profit/loss items				2
Interest expense and similar profit/loss items	-26	0	-23	-18
<b>Profit/loss before tax</b>	<b>-7,315</b>	<b>-4,255</b>	<b>-21,322</b>	<b>-12,599</b>
Tax				
<b>PROFIT/LOSS FOR THE PERIOD</b>	<b>-7,315</b>	<b>-4,255</b>	<b>-21,322</b>	<b>-12,599</b>
<b>OTHER COMPREHENSIVE INCOME</b>				
<b>PROFIT/LOSS FOR THE PERIOD</b>	<b>-7,315</b>	<b>-4,255</b>	<b>-21,322</b>	<b>-12,599</b>

## CONDENSED STATEMENT OF FINANCIAL POSITION

(Amounts in KSEK)	31 Dec 2017	31 Dec 2016
<b>ASSETS</b>		
<b>Intangible assets</b>		
Patents	3,229	1,803
<b>Total intangible assets</b>	<b>3,229</b>	<b>1,803</b>
<b>Tangible assets</b>		
Leasehold improvements	663	
Equipment, tools, fixtures and fittings	2,100	
<b>Total tangible assets</b>	<b>2,763</b>	
Prepaid expenses and accrued income	1,215	363
Cash and bank balances	36,943	18,502
<b>Total current assets</b>	<b>38,158</b>	<b>18,865</b>
<b>TOTAL ASSETS</b>	<b>44,152</b>	<b>20,668</b>
<b>EQUITY</b>		
<i>Restricted equity</i>		
Share capital	1,454	855
Reserve fund for development expenses	2,087	661
<b>Total restricted equity</b>	<b>3,541</b>	<b>1,516</b>
<i>Non-restricted equity</i>		
Share premium reserve	42,015	18,857
Profit brought forward	15,654	10,822
Profit/loss for the year	-21,322	-12,599
<b>Total non-restricted equity</b>	<b>36,347</b>	<b>17,080</b>
<b>Total equity</b>	<b>39,888</b>	<b>18,596</b>
<b>Current liabilities</b>		
Accounts payable – trade	3,343	996
Other liabilities	215	88
Accrued expenses and deferred income	706	988
<b>Total current liabilities</b>	<b>4,264</b>	<b>2,072</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>44,152</b>	<b>20,668</b>

## CONDENSED STATEMENT OF CHANGES IN EQUITY

(Amounts in KSEK)	Share capital	Reserve fund for Development expenses	Share premium reserve	Profit brought forward	Profit/loss for the year	Total equity
<b>Opening balance at 1 Jan 2016</b>	685		23,148	-2,007	-9,658	12,168
Appropriation of profits as per AGM			-23,148	13,490	9,658	-
New issue	170		19,728			19,898
Capital raising expenses			-870			-870
Allocation to reserve fund for development expenses		661		-661		
Profit/loss for the period					-12,599	-12,599
<b>Closing balance at 31 Dec 2016</b>	855	661	18,857	10,822	-12,599	18,596
(Amounts in KSEK)	Share capital	Reserve fund for development expenses	Share premium reserve	Profit brought forward	Profit/loss for the year	Total equity
<b>Opening balance at 1 Jan 2017</b>	855	661	18,857	10,822	-12,599	18,596
Appropriation of profits as per AGM			-18,858	6,259	12,599	
New issue	599		50,736			51,335
Capital raising expenses			-8,722			-8,722
Allocation to reserve fund for development expenses		1,427		-1,427		
Profit/loss for the period					-21,322	-21,322
<b>Closing balance at 31 Dec 2017</b>	1,454	2,087	42,015	15,654	-21,322	39,888

### Shareholdings disclosure

	No. of shares
Holding/value at beginning of the year	12,222,589
Holding/value at 31 Dec 2017	20,778,467
Subscription warrants issued, TO2	8,555,883
Subscription warrants issued, TO3	8,555,883
<b>Total number of shares after fully subscribed issue</b>	<b>37,890,238</b>

## CONDENSED STATEMENT OF CASH FLOWS

(Amounts in KSEK)	2017	2016	2017	2016
	3 months Oct-Dec	3 months Oct-Dec	12 months Jan-Dec	12 months Jan-Dec
<b>OPERATING ACTIVITIES</b>				
Operating profit/loss before financial items	-7,289	-4,255	-21,299	-12,583
Reversal of depreciation/amortisation	75		75	
Interest received				2
Interest paid	-26		-23	-18
<b>Cash flow from operating activities before changes in working capital</b>	<b>-7,240</b>	<b>-4,255</b>	<b>-21,247</b>	<b>-12,599</b>
Increase (Decrease) in prepaid expenses and accrued income	-303	230	-852	231
Increase (Decrease) in accounts payable	-678	217	2,347	607
Increase (Decrease) in other current liabilities	-30	773	-155	354
<b>Cash flow from operating activities</b>	<b>-8,250</b>	<b>-3,035</b>	<b>-19,906</b>	<b>-11,407</b>
<b>Investing activities</b>				
Investment in intangible assets	-466	-163	-1,427	-661
Investment in tangible assets	-2,237		-2,839	
<b>Cash flow from investing activities</b>	<b>-2,703</b>	<b>-163</b>	<b>-4,266</b>	<b>-661</b>
<b>Financing activities</b>				
New issue		19,095	42,613	19,028
<b>Cash flow from financing activities</b>	<b>0</b>	<b>19,096</b>	<b>42,613</b>	<b>19,028</b>
Cash flow for the period	-10,953	15,898	18,441	6,960
Cash and cash equivalents at the beginning of the period	47,896	2,604	18,502	11,542
<b>Cash and cash equivalents at the end of the period</b>	<b>36,943</b>	<b>18,502</b>	<b>36,943</b>	<b>18,502</b>

## NOTES TO THE FINANCIAL STATEMENTS

### Accounting policies

This year-end report has been prepared in accordance with RFR 2, Accounting for Legal Entities. The report has been prepared in accordance with IAS 34, with consideration for the exceptions and additions to IFRS specified in RFR 2. The company is not included in any group, which is why fully compliant IFRS financial statements are not applicable. The company's financial statements are prepared in accordance with the Swedish Annual Accounts Act and RFR 2, Accounting for Legal Entities.

This is the company's first report in accordance with RFR 2. The transition to presentation in accordance with RFR 2 has not had any effect on the balance sheet at the beginning of 2016, nor on comparative periods.

Under RFR 2 (issued by the Swedish Financial Reporting Board), a Parent Company must apply International Financial Reporting Standards (IFRS) as adopted by the EU, as far as this is possible within the framework of the Swedish Annual Accounts Act and the Swedish Pension Obligations Vesting Act, and with consideration for the relationship between accounting and taxation. The Recommendation sets out the exceptions and additions to IFRS that may be applied.

The company has only one reportable segment.

Disclosures according to IAS 34 Interim Reporting are provided in the Notes, and in other parts of the year-end report.

The company has applied the same recognition and measurement methods as in the most recent annual financial statements.

### Effects of new or changed IFRS standards on the company's accounting policies

#### Changed accounting policies

The changes in RFR 2, Accounting for Legal Entities, that are now effective and apply for the 2017 financial year mainly pertain to the following areas:

- Amendments to IAS 7 – Statement of Cash Flows (Disclosure Initiative)

- Amendments to IAS 12 – Income Taxes (Recognition of Deferred Tax Assets for Unrealised Losses)

These changes have not had any impact on the company.

#### *Adopted changes in RFR 2 that are not yet effective*

The Swedish Financial Reporting Board has also adopted the following changes that are not yet effective.

#### *IFRS 9 – Financial Instruments*

This new standard for financial instruments addresses the classification, measurement and recognition of financial assets and liabilities. The changes in RFR 2 in relation to IFRS 9 are effective for reporting periods starting on or after 1 January 2018. This standard does not have any impact on the company at present.

#### *IFRS 15 – Revenue from Contracts with Customers*

IFRS 15 will replace IAS 18 Revenue, IAS 11 Construction Contracts and related interpretations. This new standard uses a new five-step model framework to improve revenue recognition by identifying when control of a product or service is transferred to the customer. The changes in RFR 2 in relation to IFRS 15 become effective on or after 1 January 2018. This standard does not have any impact on the company at present.

#### *IFRS 16 – Leases*

This new leasing standard mainly entails changes in how lessees recognise leases. A lessee is required to recognise all leases as assets and liabilities on the balance sheet, unless the lease term is 12 months or less or the underlying asset has a low value. The changes in RFR 2 in relation to IFRS 16 become effective for reporting periods starting on or after 1 January 2019. The company has not yet evaluated the effects of IFRS 16.

#### **Foreign currencies**

Monetary assets and liabilities denominated in foreign currency are reported using the closing rate. Transactions in foreign currency are restated using the exchange rate at the date of the transaction.

## **Income taxes**

Income tax recognition includes both current and deferred taxes. The tax is recognised in profit or loss, unless it pertains to items recognised directly in equity. In such cases, the tax is also recognised in equity. Deferred tax is recognised according to the "balance sheet" method for all significant temporary differences. A temporary difference exists when the carrying amount of an asset or liability is greater than its tax base.

Deferred tax is calculated using the tax rate decided on the balance-sheet date (currently 22%). Deferred tax assets are recognised to the extent it is probable that future tax credits will be available, against which the temporary differences can be utilised. At 31 December 2017, carried forward tax loss amounted to MSEK 56.5, representing a deferred tax asset of MSEK 12.4. A deferred tax asset was not recognised for the carried forward tax loss because management cannot yet determine when the tax loss can be utilised against any future tax credit. As a result, the company has no tax expense, nor measurement of deferred tax.

## **Intangible assets**

Because the company is in a research phase, expenses are recognised as costs. Development expenses are recognised as an intangible asset using the revaluation model because they meet the following criteria:

- it is technically and commercially feasible to complete the intangible asset
- intent and ability to sell or use the intangible asset
- it is probable that the asset will generate future economic benefits
- the costs can be measured reliably

The cost of an internally generated intangible asset comprises all directly attributable costs necessary to create, produce, and prepare the asset to be capable of operating in the manner intended by management. Internally generated intangible assets are amortised over their estimated useful lives. No amortisation has commenced since carrying amounts pertain to granted and pending patent applications. Amortisation will only begin once the commercial use of various patents has started.

## **Tangible assets**

Tangible assets comprise expenses for improvements to leaseholds and equipment. Tangible assets are recognised at cost less depreciation. The cost includes expenses directly attributable to the acquisition of the asset.

The straight-line depreciation method is used over the estimated useful life of the asset as follows:

Expenses for improvements to	
Leaseholds	4 years
Equipment	5 years

## **Leases**

All leases for which the company is the lessee are recognised as operating leases. Lease payments are recognised as a cost on a straight-line basis over the lease term.

## **Provisions**

Provisions are recognised when the company has, or may be considered to have, an obligation resulting from a past event and it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation. One condition is that the amount of the obligation can be estimated reliably.

## **Financial Instruments**

Financial instruments recognised in the balance sheet include accounts receivable and other receivables, current investments and accounts payable. Financial liabilities are derecognised when the obligations have been settled or otherwise terminated.

## **Accounts receivable and other receivables**

The company has no accounts receivable. Other receivables are recognised as current assets, except those maturing more than 12 months after the balance-sheet date, which are classified as non-current assets. Receivables are recognised at the amount expected to be received, adjusted for individually assessed doubtful accounts.

## **Other asset, provisions and liabilities**

Other asset, provisions and liabilities are recognised at cost unless otherwise stated below.

## **Statement of cash flows**

The cash flow statement is prepared using the indirect method. The recognised cash flow only

includes transactions resulting in cash inflows and cash outflows. The company classifies cash and cash equivalents, in addition to liquid funds, as balances of liquid current assets that can easily be converted into a known cash amount and carry an insignificant risk of changes in the asset value.

### **Definitions of key figures**

#### Working capital

Total current assets (including cash and cash equivalents) less current liabilities.

#### Acid-test ratio

Total current assets (including cash and cash equivalents) relative to current liabilities.

#### Equity/assets ratio

Equity and untaxed reserves (less deferred tax) relative to total assets.

#### Earnings per share before dilution

Profit after tax divided by the average number of shares for the period.

### **Estimates and assessments**

As for most development projects, the company's operations are subject to inherent risk factors that could result in the delay or non-achievement of a final sales success. In addition to general uncertainty related to research and development activities and delays in clinical trials, there are no known trends, uncertainties, potential claims or other demands, commitments or events that are reasonably likely to have a material adverse effect on the company's prospects.

Company management makes continuous estimates and assumptions about the future. Actual outcomes will rarely be precisely in line with these estimates. The estimates and assumptions with a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities are primarily intangible assets. Where there is an indication of impairment of an asset, the recoverable amount of the asset is determined. If the carrying amount of the asset exceeds its recoverable amount, the carrying amount of the asset is reduced to its recoverable amount.

### **Loans and equity**

At the end of the period, the number of shares was 20,778,467 (12,222,589). The number of outstanding subscription warrants was 8,555,883 for TO2, and 8,555,883 for TO3.

### **Related-party transactions**

The Chief Executive Officer is not employed by the company and renders services under a consultancy agreement. For 2017, the CEO, Lars Hedbys (Ventac Partners AB) invoiced consulting fees totalling SEK 1,474,400 (1,483,200). Lars Hedbys is a partner in Ventac Holdings (Cyprus) Ltd.

In addition to Board duties, the Chairman of the Board, Agneta Edberg, was paid SEK 35,040 (0) for her contributions to Vinnova's CAMP project.

### **Contingent liabilities**

Idogen has no contingent liabilities.

## **FINANCIAL CALENDAR**

Interim report, January-March 2018	24 April 2018
Interim report, January-June 2018	21 August 2018
Interim report, January-September 2018	23 October 2018
Year-end report 2018	12 February 2019

## **IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT:**

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*This information is such that Idogen AB is obligated to publish under the EU Market Abuse Regulation (MAR) and the Swedish Securities Market Act. The information was submitted for publication, through the agency of the contact persons set out above, on 15 February 2018.*

