



# ANNUAL REPORT

## 2015

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# **BUSINESS SECTION**

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### INTRODUCTION

The Company is a clinical stage biopharmaceutical company focused on research, development and future commercialisation of cell-based immunotherapy products for the treatment of blood cancers and inherited blood disorders. The Company believes that its innovative products have the potential to address the current risks and limitations connected with allogeneic hematopoietic stem cell transplantation (HSCT), being graft-versus-host disease (GVHD), cancer relapse, opportunistic infections and limited matched donor availability. HSCT is generally regarded as the most effective curative approach to blood cancers and certain inherited blood disorders and the Company expects that HSCT could become a first-choice treatment for these diseases once current risks and limitations are addressed, thereby meeting a significant unmet medical need with its products.

The Company is based in Amsterdam-Duivendrecht, the Netherlands and its shares are listed on Euronext Amsterdam and Euronext Brussels (ticker symbol: KDS). Further information can be found at: [www.kiadis.com](http://www.kiadis.com)

### DISEASES

#### *Blood cancers (leukaemia)*

Leukaemia is a cancer of the bone marrow and blood. The four major types of leukaemia are acute myeloid leukaemia (AML), acute lymphoblastic leukaemia (ALL), chronic myeloid leukaemia (CML) and chronic lymphocytic leukaemia (CLL). Myelodysplastic syndrome (MDS) is a premalignant blood disorder that often develops into AML.

All leukaemias originate in the bone marrow where a stem cell undergoes a mutation and becomes a leukaemia cell. Once this leukaemia cell mutates, it multiplies into billions of cells. These cells, called "leukaemic blasts", do not function normally but grow and survive better than normal cells. The presence of the leukaemic blasts blocks the production of normal white blood cells which are key for a proper functioning of the immune system. As a result, the number of healthy white blood cells is usually lower than normal, severely affecting a patient's immunoprotection.

Acute leukaemias (AML and ALL) are rapidly progressing diseases whereas chronic leukaemias (CML and CLL) usually progress more slowly, with patients having more functional cells for a longer period of time. The difference between those cancer types are also reflected in the differing drug approaches for each type of leukaemia.

While people can get leukaemia at different ages, it is most common in people over the age of sixty. The most common types of leukaemia in adults are AML and CLL. ALL is the most common form of leukaemia in children.

The aim of leukaemia treatment is to achieve complete removal of all cancer cells (complete remission). This means that after treatment no sign of the disease remains, there are no detectable blasts in the bone marrow, and the patient returns to good health. In general, patients are considered cured after five years of complete remission. Patients with an acute leukaemia (ALL and AML) need to start treatment as soon as possible after diagnosis as these diseases progress rapidly, ultimately leading to death.

First and second line treatments for leukaemia include high doses of chemotherapy that may be combined with different drugs, such as cytarabine and anthracyclines. The initial phase of chemotherapy is called "induction therapy". Induction therapy may involve the simultaneous use of multiple drugs or a planned sequence of treatments. The goal of induction therapy is to deplete blood and marrow of leukaemic blast cells that will be checked by histopathology (i.e. microscopic examination of tissue). Generally, if blast cells are still evident after the first course of induction chemotherapy, a second course of the same chemotherapy is administered.

Most patients achieve initial remission. However, some patients have residual leukaemic cells in their marrow even after intensive treatment. This is referred to as "refractory leukaemia". In other patients leukaemic cells reappear. This is referred to as "relapsed leukaemia".



With refractory leukaemia, approaches such as using drugs not used in the first course of treatment may be administered in an effort to induce remission. In relapsed patients, further prognosis and treatment will be influenced by the duration of the previous remission, the patient's age and the cytogenetic findings in the leukaemia.

HSCT is generally regarded as the most effective curative approach in post remission therapy for acute leukaemia. During HSCT treatment, the bone marrow harbouring the leukaemic cells is completely destroyed and entirely replaced with stem cells from a healthy donor.

This procedure is not without inherent risks. The four major risks and limitations that prevent HSCT from broader application are:

- opportunistic infections;
- Graft-versus-Host-Disease (GVHD);
- cancer relapse; and
- donor availability

Mitigating the risks associated with HSCT should allow broader use of this therapy for patients with blood cancers.

Recent developments in cell-based immunotherapy have resulted in approaches which may allow more patients with blood cancers to go into remission, including various CAR-T approaches. These patients will then be eligible for curative HSCT.

#### *Inherited blood disorders (thalassaemia)*

Thalassaemia is a heterogeneous group of inherited blood disorders arising from defects in the genes that encode the two forms of haemoglobin (alpha and beta), resulting in improper oxygen transport and destruction of red blood cells in a patient.

Haemoglobin is the molecule in red blood cells that carries oxygen from the lungs to the body's tissues and returns carbon dioxide from the tissues back to the lungs. Haemoglobin is a four-subunit protein complex formed of two  $\alpha$ -subunits and two  $\beta$ -subunits, each with an iron-containing heme group that binds to, and carries oxygen molecules within, red blood cells. Due to spontaneous mutation, haemoglobin gene variants are present to a low degree in all populations. Although most gene variants are rare and many are harmless, certain mutations result in severe haemoglobin disorders.

The most common severe haemoglobin disorder is related to mutations in the  $\beta$ -subunits and is thus termed  $\beta$ -thalassaemia. If both genes are affected, symptoms are much more severe and the disease is then referred to as  $\beta$ -thalassaemia major.

The defects in the genes result in ineffective formation of red blood cells and damage to existing red blood cells. As a result,  $\beta$ -thalassaemia major patients typically present with life-threatening anaemia within the first year of life and if left untreated will have a life expectancy of no more than three years. Other symptoms include jaundice, enlarged organs, misshapen bones and stunted growth.

There is currently no approved curative treatment for  $\beta$ -thalassaemia major. Its main symptom, anaemia, is treated through regular and lifelong red blood cell transfusions, which are generally needed every two to four weeks. However, this frequently leads to iron overload, which is the principal cause of mortality in  $\beta$ -thalassaemia major patients. To control iron overload, iron chelation therapy is required as the standard treatment in these patients and typically begins after patients have received approximately twenty transfusions during their lifetime.

The course of the disease depends largely on whether patients are maintained on an adequate transfusion and iron chelation regime. Poor compliance with transfusion or iron chelation is associated with a poor prognosis and shortened survival. However, even with the standard of care, patients are at risk of infection from transfusions as well as toxicities related to iron chelation therapy.

Given the reduction in quality of life, morbidity and mortality in combination with the significant healthcare burden, there is need for a curative treatment for the disorder.

## PRODUCTS

The Company's lead product ATIR101 is being tested using a single-dose regimen in an open-label fully enrolled Phase II trial in patients with blood cancer who have not found a matching donor and where a partially matched (haploidentical) family member is used as donor for HSCT. The primary endpoint of transplant-related mortality at 6-months post-HSCT for the last patient in this trial was reached at the end of Q1, 2016 and top-line results were announced on 4 April 2016. In addition, the Company is enrolling blood cancer patients in a further Phase II clinical trial to study the safety and efficacy of administering a second dose of ATIR101 to further improve the HSCT outcome.

ATIR101 (Allodepleted T-cell Immunotherapy) provides for a safe donor lymphocyte infusion (DLI) from a partially matched (haploidentical) family member without the risk of causing severe Graft-versus-Host-Disease (GVHD). The T-cells in ATIR101 will help fight infections and remaining tumour cells and thereby bridge the time until the immune system has fully re-grown from stem cells in the transplanted graft.

In ATIR101, T-cells that would cause GVHD are eliminated from the donor lymphocytes using the Company's photodepletion technology, minimising the risk of GVHD and eliminating the need for prophylactic immune-suppression. At the same time, ATIR101 contains potential cancer killing T-cells from the donor that could eliminate residual cancer cells and help prevent relapse of the disease, known as the Graft-versus-Leukaemia (GVL) effect.

Therefore, ATIR101, administered as an adjunctive immuno-therapeutic on top of HSCT, provides the patient with functional, mature immune cells from a partially matched family donor that can fight infections and tumour cells but that do not cause GVHD. ATIR101 thus has the potential to make curative HSCT a viable option to many more patients.

ATIR101 has been granted Orphan Drug Designations both in the US and Europe.

Another product of the Company, ATIR201, will be developed for inherited blood disorders with an initial focus on thalassaemia, an inherited blood disorder which results in improper oxygen transport and destruction of red blood cells in a patient. The Company is collaborating with the Thalassaemia International Federation (TIF), an internationally renowned organisation that seeks to address the needs of patients, carers, healthcare professionals and the general public in the area of thalassaemia.

## STRATEGY

### *To advance ATIR101 to commercialisation*

The Company aims to advance ATIR101 to commercialisation. Based on the positive results on the primary endpoint of its single dose Phase II trial, as announced on 4 April 2016, the Company is preparing a randomised controlled Phase III trial, using a larger group of patients and will work on its clinical development plan accordingly. This Phase III trial will be conducted in order to seek approval in the European Union, the United States and Canada. The Company will also explore a potential early submission for conditional approval in the European Union and Canada, based on results of the Phase II trial.

### *To expand ATIR into additional haematological disorders*

In addition to ATIR101, the Company plans to develop product candidates for other haematological diseases and indications. Replacing diseased bone marrow and the blood forming stem cells with healthy stem cells from a suitable donor can, in principle, cure inherited blood disorders, as well as blood cancers. This is not yet routinely performed due to the high-risk nature of eliminating and replacing the patient's diseased blood forming system. The transplant-related risks of dying from infections or GVHD are the same as in blood cancers. Use of ATIR in conjunction with HSCT has the potential to minimise those risks and may also render HSCT a preferred option in diseases other than blood cancers. The Company is developing a clinical development program for the treatment of thalassaemia. Further work is being undertaken to consider a range of different applications, all of which can expand or alter the standard of care provided to those otherwise susceptible to the above complications.



### *To expand its suite of cell-based immunotherapy products*

The Company is conducting further research and business development activities to license or develop technology in the field of cell-based immunotherapy. The Company is seeking further opportunities and continues to search for additional, complementary technology it might license or acquire, that is consistent with its current or future business practices.

### *To enter into industrial partnerships with pharmaceutical and biotechnology companies*

The Company continues to explore ways in which it can collaborate with other companies. Future collaborations or partnerships may include working with partners and sharing the risk of additional clinical studies, granting licenses for commercialising the Company's technology in different geographic markets or developing the Company's technology in combination with other treatments in order to offer complementary solutions to different patients to maximise the value of ATIR.

### *To expand and defend its patent portfolio protecting its technology platforms*

The Company seeks to expand and protect its product candidates and technologies by filing and prosecuting patent applications in major commercially relevant territories and countries.

The Company has historically focused on the United States and the European Union and may in the future seek patent protection in China and other attractive markets.

### OPERATIONAL HIGHLIGHTS

- Realisation of positive data from the single dose Phase II trial with ATIR101. (Positive results on primary endpoint of this study were reported on 4 April 2016).
- Enrolment first patient into repeat-dosing Phase II trial with ATIR101.
- Establishment of a closed manufacturing process.
- Received Advanced Therapy Medicinal Product certificate for manufacturing quality and non-clinical data by the European Medicinal Agency.
- Collaboration with the Thalassaemia International Federation.
- Listing on Euronext Amsterdam and Euronext Brussels.

### FINANCIAL HIGHLIGHTS

- Operating loss increased to EUR16.0 million in 2015 from a loss of EUR6.2 million in 2014. Net loss increased from EUR7.8 million in 2014 to EUR16.5 million in 2015.
- Operating expenses for 2015 included non-cash share-based payments of EUR7.8 million.
- The equity position improved significantly and increased to EUR25.7 million at year-end 2015 compared to EUR2.7 million at the end of 2014. This is mainly due to the successful completion of the Company's Initial public Offering (IPO) in July 2015 in which the Company raised EUR34.7 million in gross proceeds.
- With net proceeds of EUR31.2 million raised in the IPO, the Company's cash position improved to EUR28.7 million at year-end 2015, which is an increase of EUR23.0 million compared to cash of EUR5.7 million at the end of 2014.

## FORWARD-LOOKING STATEMENTS

This annual report is provided to you solely for your information. This annual report, which has been prepared by the Company may not be reproduced in any form, further distributed or passed on, directly or indirectly, to any other person, or published, in whole or in part, for any purpose. Any failure to comply with these restrictions may constitute a violation of applicable securities laws. For the purposes of this notice, “annual report” means this document, its contents or any part of it.

This annual report does not, and is not intended to, constitute or form part of, and should not be construed as, an offer to sell, or a solicitation of an offer to purchase, subscribe for or otherwise acquire, any securities of the Company, nor shall it or any part of it form the basis of or be relied upon in connection with or act as any inducement to enter into any contract or commitment or investment decision whatsoever. This annual report is not an offer of securities for sale in the United States. The securities of the Company have not been registered under the us securities act of 1933, as amended (the “securities act”) or with any securities regulatory authority of any state or other jurisdiction of the United States and may not be offered or sold in the United States unless registered under the securities act or pursuant to an exemption from such registration.

This annual report is made available on the express understanding that it does not contain all information that may be required to evaluate, and will not be used by the recipients in connection with, the purchase of or investment in any securities of the Company. This annual report is accordingly not intended to form the basis of any investment decision and does not constitute or contain (express or implied) any recommendation by the Company or any of its directors, officers, employees, agents, affiliates or advisers.

Certain information in this annual report is based on management estimates. Such estimates have been made in good faith and represent the current beliefs of applicable members of the board of the Company (the Board). Those Board members believe that such estimates are founded on reasonable grounds. However, by their nature, estimates may not be correct or complete. Accordingly, no representation or warranty (express or implied) is given that such estimates are correct or complete.

This annual report may include statements that are, or may be deemed to be, “forward-looking statements”. These forward-looking statements can be identified by the use of forward-looking terminology, including but not limited to the terms “believes”, “estimates”, “anticipates”, “expects”, “intends”, “may”, “will”, or “should”, and include statements the Company makes concerning the intended results of its strategy. By their nature, forward-looking statements involve risks and uncertainties and readers are cautioned that any such forward-looking statements are not guarantees of future performance. The Company’s actual results may differ materially from those predicted by the forward-looking statements. The Company undertakes no obligation to publicly update or revise forward-looking statements, except as may be required by law.

## MESSAGE FROM THE CEO

Dear Shareholders,

It is my pleasure presenting you our first Annual Report as a listed company and I would like to welcome our new shareholders. Last year was a highly productive year for Kiadis Pharma. On 2 July 2015 we celebrated the successful listing of the Company on Euronext Amsterdam as well as on Euronext Brussels. The listing is providing us with greater financial flexibility and is raising our public profile. It has enabled us to further finance the execution of our strategy, and in particular to finance the further clinical development of our lead product ATIR101.

We have made significant progress in developing ATIR101. During 2015 full enrolment of our single dose Phase II trial was accomplished and positive results from this trial have been realized. The Company presented positive data from this trial at the American Society of Hematology (ASH) Annual Meeting in December 2015 and presented positive results on the primary endpoint of this trial at the Annual Meeting of the European Society of Blood and Marrow Transplantation (EBMT) in early April 2016. Based on these positive results, the Company will proceed with the development of ATIR101 and expects to initiate a randomised Phase III trial in the second half of 2016. In the meantime, in October 2015, we enrolled our first patient into the repeat-dosing Phase II clinical trial with ATIR101.

Furthermore, in the year 2015 we established a closed manufacturing process for ATIR101 and were granted an Advanced Therapy Medicinal Product certificate for manufacturing quality and non-clinical data by the European Medicines Agency (EMA). At the end of the year 2015 we started a collaboration with the Thalassaemia International Federation, an internationally renowned organisation that seeks to address the needs of patients, caregivers, healthcare professionals and the general public in the area of Thalassaemia. Early 2016 we announced that we had entered into a partnership with the U.S. Leukemia & Lymphoma Society, the world's largest voluntary health agency dedicated to blood cancer.

I would like to thank our employees, partners and shareholders for their determination, commitment and support to further realise our business objectives and to bring innovative live saving products closer to the market, making a real difference to the lives of many patients.



Manfred Rüdiger  
Chief Executive Officer  
Kiadis Pharma N.V.

## REPORT OF THE MANAGEMENT BOARD

### OPERATIONAL REVIEW 2015

The Company's lead product ATIR101 is being tested in a single dose Phase II trial in patients with blood cancer who have not found a matching donor and where a partially matched (haploidentical) family member is used as donor for a hematopoietic stem cell transplantation (HSCT). Full patient enrolment was reached in 2015 and positive data on this trial have been realised. The Company presented positive data from this trial at the American Society of Hematology Annual Meeting in December 2015. (The primary endpoint for the final patient in this trial was reached end March 2016. Positive results on the primary endpoint of this Phase II trial were presented at the Annual Meeting of the European Society of Blood and Marrow Transplantation on 4 April 2016). In addition, the Company initiated a repeat dosing Phase II trial with ATIR101 to study the safety and efficacy of administering a second dose of ATIR101 to further improve the HSCT outcome. The first patient in this trial was enrolled in October 2015.

For ATIR101 we established a closed manufacturing process in 2015 and were granted an Advanced Therapy Medicinal Product certificate for manufacturing quality and non-clinical data by the European Medicines Agency (EMA).

At the end of the year 2015 we started a collaboration with the Thalassaemia International Federation, an internationally renowned organisation that seeks to address the needs of patients, caregivers, healthcare professionals and the general public in the area of Thalassaemia.

The Company listed its shares via an IPO on Euronext Amsterdam and Brussels on 2 July 2015. The gross proceeds from the IPO came to a total of EUR34.7 million and net proceeds came to a total of EUR31.2 million.

### FINANCIAL REVIEW 2015

#### FINANCIAL SUMMARY

(Amounts in EUR million, except per share data)	2015	2014	Change
<b>Total revenue and other income</b>	-	-	-
<b>Total operating expenses</b>	<b>(16.0)</b>	<b>(6.2)</b>	<b>(9.8)</b>
Research and development expenses	(7.7)	(4.7)	(3.0)
General and administrative expenses	(8.3)	(1.5)	(6.8)
<b>Operating loss</b>	<b>(16.0)</b>	<b>(6.2)</b>	<b>(9.8)</b>
<b>Net finance expenses</b>	<b>(0.5)</b>	<b>(1.6)</b>	<b>1.1</b>
<b>Loss for the year</b>	<b>(16.5)</b>	<b>(7.8)</b>	<b>(8.7)</b>
<b>Net operating cash flow</b>	<b>(8.1)</b>	<b>(6.1)</b>	<b>(2.0)</b>
 <b>Cash position at end of year</b>	 <b>28.7</b>	 <b>5.7</b>	 <b>23.0</b>
 <b>Earnings per share before dilution (EUR)</b>	 <b>(1.36)</b>	 <b>(0.73)</b>	 <b>(0.63)</b>

#### REVENUE & OTHER INCOME

The Group did not record revenues and/or other income in 2015 and 2014.

## OPERATING EXPENSES

Operating expenses increased to EUR16.0 million in 2015 from EUR6.2 million in 2014. The increase is mainly a result of the expenses related to (non-cash) share-based compensation and non-recurring expenses related to the Initial Public Offering (IPO) and becoming a public company.

Research and Development expenses increased to EUR7.7 million in 2015 from EUR4.7 million in 2014. Without the expenses for share-based compensation, Research and Development expenses increased to EUR5.5 million in 2015 from EUR4.7 million in 2014, mainly due to the expansion of the workforce in research and development departments, the start of the double-dose Phase II trial with ATIR101, and increased levels of activity in the Company's laboratories.

General and Administrative expenses increased to EUR8.3 million in 2015 from EUR1.5 million in 2014. Without the expenses for share-based compensation, General and Administrative expenses increased to EUR2.7 million in 2015 from EUR1.5 million in 2014. This increase is mainly related to consulting and legal expenses for preparing for the IPO.

## OPERATING LOSS

As a result of the increase in total operating expenses, the Group's operating loss increased from EUR6.2 million in 2014 to EUR16.0 million in 2015.

## NET FINANCE EXPENSES

The 2015 net loss on financial income and expenses was EUR0.5 million, compared to a EUR1.6 million net loss on financial income and expenses in 2014.

Finance income included an extinguishment gain of EUR4.6 million related to warrants (derivatives) classified as a financial liability. This gain was partly offset by a EUR1.8 million loss from changes in the fair value of loans and a EUR1.0 million net foreign exchange loss. The foreign exchange losses are mainly due to unrealised losses on intra-group payables and receivables following a weakening of the Canadian dollar against the euro of approximately 8% during the year.

## LOSS FOR THE YEAR

As a result of the above items, the loss for the year increased by EUR8.7 million to EUR16.5 million in 2015 versus a loss of EUR7.8 million in 2014. The loss per share for 2015 increased to EUR1.36 compared to EUR0.73 for 2014.

## CASH FLOWS

Total cash and cash equivalents increased by EUR23.0 million from EUR5.7 million at year-end 2014 to EUR28.7 million at the end of 2015. The increase results from a net cash flow from financing activities amounting to EUR31.2 million less net cash used in operations of EUR8.1 million and investing activities of EUR0.1 million. Net cash from financing activities mainly follows from the Company's IPO in July 2015 in which the Company raised EUR34.7 million in gross proceeds.

## EQUITY

With the successful completion of the IPO in July 2015, the Company raised EUR31.2 million in net proceeds. As a result, the Company's equity position improved significantly and amounted to EUR25.7 million at year-end 2015 versus EUR2.7 million at the end of 2014.



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## OUTLOOK 2016

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The Company continues the development program of its products. As the Company seeks to advance its products to the market it will incur increased costs as it expands its development, regulatory and marketing capabilities by adding qualified personnel in these areas. The Company has incurred losses since its inception and expects to continue to incur losses for the foreseeable future. On the basis of the current plans and cash and cash equivalents currently available, the Company can provide for the continuity of operations exceeding the next twelve months. However, the Company requires additional funds to achieve its mid-to long term objectives. To the extent the Company will raise capital by the issuance of additional shares, existing shareholders' interest in the Company will be diluted.

Based on the positive results on the primary endpoint of the single dose Phase II trial with ATIR101, the objective is to perform a randomised controlled Phase III trial with ATIR101 in order to seek approval in the European Union, the United States and Canada. The trial is expected to be initiated in the second half of 2016. In parallel, the Company will explore a potential early submission in the second half 2016 for conditional approval in the European Union and Canada, based on the results of the single dose Phase II trial. For the ongoing repeat-dosing Phase II trial with ATIR101, the objective in 2016 is to have full patient enrolment and a read-out of the safety data.

Another expected milestone for 2016 will be the initiation of a Phase I/II Thalassaemia trial with ATIR201.

## STATEMENT OF THE MANAGEMENT BOARD

On the basis of the above and in accordance with best practice II.1.5 of the Dutch Corporate Governance Code applicable as of 1 January 2009, and Article 5:25c of the Financial Markets Supervision Act, the Managing Board confirms that the internal risk management and control systems provide a reasonable level of assurance that the financial reporting does not contain any material inaccuracies, and confirms that these controls functioned properly in the year under review. The financial statements fairly represent the Company's financial condition and the results of the Company's operations and provide the required disclosures.

It should be noted that the above does not imply that these systems and procedures provide absolute assurance as to the realization of operational and strategic business objectives, or that they can prevent all misstatements, inaccuracies, errors, fraud and non-compliances with legislation, rules and regulations.

In view of all of the above, the Managing Board confirms that, to the best of its knowledge, the financial statements give a true and fair view of the assets, liabilities, financial position and profit or loss of the company, and the management report includes a fair review of the position at the balance sheet date and the development and performance of the business during the financial year together with a description of the principal risks and uncertainties that the Company faces.

Amsterdam-Duivendrecht, 14 April 2016

*Management Board*

Manfred Rüdiger

Robbert van Heekeren







A microscopic image of several cells, possibly cancer cells, with a blue tint. The cells are spherical with prominent spiky protrusions (microvilli) extending from their surfaces. The background is a light blue, slightly out-of-focus field of similar cells.

# **CORPORATE GOVERNANCE AND RISK MANAGEMENT AND INTERNAL CONTROL SYSTEMS**

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### INTRODUCTION

The Company is a public limited liability company with its shares listed on Euronext Amsterdam and Euronext Brussels since July 2015. The Company has a two-tier board structure: the Management Board that manages the Company on a day-to-day basis and an independent Supervisory Board that supervises and advises the Management Board.

The Company is governed by Dutch law and by its Articles of Association, which can be consulted on the Company website ([www.kiadis.com](http://www.kiadis.com)).

### MANAGEMENT BOARD

The Management Board consists of one or more members, to be determined by the Supervisory Board. At present, the Management Board is composed of Dr. Manfred Rüdiger, Chief Executive Officer, and Mr. Robbert van Heekeren, Chief Financial Officer. Both members of the Management Board were appointed upon incorporation of the Company in 2015 for a period of four years.

#### *Manfred Rüdiger*

Dr. Rüdiger (51, German) holds a PhD in Biochemistry from the Max-Planck Institute for Biophysical Chemistry in Göttingen, Germany, and worked at the Technical University of Braunschweig, Germany, before he joined the industry.

Dr. Rüdiger also serves as Vice Chairman of the supervisory board of 4SC AG (listed on Xetra, regulated market).

#### *Robbert van Heekeren*

Mr. Van Heekeren (45, Dutch) holds a master's degree in Economics from Tilburg University, the Netherlands, and a master's degree in Industrial Engineering & Management Science from Eindhoven University of Technology, the Netherlands.

Members of the Management Board are appointed (and, if necessary, dismissed) by the General Meeting. The Articles of Association provide that the General Meeting appoints members of the Management Board and that the Supervisory Board may draw up a non-binding nomination of one or more nominees for each vacancy to be filled for the appointment of a person as a member of the Management Board. A resolution of the General Meeting to appoint a member of the Management Board in conformity with the nomination of the Supervisory Board shall be passed by an absolute majority of votes cast. A resolution of the General Meeting to appoint a member of the Management Board not in conformity with, or without, the nomination of the Supervisory Board shall require an absolute majority of the votes cast representing more than 50% of the Company's issued share capital.

The Articles of Association provide that the General Meeting may dismiss Management Board members at any time. A resolution of the General Meeting to dismiss a member of the Management Board pursuant to a proposal by the Supervisory Board shall be passed with an absolute majority of the votes cast. A resolution of the General Meeting to suspend or dismiss a member of the Management Board other than pursuant to, or without, a proposal by the Supervisory Board shall require an absolute majority of the votes cast representing more than 50% of the Company's issued share capital.

The Management Board is responsible for the day-to-day management of the operations of the Company. The members of the Management Board are collectively responsible for the management of the Company. Notwithstanding their collective responsibility within the Management Board, certain tasks and responsibilities have been assigned to individual members. This distribution of tasks is part of the Rules of Procedure for the Management Board which can be found on the Company website.

The functioning of and decision making within the Management Board are governed by the Rules of Procedure for the Management Board which can be found on the Company website.



The remuneration of the members of the Management Board is determined by the Supervisory Board based on the remuneration policy approved by the General Meeting. The remuneration policy for the Management Board can be found in the Section entitled 'Remuneration Policy' in this Annual Report.

## **SUPERVISORY BOARD**

The Supervisory Board consists of three or more members. At present, the Supervisory Board is composed of Mr. Mark Wegter, Chairman, Mr. Martijn Kleijwegt and Mr. Stuart Chapman. All three members of the Supervisory Board were appointed upon incorporation of the Company in 2015 for a period of four years. Further details in respect of the Supervisory Board members can be found in the Section entitled 'Report of the Supervisory Board' in this Annual Report.

Members of the Supervisory Board are appointed for a period of four years with a maximum of three four-year terms.

Members of the Supervisory Board are appointed (and, if necessary, dismissed) by the General Meeting. The Articles of Association provide that the General Meeting appoints members of the Supervisory Board and that the Supervisory Board may draw up a non-binding nomination of one or more nominees for each vacancy to be filled for the appointment of a person as a member of the Supervisory Board. A resolution of the General Meeting to appoint a member of the Supervisory Board in conformity with the nomination of the Supervisory Board shall be passed by an absolute majority of votes cast. A resolution of the General Meeting to appoint a member of the Supervisory Board not in conformity with, or without, the nomination of the Supervisory Board shall require an absolute majority of the votes cast representing more than 50% of the Company's issued share capital.

The Articles of Association provide that the General Meeting may dismiss Supervisory Board members at any time. A resolution of the General Meeting to dismiss a member of the Supervisory Board pursuant to a proposal by the Supervisory Board shall be passed with an absolute majority of the votes cast. A resolution of the General Meeting to suspend or dismiss a member of the Supervisory Board other than pursuant to, or without, a proposal by the Supervisory Board shall require an absolute majority of the votes cast representing more than 50% of the Company's issued share capital.

The Supervisory Board is responsible for supervising and advising the Management Board in its duty to manage the Company. The functioning of and decision making within the Supervisory Board are governed by the Rules of Procedure for the Supervisory Board which can be found on the Company website.

The remuneration of the members of the Supervisory Board is determined by the General Meeting.

In 2015, given that the number of members of the Supervisory Board was less than five, no committees were appointed.

## **GENERAL MEETING**

The main powers of the General Meeting relate to:

- the appointment, suspension and dismissal of members of the Management Board and the Supervisory Board;
- the approval of the remuneration policy of the Management Board;
- the approval of the remuneration of the Supervisory Board;
- the adoption of the Financial Statements and declaration of dividends;
- the release from liability of the members of the Management Board and the Supervisory Board;
- the issuance of shares or rights to shares, restriction or exclusion of pre-emptive rights of shareholders, repurchase of shares and reduction of the issued share capital;
- the amendment of the Articles of Association; and
- decisions of the Management Board involving a significant change in the Company's identity of character.

The Annual General Meeting is held within six months of the end of the financial year in order to discuss and, if applicable, approve, the annual report, the annual accounts and any of the other topics mentioned above.

The Annual General Meeting and, if necessary, other General Meetings, are convened by the Management Board or the Supervisory Board. The agenda and explanatory notes are published on the Company website.

According to the Articles of Association, shareholders who, individually or jointly, represent at least 3% of the issued capital have the right to request the Company that items be placed on the agenda. Such requests need to be received in writing by the Company at least sixty days before the date of a General Meeting.

As the Company was listed on Euronext Amsterdam and Euronext Brussels in July 2015, no Annual General Meeting was held in 2015.

## **AMENDMENT OF THE ARTICLES OF ASSOCIATION**

The General Meeting decides on an amendment of the Articles of Association by an absolute majority of votes cast. A decision to amend the Articles of Association may only be taken at the proposal of the Management Board, subject to approval of the Supervisory Board.

## **SHARE CAPITAL, SHARES, VOTING RIGHTS AND SUBSTANTIAL HOLDINGS**

Upon the listing of the Company on Euronext Amsterdam and Euronext Brussels, and on 31 December 2015, the Company's authorized share capital amounted to EUR 5,000,000, divided into 50,000,000 ordinary shares, each with a nominal value of EUR 0.10.

After completion of the listing of the Company on Euronext Amsterdam and Euronext Brussels in July and August 2015, and on 31 December 2015, the Company's issued share capital amounted to EUR 1,347,164.40, divided into 13,471,644 ordinary shares, each with a nominal value of EUR 0.10.

The ordinary shares in the Company are listed on Euronext Amsterdam and Euronext Brussels (symbol: KDS, ISIN code: NL0011323407). All issued shares are fully paid-up.

There are no shares having specific voting rights, voting limitations or not having voting rights or dividend rights. When convening a General Meeting, the Management Board is entitled to determine a registration date in accordance with the relevant provisions of the Dutch Civil Code.

Pursuant to the Dutch Financial Supervision Act (Wet op het financieel toezicht), substantial holdings in the Company must be disclosed to the Netherlands Authority for the Financial Markets (Stichting Autoriteit Financiële Markten) (AFM). According to the register kept by the AFM the following shareholders disclosed that they have a direct or indirect (potential) interest between 3% and 25% in the Company's total share capital as per 1 January 2016:

- Esprit Nominees Limited
- Lenildis Holding B.V.
- Achmea Pensioen- en Levensverzekeringen N.V. (via Life Sciences Partners B.V.)
- Life Sciences Partners II B.V.
- Alta Partners Management VIII, LLC
- Quest for Growth N.V.
- Manfred Rüdiger
- Noordelijke Ontwikkelings- en Investeringsmaatschappij N.V.

## ISSUE OF SHARES; AUTHORITIES OF THE MANAGEMENT BOARD

The issuance of Company shares takes place upon a decision by the Management Board which decision is subject to the approval of the Supervisory Board. The scope of this power of the Management Board is determined by the General Meeting. In the General Meeting of 30 June 2015 this power was granted for a period of five years following 30 June 2015, up to a maximum of 20% of the number of ordinary shares outstanding as of the settlement date of the Company's listing on Euronext Amsterdam and Euronext Brussels.

## REPURCHASE OF OWN SHARES; AUTHORITIES OF THE MANAGEMENT BOARD

The acquisition of fully paid-up Company shares by way of repurchase takes place upon a decision by the Management Board which decision is subject to the approval of the Supervisory Board. The scope of this power of the Management Board is determined by the General Meeting. In the General Meeting of 30 June 2015 this power was granted for a period of 18 months following 30 June 2015 for such number of shares in the capital of the Company as is permitted under the terms of article 2:98 paragraph 2 of the Dutch Civil Code, in accordance with the Company's Articles of Association and for a consideration of at least EUR 0.01 per share and which may not exceed the average closing price of the shares on Euronext Amsterdam and Euronext Brussels during five consecutive trading days preceding the day of repurchase increased by 10%.

## DUTCH CORPORATE GOVERNANCE CODE

The current Dutch Corporate Governance Code ("Code") entered into force on 1 January 2009. The Code applies to all companies whose registered offices are in the Netherlands and whose shares or depositary receipts for shares have been admitted to listing on a stock exchange, or more specifically to trading on a regulated market or a comparable system.

The Code contains principles and best practice provisions that regulate relations between the management board, the supervisory board and the shareholders, and is based on a "comply or explain" principle. Accordingly, the Company is required to disclose in its annual report which principles and best practices of the Code it does not apply and the reason why. The full text of the Code can be found on <http://commissiecorporategovernance.nl/corporate-governance-code>.

## GOVERNANCE FRAMEWORK

The Company's overall governance framework and the most important governance elements at each level are the following:

- for the shareholders the Articles of Association;
- for the Supervisory Board the Rules of Procedure of the Supervisory Board; and
- for the Management Board the Rules of Procedure of the Management Board.

## NON-COMPLIANCE WITH THE CODE

The Company acknowledges the importance of good corporate governance, endorses the underlying principles of the Code and applies these principles and the Code's best practice provisions, subject to the exceptions set out below.

*The Company shall have a code of conduct (provision II.1.3 of the Code).*

This code of conduct is being drafted.

*All supervisory board members, with the exception of not more than one person, shall be independent (provision III.2.1 of the Code).*

The three present members of the Supervisory Board are not independent within the meaning of this provision. These Supervisory Board members are employed by and have been appointed upon nomination of three of the major shareholders of the Company. These three major shareholders have a long-term interest in the Company and were willing to back this up by making senior partners with relevant knowledge and experience available to the Company. The Supervisory Board considers that Messrs. Wegter, Chapman and Kleijwegt fit the intended profile of the Supervisory Board and that their contributions outweigh any perceived disadvantage of non-independence. In addition, the Company deems continuity in the composition of the Supervisory Board to be of great importance.

*The supervisory board shall prepare a profile of its size and composition (provision III.3.1 of the Code).*

The Supervisory Board has prepared a profile of its composition (but not of its size) which has been made generally available and is posted on the Company's website. However, the Supervisory Board has not strictly followed the recommendation of this provision to formulate an explicit target on diversity in terms of, among other things, gender or age, and the Supervisory Board does not strictly follow the recommendation for an explicit target in this respect. The overriding principle shall remain that the Supervisory Board should have a diverse composition of members with a valuable contribution to the Company in terms of experience and knowledge of the industry in which the Company is active, or other business knowledge.

*Supervisory board members shall follow an introduction programme after their appointment (provision III.3.3 of the Code).*

The Company's Supervisory Board members all have substantial experience with the Company. Therefore, an introductory program was not deemed necessary up to this moment. However, when in the future new members join the Company's Supervisory Board, the Company will re-evaluate the need for such an introductory program.

*The supervisory board shall draw up a retirement schedule (provision III.3.6 of the Code).*

The Supervisory Board has not drawn up a retirement schedule yet because it is the first term on the listed Company for all Supervisory Board members. The Supervisory Board plans to draw up such a schedule before the first term will have ended.

*The supervisory board shall elect a vice-chairman (provision III.4.1 of the Code).*

Up to this moment the Supervisory Board has not felt the need to appoint a vice-chairman. Should this change in the future, the Supervisory Board may elect a vice-chairman. The Rules of Procedure of the Supervisory Board already provide for this possibility.

*The chairman of the supervisory board shall not be a former member of the management board of the company (provision III.4.2 of the Code).*

Mr. Wegter, chairman of the Supervisory Board, was a member of the Kiadis Pharma B.V. management board from 4 September 2009 through 22 February 2012.

*The supervisory board shall be assisted by the company secretary (provision III.4.3 of the Code).*

Up to this moment the Supervisory Board has not felt the need to appoint a company secretary. Should this change in the future, the Supervisory Board may appoint a company secretary.

*The company shall draw up regulations governing ownership of and transactions in securities by management or supervisory board members, other than securities issued by their 'own' company (provision III.6.5 of the Code).*

These regulations are being drafted.

*The general meeting of shareholders may pass a resolution to cancel the binding nature of a nomination for the appointment of a member of the management board or of the supervisory board and/or a resolution to dismiss a member of the management board or of the supervisory board by an absolute majority of the votes cast (provision IV.1.1 of the Code).*

Considering the remaining shareholdings and involvement of the Company's current shareholders, the Company deems it appropriate that any resolutions of the General Meeting to cancel the binding nature of a nomination for the appointment of a member of the Management Board or of the Supervisory Board and/or a resolution to dismiss a member of the Management Board or of the Supervisory Board without a prior proposal of the Supervisory Board requires an absolute majority of the votes cast in a meeting where at least half of the Company's issued share capital is represented.

*Meetings with analysts and presentations to analysts and (institutional) investors shall be announced in advance on the company's website and by means of press releases. Shareholders may follow these meetings and presentations in real time. After the meetings, the presentations shall be posted on the company's website (provision IV.3.1 of the Code).*

The Company does not announce, for practical reasons, meetings with analysts and presentations to analysts and (institutional) investors, nor does the Company provide for shareholders to follow these meetings and presentations in real time or post the presentations on its website. In principle no price-sensitive information shall be disclosed in the course of any contact with analysts and (institutional) investors, unless appropriate confidentiality agreements have been entered into and in keeping with

the applicable legal framework.

*The company may not pay fees to parties for carrying out research for analysts' reports or for the production or publication of analysts' reports (provision IV3.3 of the Code).*

The Company may pay fees for carrying out research for analysts' reports or for the production or publication of analysts' reports but if the Company pays such fees, this will be mentioned in the report, i.e. "this rapport has been commissioned by the company".

*Analysts meetings and presentations to and direct discussions with institutional (investors) may not take place shortly before the publication of the regular financial information (provision IV3.4 of the Code).*

The Company will have meetings, presentations and discussions with institutional (investors) shortly before the publication of its regular financial information, provided that such meetings, presentations and discussions regard non-financial topics.

*The company shall formulate an outline policy on bilateral contacts with the shareholders (provision IV.3.13 of the Code).*

This policy is being drafted.

## RISK MANAGEMENT AND INTERNAL CONTROL SYSTEMS

In order to manage the main risks faced by the Company and to offer reasonable assurance that the Company's targets can be realised, the financial information is reliable and applicable laws and regulations are observed, the Management Board has the responsibility to develop, implement and operate adequate risk management and internal control systems. The Supervisory Board has a control function with respect to the systems of risk management and internal control. Based on internal evaluations, discussions with the Supervisory Board and audits by external parties, these systems are being optimised as an ongoing process in the Company. Currently, additional protocols and documentation are being put in place. It should be noted that these systems cannot provide absolute assurance as to the realisation of the Company's targets or that they can prevent all misstatements, errors and non-compliances with legislation, rules and regulations.

The Management Board and departmental managers analyse in a continuous process the potential risks, evaluating impact and likelihood, and determine appropriate measures to minimise these risks. Meetings of the Management Board with departmental managers and with the Supervisory Board take place regularly to review developments, to set targets and to evaluate the realization of targets. In such meetings the financial position of the Company is reviewed and budgets are made, which are followed up and regularly adjusted to changing prospects. Supervision and monitoring activities are performed by the senior management on a daily basis. The risk management and internal control system with regard to the financial reporting process is designed to provide reasonable assurance that the books and records properly reflect transactions necessary to permit preparation of financial statements, that the financial reporting is consistent and in compliance with legal regulations and generally accepted accounting principles and that published financial data do not contain any material misstatements. The system also provides reasonable assurance that receipts and expenditures of the Company are only made by persons authorised to do so and that assets are safeguarded. As part of this system, various internal rules and regulations have been set, including standard operating procedures, the dual-control principle, spot checks and signatory rules.

The Company is exposed to various risks. Its risk appetite is different for the various risk categories the Company is exposed to. Strategic risks and opportunities may affect the Company's strategic ambitions. The Company is prepared to take moderate to high strategic risks to achieve its strategic ambitions, creating a right balance between risk and long-term reward. Operational risks include adverse unexpected developments resulting from internal processes, people and systems or from external events which are linked to the actual operation of the business. The Company aims to minimise these risks, only accepting a low level, to ensure that quality standards are unaffected. Compliance risks relate to unanticipated failures to comply with applicable laws and regulations. The Company aims to minimise these risks. Aim is to be fully compliant with these laws and regulations. The financial risks relate to treasury, tax and accounting and reporting. The Company is prudent also with respect to these financial risks and aims for full compliance with financial reporting rules and regulations.

The risks and uncertainties described below are a list of risks and uncertainties currently known to the Company and which the Company deems material. Additional risks and uncertainties, not presently known to the Company, or which the Company currently deems immaterial, may also have an adverse effect on the Company's business, financial condition, results of operations or prospects and could adversely affect the price of its shares. All these factors are contingencies which may or may not occur. The Company may face the risks and uncertainties described below simultaneously.

### COMMERCIALISATION AND MARKET RISKS

*The market opportunities for the Company's products may be smaller than currently anticipated, lowering potential revenue for the Company.*

The Company makes projections of both the number of people who have the indications that the Company is targeting, as well as the number of people with these indications that are in a position to receive a transplantation and who have the potential to benefit from treatment with an ATIR™ product. These projections are derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, and market research but are highly contingent on a number of variables that are difficult to predict and may prove to be too high, resulting in a smaller population of patients who could benefit from ATIR™ products than the Company currently anticipates which would result in lower potential revenue for the Company.



***If the Company's products do not gain market acceptance by regulators, among physicians, patients, healthcare providers, healthcare payers or the medical community as a whole, the Company may not be able to achieve revenues and its business will be materially adversely affected.***

The Company incurs substantial research and clinical development costs before it can confirm the scientific validity or commercial viability of a product. Even if the European Medicines Agency (EMA), the United States Food and Drug Administration (FDA), the Canadian Therapeutic Products Directorate (TPD) or any other regulatory authority approves the marketing of ATIR™, or any other products that the Company may develop, physicians, healthcare providers, patients or the medical community may not accept or use them. The degree of market acceptance of ATIR™ and any other products will depend on a variety of factors, including:

- the timing of market introduction;
- the number and clinical profile of competing products;
- the Company's ability to provide acceptable evidence of safety and efficacy;
- relative convenience and ease of administration;
- cost-effectiveness;
- availability of coverage, reimbursement and adequate payment from health maintenance organisations and other insurers, both public and private;
- prevalence and severity of adverse side effects; and
- other potential advantages over alternative treatment methods.

If ATIR™ or any other products that the Company may develop fail to achieve market acceptance, the Company may not be able to generate sufficient revenue. As a result, the Company may be required to seek additional financing. In addition, the Company targets specific indications with discrete patient populations. The Company therefore may have to achieve significant market penetration in each target market and obtain relatively higher prices for its products to achieve profitability. The Company may make substantial investments in clinical development and commercialisation without any assurance that it will be able to attain significant market share at a price that would enable it to recover its investments. If the Company is unable to do so, its business, financial condition and results of operations would be materially adversely affected.

***The Company operates in a highly competitive and rapidly changing industry. If the Company is unable to compete effectively, its business, financial condition and results of operations could be materially adversely affected.***

The Company operates in the highly competitive pharmaceutical and biotechnology industries. It seeks to develop and market products that, if approved, will compete with drugs, medical devices and other therapies that currently exist or are being developed. The Company may face competition from fully integrated pharmaceutical companies, biotechnology companies, academic institutions, government agencies and private and public research institutions in the European Union, the United States, Canada and other jurisdictions, as well as early stage development companies that collaborate with larger competitors to bring novel products to the market. The Company's competitors have developed or may be developing alternative products for indications into which the Company may expand, such as inborn diseases of the blood building system. The Company's competitors may have substantially greater financial, technological, manufacturing, marketing, managerial, regulatory and research and development resources and experience. The Company's competitors may also:

- develop and patent processes or products earlier than the Company;
- obtain regulatory approvals for competing products more rapidly than the Company;
- develop and commercialise products that are less expensive, safer, more effective or more convenient to administer than the Company's products; and
- improve upon existing technologies or develop new or different therapies that render the Company's products or technologies obsolete.

The pharmaceutical and biotechnology industries are characterised by rapid change and the Company expects competition to intensify as scientific, clinical or technical advances are made. These advances may render the Company's products obsolete or non-competitive. The emergence of a new standard of care in target markets may also result in the Company's products becoming obsolete. Should any of these factors occur, the Company's business, financial condition and results of operations could be materially adversely affected.

***Adverse events in the field of cell-based products could negatively influence and damage the perception of the Company's products and adversely affect its business, financial condition and results of operations.***

The commercial success of the Company's products will depend in part on public acceptance of the use of cell-based therapy for the treatment of human diseases. Adverse events in clinical trials of the Company's products or in clinical trials of others developing cell-based products and the resulting publicity, as well as any other adverse events in the field of cell-based therapy that may occur in the future, could result in a decrease in demand for any products that the Company may develop. If public perception is influenced by claims that cell-based therapy is unsafe, ineffective, or prohibitively expensive the Company's products may not be accepted by the general public, medical community, or insurers. Future adverse events in cell-based therapy could also result in greater governmental regulation, stricter labelling requirements and potential regulatory delays in the testing or approvals of the Company's products. Any increased scrutiny could delay or increase the costs of obtaining regulatory approval for the Company's products, which could have a material adverse effect on the Company's business, results of operations and financial condition.

***If the Company evolves from a company primarily involved in the clinical development of products to one also involved in the commercialisation of products, the Company may encounter difficulties in managing its growth and expanding its operations successfully.***

If the Company advances its products through clinical trials, it will need to expand its development, regulatory, marketing and supply chain capabilities or contract with third parties to provide these capabilities for it. The Company's ability to realise its commercialisation strategy and manage any growth will require the Company to continue to recruit and train additional qualified personnel and make appropriate changes to its operational, financial and management controls. The Company may experience a delay in becoming aware of certain issues or information material to management decisions. The expansion of its operations, including potential expansion into global markets outside of the European Union, the United States and Canada, may lead to significant costs, new challenges and risks and may divert the attention of the Company's management and the Company's business development resources. Any inability to manage anticipated growth, including as a result of failing to realise the Company's commercialisation strategy for ATIR101, could adversely affect its business, financial condition or results of operations.

***Governments, especially in the European Union and Canada, often impose strict price controls, which may adversely affect the Company's future profitability.***

In some markets, especially in the European Union and Canada, prescription drug pricing is subject to governmental control which can vary by country and degree. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, the Company may be required to conduct a post-authorisation clinical trial that compares the cost-effectiveness of the Company's product to other available therapies. If reimbursement of the Company's products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels or the pricing negotiation is considerably delayed, the Company may be unable to achieve or sustain profitability.

***If the Company fails to obtain adequate coverage and reimbursement from insurers, both public and private, commercially viable markets for its products may not develop or may be smaller than expected and the Company's business, financial condition and results of operations could be materially adversely affected.***

The commercial success of the Company's future products depends in part on whether third-party coverage and reimbursement will be available for the ordering of products by the medical profession for use by patients. In the United States, Medicare,

Medicaid, health maintenance organisations and other insurers, both public and private, are increasingly attempting to manage healthcare costs by limiting both the coverage and the level of reimbursement of new products. As a result, they may not cover or provide adequate payment for the Company's products. In the European Union and other markets, the Company's ability to obtain coverage or reimbursement may be affected by laws governing public and private insurance and other factors. If these insurers, both public and private, do not view the Company's products as cost-effective, reimbursement may not be available to patients or may be insufficient to allow the Company's products to be marketed on a competitive basis. Legislative or regulatory efforts to reform government healthcare programs, changes to private coverage and reimbursement policies and cost containment initiatives could lower prices or reimbursement levels or result in rejection of the Company's products. Any of these factors could impair the development of a commercial market for the Company's products and its business, financial condition and results of operations could be materially adversely affected.

## **RISKS RELATING TO INTELLECTUAL PROPERTY AND KNOW-HOW**

### ***The duration and scope of the Company's patents may not be sufficient to effectively protect its products and business.***

Patents have a limited lifespan. For example, if renewal fees are paid timely, a European patent expires 20 years after its (effective) filing date. The maximum lifespan of a patent in the United States is generally of the same order. In the European Union, an extension of the duration of protection for a pharmaceutical product on the basis of a supplementary protection certificate could be applied for after a valid market authorisation is obtained and if the product is specifically covered by a basic patent in force. As a result, an additional term of protection could be obtained for the relevant product on top of the maximum lifespan of the patent. The term of the allowed extension varies, and in principle is at most five years. In the United States, patents may qualify for an extended period if certain criteria are met (e.g. in case of significant delays during patent prosecution or during FDA approval for bringing a drug covered by a patent to market). Consequently, despite these general possibilities for obtaining a certain extension of the duration of protection based on a patent if certain criteria are met, the protection provided by a patent is limited in time. Even if additional patents covering the Company's product candidates are obtained, the expiration of a patent may leave the Company more vulnerable to competition from biosimilar or generic alternatives. Certain of the Company's issued patents relevant for ATIR™ or other aspects of the Company's technology have already expired, and others will expire in the coming years.

Moreover, patents have a limited scope of protection. The Company's patents may provide protection for certain aspects of its products and business, but leave other aspects unprotected, as a consequence of which the technology protected by the patents is limited. Additionally, the Company's patents only cover a limited number of jurisdictions, and leave other jurisdictions uncovered, as a result of which the protection provided by the patents is geographically limited.

### ***Issued patents covering the Company's product candidates could be found invalid or unenforceable if challenged in court or before the U.S. Patent and Trademark Office, the European Patent Office or another issuing body.***

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. Accordingly, the Company cannot predict with certainty the breadth of claims that will be allowed in patents, nor can it predict with certainty the outcome of disputes about the infringement, validity, or enforceability of its patents.

The Company's patent protection in respect of its products may be limited if its issued patents were to be declared invalid or narrowed in scope as a result of any re-examination proceeding, opposition proceeding or judicial action. Although issued U.S. and Canadian patents enjoy a presumption of validity, this presumption can be overcome by clear and convincing evidence to the contrary. A challenge to the Company's existing patents or future patents, if issued, could result in a ruling adverse to the Company that could invalidate such patents or substantially reduce the scope of protection afforded by them. A court may also determine, retrospectively, that despite the issuance of the patent by the U.S. Patent and Trademark Office, the European Patent Office or another issuing body, the corresponding patent application did not meet the statutory requirements. If a competitor or other third party were to successfully challenge the Company's patents, and claims in these patents were consequently narrowed or invalidated, the Company's ability to protect the related product from competition could be compromised. However, to date, there has been no re-examination of, opposition against, or judicial determination of the validity or scope of the patents in which the Company has rights. Patent laws also vary by jurisdiction, and, accordingly, the degree of protection afforded to the

same technology, if any, may differ depending on the jurisdiction. In addition, pending and future patent applications to which the Company has rights may not issue or concur with the scope of claims sought by the Company, if at all, or the scope of claims the Company or its licensors are seeking may not be sufficiently broad to protect the Company's products. If the Company's patents expire or if a challenge to an existing patent is successful, there could be a material adverse effect on the Company's business, financial condition, results of operations and prospects.

The Company owns or licenses pending patent applications. These applications could provide for further patent protection after the current patents expire. There is a risk, however, that these applications, or patent applications in general, will not be issued timely, or that they may not be issued at all. In particular, claims directed to dosing and dose adjustment may be substantially less likely to issue in light of the recent United States Supreme Court decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* Further, any patents issuing from these applications could be vulnerable to future validity challenges based on *Mayo* and subsequent court decisions that further clarify the scope of *Mayo*. In *Mayo*, the Court held that claims directed to methods of determining whether to adjust drug dosing levels based on drug metabolite levels in the blood were not patent eligible because they were directed to a law of nature. This decision may have wide-ranging implications on the validity and scope of pharmaceutical method claims, although its full impact will not be known for many years.

The Company's competitors would be able to offer and sell products based on the Company's compounds so long as they do not infringe any valid patents or other proprietary rights that the Company or others, including the Company's licensors, may have. Such risks for the Company will increase if the Company or its licensors are not able to obtain additional patents protecting aspects of ATIR™, such as product improvements, formulations, methods of production, novel uses of the relevant compounds, and generally the ATIR™ cell product. Even if the pending and future patent applications to which the Company has rights were to result in issued patents, they could also be subject to re-examination or opposition proceedings or judicial determination of invalidity.

***If the Company fails to enforce adequately or protect its intellectual property rights its business may be harmed.***

The Company's commercial success depends in part on obtaining and maintaining trade secrets or confidential know-how and current and future patent protection for its products, the methods used to manufacture those products and the methods for treating patients using those products and the combined marketing of drug, device and method. Failure to protect trade secrets or confidential know-how or to obtain, maintain or extend patent protection could materially adversely affect the Company's ability to compete.

The Company's ability to protect its products and platform is uncertain because legal means, such as patents and orphan drug market exclusivity, afford only limited protection and may not adequately protect the Company's rights or permit it to gain or keep any competitive advantage. The specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, technical and factual issues. Changes in either patent laws or interpretations of patent laws in the European Union, the United States, Canada or other jurisdictions may diminish the value of the Company's intellectual property or narrow the scope of its patent protection.

Patents also will not adequately protect the Company's products if competitors devise ways of making or using these products without legally infringing the Company's patents. The U.S. Federal Food, Drug and Cosmetic Act and FDA regulations and policies, along with equivalents in other jurisdictions provide incentives to manufacturers to challenge patent validity or create modified, non-infringing versions of a drug or biological product in order to facilitate the approval of abbreviated new drug applications (NDAs) for generic substitutes or biologics licence applications for biosimilars. These types of incentives encourage manufacturers to submit NDAs and biosimilar applications that rely on literature and clinical data not prepared for or by the sponsor. In addition, in some jurisdictions, competitors may be able to develop their own products without consequences until and through clinical Phase III if a so-called research exemption or safe harbour exemption (e.g. "Bolar-type exemptions") applies. The scope of these exemptions can vary from country to country. In some jurisdictions, such provisions could provide for an exemption from patent infringement regarding research and tests carried out for scientific purposes or in order to obtain regulatory approval (sometimes only for generic human medicinal products). In certain jurisdictions, the Company may challenge a competitor based on the Company's intellectual property rights only after market approval and when market entry of the competing drugs is imminent or has taken place.

There can be no assurance that the Company would prevail in any intellectual property infringement action or will be able to obtain a licence to any third-party intellectual property rights on commercially reasonable terms, successfully develop non-infringing alternatives on a timely basis, or license non-infringing alternatives, if any exist, on commercially reasonable terms.

The Company may not have the resources to reliably detect infringements of intellectual property rights, and even if it detects an infringement it may not be able to trace the source of the infringement, or uphold its rights. The Company may need to resort to litigation to enforce or defend its intellectual property rights, including any patents issued to it. If a competitor or collaborator files a patent application claiming technology also invented by the Company, in order to protect its rights, the Company may have to participate in an expensive and time-consuming opposition proceeding before the European Patent Office, the United States Patent and Trademark Office or patent authorities or courts in other jurisdictions, with an uncertain outcome and which may have a material adverse effect on the Company's business, financial condition, results of operations and prospects.

***The Company may not be able to protect or enforce its intellectual property rights in all jurisdictions.***

Competitors may use the Company's technologies in jurisdictions where the Company has not obtained patent protection to develop their own products such as China and may export otherwise infringing products to territories where the Company has patent protection but where enforcement is not as well developed as in the United States or the European Union. These products may compete with the Company's products in jurisdictions where the Company does not have any issued patents. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favour the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for the Company to stop the infringement of its patents or marketing of competing products in violation of its proprietary rights generally. Proceedings to enforce the Company's patent rights in foreign jurisdictions could result in substantial cost and divert the Company's efforts and attention from other aspects of its business. The inability of the Company to protect or enforce its intellectual property rights throughout the world could have a material adverse effect on its business, prospects, financial condition and results of operations.

***Confidentiality agreements with employees and third parties may not prevent unauthorised disclosure of trade secrets and other proprietary information and may not provide an adequate remedy.***

The Company considers proprietary trade secrets and confidential know-how and unpatented knowhow to be important to its business. The Company relies on trade secrets and confidential know-how to protect its technology, especially where the Company does not believe that patent protection is appropriate or obtainable. However, trade secrets and confidential know-how are difficult to protect. The Company's current or former employees, consultants, contractors, outside scientific collaborators and other advisers may unintentionally or wilfully disclose the Company's confidential information, including to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorised disclosure of confidential information. Enforcing a claim that a third party obtained illegally and is using trade secrets and confidential know-how illegally is expensive and time consuming and the outcome is unpredictable. Failure to obtain or maintain trade secret and confidential know-how trade protection could adversely affect the Company's competitive business position. Moreover, the Company's competitors may independently develop equivalent knowledge, methods and know-how and may even apply for patent protection in respect of the same. If successful in obtaining such patent protection, the Company's competitors could limit how the Company uses its trade secrets and confidential know-how, which may have a material adverse effect on the Company's business, financial condition, results of operations and prospects.

***If the Company or the licensors of intellectual property that the Company owns or uses infringe intellectual property rights of third parties, the Company may face increased costs or it may be unable to commercialise its products.***

There is a risk that the Company or the licensors of intellectual property that the Company owns or uses may have infringed, are infringing, or will infringe the proprietary rights of third parties because patents and pending applications belonging to third parties exist in the European Union, the United States, Canada and elsewhere in the world in the areas the Company's research is conducted. Because patent applications take several years to complete, there may be currently pending applications, unknown to the Company, which may later result in issued patents that cover the production, manufacture, commercialisation or use of



the Company's products. Many of the Company's employees were previously employed at universities or other biotechnology or pharmaceutical companies. Although no claims are currently pending, the Company may be subject to claims that these employees or the Company have inadvertently or otherwise used or disclosed trade secrets and confidential know-how or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If the Company fails in defending such claims, in addition to paying monetary damages, the Company may lose valuable intellectual property rights or personnel. In addition, the production, manufacture, commercialisation or use of its products may infringe existing patents of which it is not aware. As a result of intellectual property infringement claims, or to avoid potential claims, the Company might:

- be prohibited from selling or licensing any product that it may develop unless the patent holder licenses the patent to the Company, which it is not required to do;
- be required to pay substantial royalties or grant a cross licence to its patents to another patent holder;
- be required to pay substantial damages for past infringement, which it may have to pay if a court determines that the Company's products or technologies infringe a competitor's patent or other proprietary rights; or
- be required to redesign the formulation of a product such that it does not infringe, which may not be possible or could require substantial funds and time.

***Intellectual property rights of third parties could adversely affect the Company's ability to commercialise its products.***

If patents issued to third parties contain valid claims that cover the Company's compounds or their manufacture or uses or assays relevant to the Company's development plans, the Company may be required to obtain licences to these patents or to develop or obtain alternative technology. If a patent is issued that covers the Company's compounds or their manufacture or uses or assays related to the Company's development plans then the Company may not be in a position to commercialise the related product unless it successfully pursues litigation to have that patent invalidated or enters into a licensing arrangement with the patent holder. Any such litigation would be time consuming and costly, and the outcome would not be guaranteed. The Company cannot be certain that it would be able to enter into a licensing agreement with the patent holder on commercially reasonable terms, if at all. In either case, the Company's business prospects could be materially adversely affected.

## **DEVELOPMENT RISKS**

***The Company's future commercial potential depends on its ATIR™ products, in particular ATIR101. If the Company is unable to commercialise ATIR101, or experiences significant delays in doing so, its business, financial condition and results of operations would be materially adversely affected.***

ATIR101 for leukaemia, the Company's most advanced ATIR™ product in development, is currently in Phase II clinical testing. The Company's ability to generate product revenue in the future will depend significantly, if not solely, on the successful clinical development and commercialisation of ATIR101. If the products that the Company is pursuing fail, it will have to develop, acquire or license new products. Any of the Company's products could be unsuccessful if it:

- does not demonstrate acceptable safety and efficacy in preclinical studies or clinical trials or otherwise does not meet applicable regulatory standards for approval;
- results in unacceptable adverse side effects;
- does not offer therapeutic or other improvements over existing or future products used to treat the same conditions;
- is not accepted in the medical community or by insurers, either public or private; or
- is not capable of being produced in commercial quantities at acceptable costs.

The Company does not expect ATIR101 to be commercially available before 2020, if at all, in any market. Although the Company intends to apply for conditional marketing authorisation for ATIR101 in the European Union and Canada which would allow for ATIR101 to be commercially available in the European Union and Canada prior to this date, ATIR101 may not meet applicable regulatory standards for such approval. The results of the clinical trials to date cannot provide assurance that acceptable efficacy or safety will be shown upon completion of either the ongoing or the planned Phase II clinical and Phase III clinical trials, if any.



Many products that show promise in Phase I trials fail in later clinical trials. If the Company is unable to make ATIR™ commercially available, or experiences significant delays in doing so, its business, financial condition and results of operations would be materially adversely affected.

Given the general applicability of the Company's technology platform to the development of the products it currently has in its pipeline and may develop in the future, failure to obtain marketing authorisation for ATIR101 or new products would adversely affect the Company's ability to develop other programs and would have an adverse effect on the Company's business, financial condition and results of operations or prospects.

***Any delay in commencing or completing, or inconclusive or negative results from, clinical trials would harm the Company's ability to market a product, generate revenues and have a material adverse effect on its business, financial condition and results of operations.***

Clinical trials are expensive and complex. They can take many years to complete and have uncertain outcomes. The Company estimates that clinical trials of ATIR™ will continue for a significant period of time. Failure of a product can occur at any stage of the testing and the Company may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent commercialisation of the Company's products. These events include, but are not limited to:

- delays in securing clinical investigators or trial sites for the Company's clinical trials;
- delays in obtaining regulatory approval to commence or continue a clinical trial;
- slower than anticipated rates of patient recruitment and enrolment;
- negative results from clinical trials;
- inconclusive results;
- the development of unforeseen side effects in patients or unforeseen safety issues;
- dosing issues;
- introduction of new therapies or changes in standards of practice or regulatory guidance that render the Company's clinical trial endpoints or the targeting of the Company's proposed indications obsolete;
- inability to monitor patients adequately during or after treatment or problems with investigator or patient compliance with the trial protocols; and
- inability to replicate in third-party or the Company's future studies the safety and efficacy data obtained from a limited number of patients in the Company's previous and ongoing trials.

If the Company suffers any significant delays, setbacks or negative results in its clinical trials or if the Company's clinical trials are terminated, it may be unable to continue development of its products and its development costs could increase significantly, which could have a material adverse effect on its business, financial condition and results of operations.

***The Company's applications for regulatory approval could be delayed or denied due to problems with clinical trials conducted before the Company in-licensed some of the Company's products. Should this occur, the Company's future results may be compromised and its ability to conduct clinical trials may be severely hampered.***

The Company currently licenses some of the compounds and products used in its research programs from third parties, particularly the Theralux product portfolio, for which the Company has an exclusive license. The Company's present development involving these compounds relies upon previous research conducted by third parties over whom the Company had no control. In order to receive regulatory approval for a product, the Company needs to present all relevant data and information obtained during its research and development, including research conducted prior to the Company licensing the product. Any problems that emerge from preclinical research and testing conducted prior to the Company in-licensing may affect future results or the Company's ability to document prior research and to conduct further clinical trials, which could have a material adverse effect on its business, financial condition and results of operations.

***If the Company fails to enrol patients in clinical trials for the Company's products in clinical development or if patients discontinue their participation, the clinical trials could be delayed, their results compromised, or their costs higher and the Company may suffer a meaningful delay or incur significantly higher costs in developing the Company's products.***

The Company may encounter delays in the regulatory approval process if the Company or physicians who may conduct clinical trials or evaluations of ATIR™ products, are unable to enrol enough patients to complete clinical trials in a timely and cost-effective manner. Patient enrolment depends on many factors, including the size of the patient population, the nature of the protocol, competitive protocols, the proximity of patients to clinical sites and the eligibility criteria for the trial. ATIR101 is presently focused on end stage cancer, and patients will have had to exhaust conventional treatment options before enrolling in clinical trials of ATIR101. Moreover, when one product is evaluated in multiple clinical trials simultaneously, patient enrolment in ongoing trials can be adversely affected by negative results from completed trials. Patients who have enrolled may discontinue their participation at any time during the trial, whether due to adverse effects, withdrawal of consent, real or perceived ineffectiveness of the therapy or other reasons. If the Company fails to enrol patients in clinical trials or if patients discontinue their participation, this could have a material adverse effect on its business, financial condition and results of operations.

## **RISKS RELATING TO THE REGULATORY ENVIRONMENT**

***If the Company fails to obtain or maintain orphan drug status for ATIR101 in the indications that are important to its business, the Company would likely have limited or shortened protection or market exclusivity for ATIR101.***

The Company's strategy is to apply its ATIR™ products and its Theralux technology initially to indications for which it currently has orphan drug status, or for which it expects to qualify for orphan drug status in order to obtain market exclusivity for these products, in particular ATIR101. While the Company has rights to patents relating to the Theralux technology, these patents would likely afford only limited protection and the Company does not rely on them to provide it with market exclusivity for ATIR101. Orphan drug status confers market exclusivity upon the first product to receive marketing approval by the relevant market authorisation authority for the market and entails the right to exclusively market the product for the specified disease, during a period of seven years in the United States and a maximum of ten years for the European Union. The period of exclusivity in the European Union may be reduced to six years if, at the end of the fifth year, the product no longer meets the criteria for orphan drug designation if, among other things, it is established that the product is sufficiently profitable not to justify market exclusivity. To date, the Company has been granted orphan drug designations in the United States and in the European Union in respect of ATIR101 for the prevention of GVHD and for the treatment of AML. There is no assurance that the Company will be able to obtain or maintain market exclusivity for its products in indications that are important to its business. Once granted, exceptions to market exclusivity through orphan drug status may be granted to other applicants if the Company is unable to supply sufficient quantities of the product, or if a potential product based on the same compound of a second applicant is clinically superior.

Changes to the current regulatory frameworks governing orphan drugs may impact existing and future market exclusivities provided as a result of orphan drug designation. A potential regulatory change could be, for example, the criteria to be considered in the assessment of similarity between product candidates. Even if the Company were to succeed in obtaining and maintaining market exclusivity through orphan drug status, the orphan drug regulations would not preclude competitors from developing or marketing different products for the same indications to which its products are directed, or from independently developing versions of the Company's products for different indications.

If the Company fails to obtain or maintain market exclusivity for its products through orphan drug status, or if the commercial value of market exclusivity is diminished, its competitive position or financial and commercial prospects could be materially adversely affected.

***The Company's products are subject to extensive regulation, which can be costly and time consuming to comply with, and the Company may not obtain approvals for the commercialisation of any of its products.***

The Company is not permitted to market any product until it receives approval from the appropriate regulatory authorities. The Company must obtain approval of the product from the appropriate regulatory authority of each jurisdiction where it wishes to

market its product before it can commence clinical trials or marketing of its products in those countries. The Company has not received marketing approval from any regulatory authority for any of its products.

The Company invests substantial time and resources in preclinical studies, clinical trials and the preparation and submission of applications without any assurance that the Company will obtain regulatory approval or recoup its investment. The EMA, FDA, TPD and other regulatory authorities exercise substantial discretion in the approval process. The number, size and design of preclinical studies and clinical trials that will be required for the FDA or other regulatory approval will vary depending on the product, the product's primary indication and the specific regulations and guidance documents applicable to any particular product. The FDA, the EMA, the TPD and other regulatory authorities can delay, limit or deny approval of a product for many reasons, including but not limited to:

- concerns relating to the product's safety or efficacy;
- concerns relating to the design, control or conduct of preclinical studies and clinical trials;
- sponsor or patient withdrawals from clinical trials, or other negative responses from such participants;
- adverse or ambiguous results at any clinical stage;
- the failure of more advanced clinical results to confirm positive results from preclinical studies or earlier clinical trials;
- differing interpretations of clinical data relating to the Company's products, or challenges to their accuracy or adequacy;
- the development or observation of adverse side effects;
- conditions in the Company's or the Company's third-party manufacturers' processes or facilities; or
- regulatory changes requiring new or different evidence of safety and efficacy for the product's primary indication.

Should any of these factors occur, regulatory approval of the Company's products could be delayed or have conditions placed upon it. Failure to obtain regulatory approval in a timely manner, in a limited manner or at all would have a material adverse effect on the Company's business, financial condition or results of operations.

In addition, if the Company were to apply for accelerated assessment or fast track designation, it may not be successful due to a number of factors, including but not limited to failure to convince the relevant regulatory authority of the innovative qualities of the Company's product; adverse results from its sponsored or physician-initiated clinical trials; problems with the technology underlying the Theralux platform; and failure to convince the relevant regulatory authority that the Company's products merit such consideration.

***If the Company fails to comply with ongoing regulatory obligations and restrictions following regulatory approval of any product, regulatory authorities may take enforcement action against the Company, for example, any regulatory approval granted could be revoked and sale of the Company's products could be suspended or financial penalties could be imposed.***

If any of the Company's products are approved by the FDA, the EMA, the TPD or another regulatory authority, the Company would be subject to extensive regulatory requirements over product manufacturing, testing, labelling, packaging, storage, advertising, promotion, distribution, export, adverse event reporting and record keeping. The Company and its suppliers, contract manufacturers and contract testing laboratories would also be subject to inspection by the FDA or other regulatory authorities to determine compliance with these requirements. In addition, laboratory facilities in the European Union that wish to manufacture ATIR™ products must be licensed by the relevant European Union Member State regulatory authorities.

Regulatory authorities may also impose significant limitations on the indicated uses or marketing of the Company's products, which could reduce the potential market for its products. The Company may incur substantial costs in conducting post-marketing clinical studies on which regulatory approvals are conditioned. Previously unknown problems with the product may also result in restrictions on the marketing of the product and could include withdrawal of the product from the market.

In addition, new statutory requirements or additional regulations may be enacted. The Company cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or elsewhere. If the Company is not able to maintain regulatory compliance, it might not be permitted to market

its products and its business could suffer.

Failure to comply with the requirements of the FDA, the EMA, the TPD and other applicable regulatory authorities may subject the Company to administrative or judicially imposed sanctions. These sanctions include warning letters, civil and criminal penalties, injunctions, product seizure or recall, import bans, restrictions on the conduct of the Company's operations, total or partial suspension of production and refusal to approve pending NDAs, supplements to approved NDAs or their equivalents in other jurisdictions and financial penalties. If the Company is subject to any of these sanctions, its competitive position or financial and commercial prospects could be materially adversely affected.

## OPERATIONAL RISKS

***Due to the Company's limited resources and access to capital, the Company must prioritise development of certain products and its decision to pursue these products may prove to be unsuccessful as they may never receive regulatory approval or achieve profitability.***

Because the Company has limited resources and access to capital to fund its operations, the Company's management must make significant prioritisation decisions on which products to pursue and the amount of resources to allocate to each product. The Company's current development activities are focused primarily on the clinical development of ATIR101. To date, the Company has only allocated limited resources towards the development of ATIR201. These, and future decisions concerning the allocation of research, management and financial resources towards particular products or therapeutic areas may not lead to the development of viable commercial products and may divert resources from better opportunities. Similarly, these and future decisions to delay or terminate product development programs could cause the Company to miss valuable opportunities. If the Company makes incorrect determinations regarding the market potential of its products or misreads trends in the biotechnology industry for cancer or non-cancer therapies, its business, financial condition and results of operations could be materially adversely affected.

***If defects in, or the use or misuse of, the Company's products results in personal injury or death, either at the clinical or commercial stage, the Company would be exposed to expensive liability claims and adverse publicity and the Company may not be able to maintain liability insurance on reasonable terms or at all.***

Patients who participate in the Company's clinical trials may suffer adverse side effects as a result of the use of the Company's products. Although the Company's clinical studies to date appear to indicate that the administration of ATIR101 is safe, even at higher doses, the Company cannot predict the possible harms or side effects that may result from these clinical trials. The Company relies on the expertise of physicians, nurses and other associated medical personnel in administering its products to patients in clinical trials. If these medical personnel are not properly trained to administer, or are negligent in the administration of the Company's products, the therapeutic effect of the Company's products may be diminished or the patient may suffer critical injury. Preliminary indications of safety from early clinical trials do not ensure that more advanced clinical trials will confirm those results. Long-term adverse effects may also develop after clinical trials of products or after products are approved for commercial sale. Even if the Company, the sponsors of physician-initiated clinical trials involving the Company's products or regulatory authorities believe that clinical data support the products' safety and efficacy, such data may be incorrect or interpreted wrongly. In addition, there can be no assurance that physicians and patients will comply with any warnings or instructions relating to the Company's products. Generally, regulatory authorities such as the FDA and the EMA do not regulate a physician's choice of treatment and "off-label" use of the Company's products for indications for which the product has not been authorised or misuse of the Company's products may subject the Company to liability. Any claims against the Company, regardless of their merit, could be difficult and costly to defend and could materially adversely affect the market for the Company's products or any prospects for commercialisation of its products. Although the Company believes that it has in place insurance policies for its current or future clinical trials and any other liability insurance on terms in line with industry practice, these insurance policies may prove insufficient to cover any liability claims brought against the Company. Because of increasing costs of insurance coverage, the Company may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. Should any of these events occur, it would have a material adverse effect on the Company's business, financial condition or results of operations.

***The Company is a party to certain agreements that contain liability or indemnification provisions under which the Company may claim damages from its counterparties and under which its counterparties may claim damages from it, including damages caused by product defects.***

The Company is a party to certain agreements that contain liability or indemnification provisions under which the Company or the counterparty may claim damages. In the event the Company needs to claim damages from a counterparty, it may not receive payments covering its damages in full, either because the applicable provision is unenforceable for any reason or because the counterparty is unable to pay (due to insolvency or otherwise). Although in many cases the Company tries to limit its liability, such limitations may not be enforceable in certain jurisdictions or effective in the event that it needs to pay damages and the Company nevertheless could become liable to make substantial payments. If the Company must make substantial liability payments under an agreement, this could have a material adverse effect on the Company's business, results of operations and financial condition.

***The Company has acquired and may in the future acquire businesses or engage in other transactions that could disrupt its operations.***

The Company has grown in part by making acquisitions in Europe and North America. The Company may selectively consider further acquisitions. The Company's valuation of any businesses or assets it acquires may prove incorrect and the Company cannot assure that it will realise the financial and strategic goals that were contemplated at the time of any transaction. The Company's due diligence reviews may fail to identify risks or problems, such as issues with the acquired company's product quality, clinical data or intellectual property position, unlicensed use of third-party intellectual property rights or regulatory violations. Acquisitions may result in significant write-offs and the Company may assume known and unknown contingencies related to product liability, intellectual property, financial disclosures, accounting practices, internal controls or other liabilities. The Company may also have tax exposures or lose anticipated tax benefits as a result of acquisitions or integration of merged entities.

Following an acquisition, the Company's ongoing business may be disrupted and the Company's management attention may be diverted by transition or integration issues. The Company may have higher than anticipated costs in continuing research and development of acquired products. If existing or modifying pre-existing contractual relationships may be costly to the Company or disruptive to its partners, suppliers or contractors, the Company may also have to comply with obligations assumed under relationships into which it would not have entered. If the Company is unable to successfully integrate acquisitions into its existing business, its relationships with current and new employees and strategic partners could suffer.

Any of these circumstances, should they occur, could have a material adverse effect on the Company's business, results of operations and financial condition.

***The Company's clinical development activities rely heavily on sensitive and personal information, an area which is highly regulated by privacy laws. If the Company is unable to generate, maintain or access essential patient samples or data to continue its research and development efforts, its business could be materially adversely affected.***

As a result of the Company's clinical development, the Company will have access to very sensitive data regarding the patients enrolled in its clinical trials. This data will contain information that is personal in nature. The maintenance of this data is subject to certain privacy-related laws, which impose administrative burdens, substantial costs and litigation risks upon the Company. For example, the rules promulgated by the U.S. Department of Health and Human Services under the Health Insurance Portability and Accountability Act ("HIPAA") create national standards to protect patients' medical records and other personal information in the United States. These rules require that healthcare providers and other covered entities obtain written authorisations from patients prior to disclosing protected healthcare information of the patient to companies such as the Company. If the patient fails to execute an authorisation or the authorisation fails to contain all required provisions, then the Company will not be allowed access to the patient's information and the Company's research efforts can be substantially delayed. Furthermore, use of protected health information that is provided to the Company pursuant to a valid patient authorisation is subject to the limits set forth in the authorisation (i.e., for use in research and in submissions to regulatory authorities for product approvals). As such, the Company is required to implement policies, procedures and reasonable and appropriate security measures that



protect individually identifiable health information it receives from covered entities and that ensure such information is used only as authorised by the patient. Any violations of these rules by the Company could subject the Company to civil and criminal penalties and adverse publicity and could harm the Company's ability to initiate and complete clinical trials required to support regulatory applications for its products. In addition, HIPAA does not replace federal, state, or other laws that may grant individuals even greater privacy protections. The Company cannot assure that future legislation will not prevent it from generating or maintaining personal data or that patients will consent to the use of their personal information; either of these circumstances may prevent the Company from undertaking or publishing essential research, which could have a material adverse effect on the Company's business, results of operations and financial condition.

***If the Company's facilities become inoperable, or if the Company is unable to renew its lease, the Company may be unable to perform its clinical development activities and its business, financial condition and results of operations may be harmed.***

The Company does not have fully redundant laboratory facilities. The Company performs certain of its critical clinical development in leased facilities in Amsterdam, the Netherlands. These facilities may be harmed or rendered inoperable by flooding, fire, severe weather conditions, power failures or other natural or man-made disasters. There is no assurance that the Company will be able to renew its lease on acceptable terms upon the lapse of the current or an extended subsequent term. If the Company is unable to perform its research and clinical development activities, it may suffer delays to its clinical programs or harm to its reputation. The Company could also incur significant costs to repair damage to or find new facilities and the equipment it uses to perform its research and clinical development. The Company's insurance coverage for damage to its property and the disruption of its business may not be sufficient to cover all of the Company's potential losses, including the loss of time as well as the costs of lost opportunities, and may not continue to be available to the Company on acceptable terms, or at all.

***Claims relating to improper handling, storage or disposal of hazardous chemical or biological materials could occur and defending against such claims could be time consuming and expensive.***

The Company's research and development involves the controlled use of hazardous materials, including chemicals and biological materials such as chemical solvents and human cells. The Company's operations also generate hazardous waste products. The Company cannot eliminate the risk of accidental contamination or discharge and any resultant injury from these materials. Various laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. The Company may be sued for any injury or contamination that results from the Company's use or the use by third parties of these materials. Compliance with environmental laws and regulations may be expensive and current or future environmental regulations may impair the Company's research, development and production efforts, which could have a material adverse effect on the Company's business, results of operations and financial condition.

## **RISKS RELATING TO THE COMPANY'S DEPENDENCE ON THIRD PARTIES AND KEY PERSONNEL**

***The Company relies on third parties who exclusively license intellectual property rights relating to the Theralux platform to it. If any such exclusive licence is terminated, the Company may be unable to commercialise and market the ATIR™ products.***

The Company has an exclusive licence for the exploitation of intellectual property rights relating to the Theralux platform granted by the University of Montreal and Maisonneuve-Rosemont Hospital. Under this licence, the Company is required to, among other things, develop, obtain regulatory approval of, seek intellectual property protection for and commercialise products based on the Theralux technology. The Company's ability to comply with these requirements may be affected by factors including but not limited to the availability of financing, the current regulatory environment, the results of clinical trials, or physician and patient response to ATIR™ products. If a breach of certain important terms of the licence were to occur and not be remedied, the licensors may assert their right to terminate the licence. If the licensors were to terminate the licence, the Company would be prevented from continuing its use of this technology in clinical trials or, if the Company's products are approved for marketing, in commercial sales. The loss of rights under this licence could preclude the Company from further developing, commercialising and marketing ATIR101 and other products, which would have a material adverse effect on the Company's business, financial condition, results of operations and prospects.

***The Company may be unable to enter into or maintain strategic alliances or collaborations which could affect its possibilities to commercialise certain early stage products.***

The Company may seek strategic alliances or collaborations to further the clinical development and commercialisation of certain of its products, such as ATIR101, as they would likely require expensive and time consuming clinical trials. In seeking strategic partners, the Company faces significant competition from other early stage or clinically-focused companies as well as public and private research institutions. There can be no assurance that the Company will be able to enter into strategic alliances on terms favourable to it, or at all.

***The Company relies on third parties to manufacture certain of its products and technologies. If the Company is unable to enter into or maintain its arrangements with third party manufacturers under favourable terms, the Company's ability with respect to development activities and the Company's ability to generate sufficient product revenues could be harmed and its business, financial condition and results of operations could be materially adversely affected.***

The Company does not operate manufacturing facilities for the clinical production of its products and related technologies. The manufacturing of the TH9402 compound is outsourced to Piramal Healthcare and Teva Pharmaceuticals, and the manufacturing of ATIR101 to the Maisonneuve-Rosemont Hospital and DRK-Blutspendedienst Hessen, as a consequence of which these parties are essential to the Company's current manufacturing processes. The Company's reliance on suppliers, contract manufacturers and contract testing laboratories limits the Company's control over quality assurance, quality control, transport and delivery schedules.

If the Company were to experience an unexpected loss of supply of, or if any supplier were unable to meet the Company's demand for, any of its products, it could experience delays in its research and development activities, planned clinical studies or commercialisation of approved products. The Company could be unable to find alternative suppliers of acceptable quality who can deliver appropriate volumes at acceptable cost. Moreover, the Company's suppliers are often subject to strict manufacturing requirements and rigorous testing requirements, which could limit or delay the production. The long transition periods involved in the change of manufacturers and suppliers, if necessary, would significantly delay the Company's clinical studies and the commercialisation of its products. The Company also needs to work with manufacturing facilities and third-party suppliers that are licensed by the FDA, the TPD, regulatory authorities of European Union Member States and other authorities and must comply with regulations of such authorities, requiring the Company and its third-party suppliers to spend significant time, money and effort in the areas of design and development, testing, production, record-keeping and quality control to assure that the products meet applicable specifications and other regulatory requirements. Any of these third-party suppliers and the Company also may be subject to audits by the appropriate regulatory authorities. If any of the Company's third-party suppliers fails to comply with applicable good manufacturing practices (GMP) or other applicable manufacturing regulations, the Company's ability to develop and commercialise its products or product candidates could suffer significant interruptions.

The Company faces risks inherent in relying on a limited number of contract manufacturers such as Piramal Healthcare and Teva Pharmaceuticals, as any disruption, such as a fire, natural hazards or vandalism at a contract manufacturer could significantly interrupt the Company's manufacturing capability. Business interruption insurance may not adequately compensate the Company for any losses that may occur and the Company would have to bear the additional cost of any disruption.

If the Company achieves regulatory approval for any of its products, the Company's manufacturers and suppliers may not be able to increase production to suitable commercial levels. Any failure to achieve and maintain high quality manufacturing standards could result in patient injury or death, product recalls or withdrawals, regulatory censure or lawsuits. Manufacturing errors, disruptions and difficulties in obtaining export and import approvals could contribute to cost overruns, impair the Company's ability to manage inventory, cause delays in shipments and cancellation of orders that may adversely affect its relationships with future customers and potentially allow competitors to penetrate the Company's customer accounts. In addition, contract manufacturers and contract testing laboratories may prioritise capacity for the Company's competitors or increase prices charged to the Company, which could harm the Company's ability to generate sufficient product revenues.

For all of the above reasons, a significant disruptive event at a supplier or contract manufacturer would have a material adverse effect on the Company's business, prospects, financial condition and results of operations.



***If third parties on which the Company depends to conduct its clinical studies do not perform as contractually required, fail to satisfy regulatory or legal requirements or miss expected deadlines, the Company's development program could be delayed with materially adverse effects on its business, financial condition, results of operations and prospects.***

The Company relies and may rely on clinical research organisations (CROs), clinical data management organisations and consultants to design, conduct, supervise and monitor clinical studies. The Company and its CROs are required to comply with various regulations, including good clinical practices (GCP), which are enforced by the FDA, guidelines of the competent authorities of the member states of the European Economic Area (EEA), the TPD and comparable foreign regulatory authorities to ensure that the health, safety and rights of patients are protected in clinical development and clinical trials, and that trial data integrity is assured. Regulatory authorities ensure compliance with these requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If the Company or any of its CROs fail to comply with applicable requirements, the clinical data generated in the Company's clinical trials may be deemed unreliable and the FDA, the EMA, the TPD or other comparable foreign regulatory authorities may require the Company to perform additional clinical trials before approving its marketing applications. The Company cannot assure that upon inspection by a given regulatory authority, such regulatory authority will determine that any of its clinical trials comply with such requirements. In addition, the Company's clinical trials must be conducted with products that are GMP produced. Failure to comply with these regulations may require the Company to repeat pre-clinical and clinical trials, which would delay the regulatory approval process.

The Company's CROs are not its employees and, except for remedies available to the Company under its agreements with such CROs, the Company cannot control whether or not they devote sufficient time and resources to its ongoing clinical and pre-clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to the Company's clinical protocols, regulatory requirements or for other reasons, the Company's clinical trials may be extended, delayed or terminated and the Company may not be able to obtain regulatory approval for or successfully commercialise its products in development. As a result, the Company's operations and the commercial prospects for its products in development would be harmed, its costs could increase and its ability to generate revenues could be delayed.

Because the Company has relied on third parties, its internal capacity to perform these functions is limited. Outsourcing these functions involves risk that third parties may not perform to the Company's standards, may not produce results in a timely manner or may fail to perform at all. In addition, the use of third-party service providers requires the Company to disclose its proprietary information to these parties, which could increase the risk that this information will be misappropriated. The Company currently has a small number of employees, which limits the internal resources it has available to identify and monitor its third-party providers. To the extent the Company is unable to identify and successfully manage the performance of third-party service providers in the future, its business may be adversely affected. Though the Company carefully manages the relationships with its CROs, there can be no assurance that the Company will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on the Company's business, financial condition and prospects.

If the Company cannot contract with acceptable third parties on commercially reasonable terms, or at all, or if these third parties do not carry out their contractual duties, satisfy legal and regulatory requirements for the conduct of pre-clinical studies or clinical trials or meet expected deadlines, the Company's clinical development programs could be delayed and otherwise adversely affected. The Company is responsible for ensuring that each of its clinical studies is conducted in accordance with the general investigational plan and protocols for the study. The FDA, the EMA and other regulatory authorities require clinical trials to be conducted in accordance with GCP, including for conducting, recording and reporting the results of preclinical studies and clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. The Company's reliance on third parties that it does not control does not relieve it of these responsibilities and requirements. Any such event could have a material adverse effect on the Company's business, financial condition, results of operations and prospects.

***The failure to attract and retain senior management and skilled personnel could impair the Company's development and commercialisation efforts.***

The Company is highly dependent on the members of the Company's Management Board, its senior management and its key scientific and technical personnel. The loss of the services of any member of the Management Board, senior management or key scientific or technical staff may significantly delay or prevent it from achieving its development and other business objectives and could have a material adverse effect on the Company's business, financial condition and results of operations. If the Company does not have sufficient numbers of skilled employees to support its research, development, commercialisation, regulatory compliance or management functions, or if its employees lack the skills necessary for the development of its operations and the challenges of being a public company, the Company may be dependent on consultants and advisers, if available on terms acceptable to it (if at all), who may have conflicts of interest or other commitments, such as consulting or advisory contracts with other organisations that may affect their ability to contribute to the Company. If the Company is unable to attract and retain sufficient scientific, technical and managerial personnel, the Company will be unable to advance its clinical programs, commercialise any approved products or expand its business, which may have a material adverse effect on the Company's business, financial condition, results of operations and prospects.

## **FINANCIAL RISKS**

***The Company has a history of operating losses and anticipates that it will continue to incur operating losses for the foreseeable future.***

The Company has incurred losses since its inception in 1997. The Company expects to continue to incur losses for the foreseeable future and expects these losses to increase significantly as it continues the clinical development of, and seeks regulatory approval for, its products, and will commercialise any approved products (if any). In addition, as the Company seeks to advance its products through clinical trials, including Phase III clinical trials, it will incur increased costs as it expands its development, regulatory and marketing capabilities by adding qualified personnel in these areas.

***The Company has never generated any revenue from product sales and its ability to generate revenue from product sales and become profitable depends significantly on its success in commercialising its product candidates that may be hard to achieve.***

The Company has not generated any revenue from product sales. To achieve and maintain profitability, the Company will need to generate significant revenues from sales of products that it does not expect in the foreseeable future, if at all. Should the Company fail to receive regulatory approval to commence or complete clinical trials or to market any or all of its products, or if such products fail to gain market acceptance, the Company's business, financial condition and results of operations would be materially adversely affected. If the Company achieves profitability in the future, it may not be able to sustain profitability in subsequent periods. It is likely that the Company will experience fluctuating revenues, operating results and cash flows. As a result, period-to-period comparisons of financial results are not necessarily meaningful and results of operations in prior periods should not be relied upon as an indication of future performance.

***If the Company fails in obtaining substantial additional funding, it will be unable to complete its research and development programs or commercialise any of its products.***

On the basis of the current plans and cash and cash equivalents currently available, the Company can provide for the continuity of operations exceeding the next twelve months. However, the Company requires substantial additional funds to achieve its mid- to long term objectives. Additional funds are required to conduct further research and clinical development, to obtain, maintain and enforce its patents and other intellectual property rights, to manufacture and market any products that may be approved for commercial sale, if any, to take advantage of new business opportunities to broaden and diversify its research and development portfolio and to meet its payment obligations under its loan arrangements and royalty and milestone arrangements.

The Company's future funding requirements will depend on many factors, including the progress and cost of its clinical trials and research and development activities; the outcome, timing and cost of regulatory approvals by the EMA, the FDA and any other comparable regulatory authority; the cost of establishing sales, marketing, manufacturing and distribution capabilities for any product candidates for which the Company may receive regulatory approval, if any; the effects of competing technological and market developments and the terms and timing of establishing potential license agreements or other partnerships.

The Company intends to seek additional capital necessary to fund its operations through equity offers, debt financings, collaboration and licensing arrangements, or a combination of one or more of these funding sources, if available. There can be no assurance that such funding will be available in a timely manner, on favourable terms, or at all, or that such funds, if raised, would be sufficient to enable the Company to continue to implement its long term business strategy. If the Company is unable to raise such additional funds, it may need to delay, scale back or cease expenditures for some of its products or some of its long-term research, development and commercialisation programs, or grant rights to third parties to develop and market products that the Company would otherwise prefer to develop and market itself, thereby reducing their ultimate value to the Company. The failure to raise capital when needed would reduce the Company's business, financial condition, results of operations or prospects.

***In order to finance acquisitions the Company may engage in transactions that could dilute the ownership interests of shareholders, and the terms of any additional funding may adversely affect a shareholder's rights and diminish the future prospects of the Company.***

To finance any acquisitions, the Company may choose to issue shares or securities convertible into or exchangeable for shares as consideration, which would dilute shareholders' interest in the Company. Alternatively, it may be necessary for the Company to raise additional funds for acquisitions by incurring indebtedness. Such additional funds may not be available on terms that are favourable to the Company, if at all. If the Company is unable to obtain the necessary financing, it may have to delay or may be unable to complete an acquisition.

***Exchange rate fluctuations could negatively affect the Company's financial condition.***

The consolidated financial statements of the Company are presented in euro. However, since the Company has and will have transactions with international service providers with whom payment terms are denominated in a currency other than the euro, the Company incurs part of its expenses in foreign currencies, leading to a currency risk. Also in case of future sales a significant part is expected to be realized in foreign currencies. The Company did not enter into any currency hedging arrangements in order to cover currency risks. As a result, the Company's business will be affected by fluctuations in foreign exchange rates, which may have a negative impact on the financial results.

***The Company's tax liability may be materially different from what is reflected in its income tax provisions and related balance sheet accounts.***

The Company is subject to income taxes in the Netherlands and other jurisdictions. The Company's calculation of income taxes is based in part on its interpretations of applicable tax laws in the jurisdictions in which it operates. Although the Company believes its tax estimates to be reasonable, there is no assurance that the final determination of its income tax liability will not be materially different from what is reflected in the Company's income tax provisions and related balance sheet accounts. Should additional taxes be assessed as a result of new legislation, tax litigation or an audit, if the effective tax rate should change as a result of changes in tax laws, or if the Company were to change the locations in which it operates, there could be a material adverse effect on its income tax provision and net income. Further changes in the tax laws of the jurisdictions in which the Company operates could arise as a result of the base erosion and profit shifting (BEPS) project being undertaken by the Organisation for Economic Co-operation and Development (OECD). The OECD, which represents a coalition of member countries that encompass certain of the jurisdictions in which the Company operates, is undertaking studies and publishing action plans that include recommendations aimed at addressing what they believe are issues within tax systems that may lead to tax avoidance by companies. It is possible that the jurisdictions in which the Company does business could react to the BEPS initiative or their own concerns by enacting tax legislation that could adversely affect the Company or shareholders through increasing the Company's tax liabilities.

## REPORT OF THE SUPERVISORY BOARD

### INTRODUCTION

The Supervisory Board is responsible for supervising and advising the Management Board in its duty to manage the Company. In carrying out its duties, the Supervisory Board is guided by the Articles of Association of the Company, its Rules of Procedure, applicable law, the Dutch Corporate Governance Code applicable as of 1 January 2009 ("Code") and the overall interests of the Company and its business.

In the Company's two-tier corporate structure under Dutch law, the Supervisory Board is a separate body operating fully independently of the Management Board.

### COMPOSITION OF THE SUPERVISORY BOARD AND BACKGROUND INFORMATION ON THE SUPERVISORY BOARD

The Supervisory Board at present consists of the members set out below.

Name	Age	Nationality	Date of initial appointment <sup>(1)</sup>	Current term of office
Mr. Mark Wegter	46	Dutch	2001	2019
Mr. Martijn Kleijwegt	60	Dutch	2006	2019
Mr. Stuart Chapman	45	English	2013	2019

<sup>(1)</sup> The presented information refers to the year of appointment to the supervisory board of Kiadis Pharma B.V., the holding entity of the Kiadis Pharma group of companies prior to the Company listing at Euronext Amsterdam and Euronext Brussels mid 2015.

Mr. Mark Wegter is Chairman of the Supervisory Board. In 2015, given that the number of members of the Supervisory Board was less than five, no committees were appointed.

#### *Mark Wegter*

Mr. Wegter graduated from the Erasmus University of Rotterdam, the Netherlands, with a degree in economics. In 1998, Mr. Wegter joined Life Sciences Partners, becoming a general partner in 2001. Mr. Wegter holds positions at various Life Sciences Partners entities that manage Life Sciences Partner funds.

Mr. Wegter is not considered to be independent within the meaning of the Code.

#### *Martijn Kleijwegt*

Mr. Kleijwegt graduated from the University of Amsterdam, the Netherlands, with a degree in economics. Mr. Kleijwegt founded Life Sciences Partners in 1998 and has been managing partner of Life Sciences Partners ever since. Mr. Kleijwegt is managing director of various Life Sciences Partners entities that manage Life Sciences Partner funds. He is also a member of the board of the European Venture Capital Association.

Mr. Kleijwegt is not considered to be independent within the meaning of the Code.

#### *Stuart Chapman*

Mr. Chapman graduated from the University of Loughborough, United Kingdom, with a degree in economics. Mr. Chapman co-founded DFJ Esprit in 2006 and has been managing partner of DFJ Esprit (now named Draper Esprit) ever since.

Mr. Chapman is not considered to be independent within the meaning of the Code.

The targeted profile of the composition of the Supervisory Board is reflected in its Rules of Procedure, which are published on the Company website. The composition of the Supervisory Board is diverse in nationality (two Dutch, one English), background, knowledge and experience. However, the Supervisory Board wishes to increase its number of independent members (within the meaning of the Code) and will thus propose to nominate two new independent members for the Supervisory Board at the next General Meeting.

## MEETINGS AND BUSINESS TOPICS

The Supervisory Board convened three times during 2015 with the Management Board and in addition had regular contact with the Management Board throughout the year by means of telephone conferences and individual discussions. The Chairman and CEO had regular meetings throughout the year, including preparatory meetings prior to the Supervisory Board Meetings.

None of the members of the Supervisory Board were frequently absent.

The meetings addressed the development program for the Company's lead product ATIR™ (clinical, regulatory, manufacturing and quality), financial matters (cash flow and budget 2015), outlook beyond 2015 (competitive landscape), corporate/fiscal restructuring and potential acquisition/licensing opportunities, and paid particular attention to the search for new capital specifically the Initial Public Offering (IPO) that took place mid 2015.

As part of the meetings, the Supervisory Board reviewed the main risks of the business, being:

- the Company being dependent on the success of one key product, ATIR™;
- the Company's progress on achieving clinical and regulatory milestones and successes, there being no certainty that these milestones/successes will actually be achieved;
- that if the Company fails to enrol patients in clinical trials for its products, the clinical trials could be significantly delayed;
- the Company relying on third parties to manufacture its products;
- the Company being active in a highly competitive and rapidly changing industry;
- the Company not yet having a positive operational cash flow and therefore being dependent on financial markets and/or licensing/partnership revenues for funding. If such funding cannot be obtained, the Company will be unable to complete its development programs or commercialise its products;
- the Company being dependent on the availability and commitment of key, skilled employees;
- the duration and scope of the Company's patents not being sufficient to effectively protect its products and business.

All these risks were discussed with the Management Board and where possible actions were undertaken to minimise the Company's exposure. In addition, the Company manages and controls its risks, insofar as possible, by means of a risk management and internal control system. The Management Board reports regularly to and discusses with the Supervisory Board on the Company's risk management and internal control system and the compliance therewith.

The Company risks and the Company's risk management and control system are further described in the Section entitled 'Corporate Governance and Risk Management and Internal Control Systems' in this Annual Report.

As the Company did not become listed until mid 2015, the Supervisory Board did not perform an evaluation of its functioning as a whole or of the functioning of individual Supervisory Board members in 2015.

## FINANCIALS AND AUDITING

The Supervisory Board, together with the CFO, discussed the 2015 financial statements with a special emphasis on complex transactions. Furthermore, the Supervisory Board met with the external auditor to discuss its audit and observations of the 2015 financial statements. The 2015 Financial Statements were approved by the Supervisory Board in its meeting on 14 April 2016.

## FINANCIAL STATEMENTS 2015

The Financial Statements were audited by KPMG Accountants N.V. who were elected as the Company's external auditor in 2015. The Supervisory Board will submit the 2015 Financial Statements to the 2016 Annual General Meeting, and will propose that the shareholders adopt them and release the Management Board from all liability in respect of its managerial activities and release the Supervisory Board from all liability in respect of its supervision of the Management Board.

Amsterdam-Duivendrecht, 14 April 2016

### *Supervisory Board*

Mark Wegter, Chairman

Martijn Kleijwegt

Stuart Chapman

## REMUNERATION REPORT

### REMUNERATION POLICY 2015

The Company's current remuneration policy for members of its Management Board was approved by the General Meeting on 30 June 2015 immediately prior to the listing of the Company on Euronext Amsterdam and Euronext Brussels at the beginning of July. The policy provides for competitive compensation so as to enable the Company to recruit and maintain competent management. Its general principles are:

- an annual fixed salary according to industry standards; and
- a variable salary that would be linked to milestones/performance objectives to be set annually by the Company's Supervisory Board, whereby the variable salary could have two (2) components:
  - an annual cash bonus payment according to industry standards; and/or
  - granting of share options and/or performance share awards in accordance with an employee incentive plan to be adopted by the Company.

A scenario analysis based on provision II.2.1 of the Dutch Corporate Governance Code was made.

### ACTUAL REMUNERATION IN 2015

Details of actual remuneration in 2015 for the Management Board can be found in note 24 'Related Parties' of the Consolidated Financial Statements.

Prior to its listing, the Company had in place a share option program and a bonus plan. Details in respect of the number of shares for the Management Board, potential issuance and vesting/lock-up can be found in note 15 'Employee Benefits' and note 24 'Related Parties' of the Consolidated Financial Statements.

### REMUNERATION POLICY FOR 2016

The Supervisory Board intends to propose to the General Meeting an amended remuneration policy for the Management Board for the financial year 2016, by giving the policy more substance, taking into account evolving market practices and reinforcing a performance-oriented culture focused on criteria relevant to the Company's strategy. As the drafting of this policy has not yet been completed, no overview of the 2016 remuneration policy can be presented in this remuneration report.

### PENSIONS

The members of the Management Board participate in the Dutch pension scheme for the Company. Details of actual pension payments in 2015 can be found in note 24 'Related Parties' of the Consolidated Financial Statements.

### EARLY RETIREMENT

There are no agreed arrangements for the early retirement of members of the Management Board.

Amsterdam-Duivendrecht, 14 April 2016

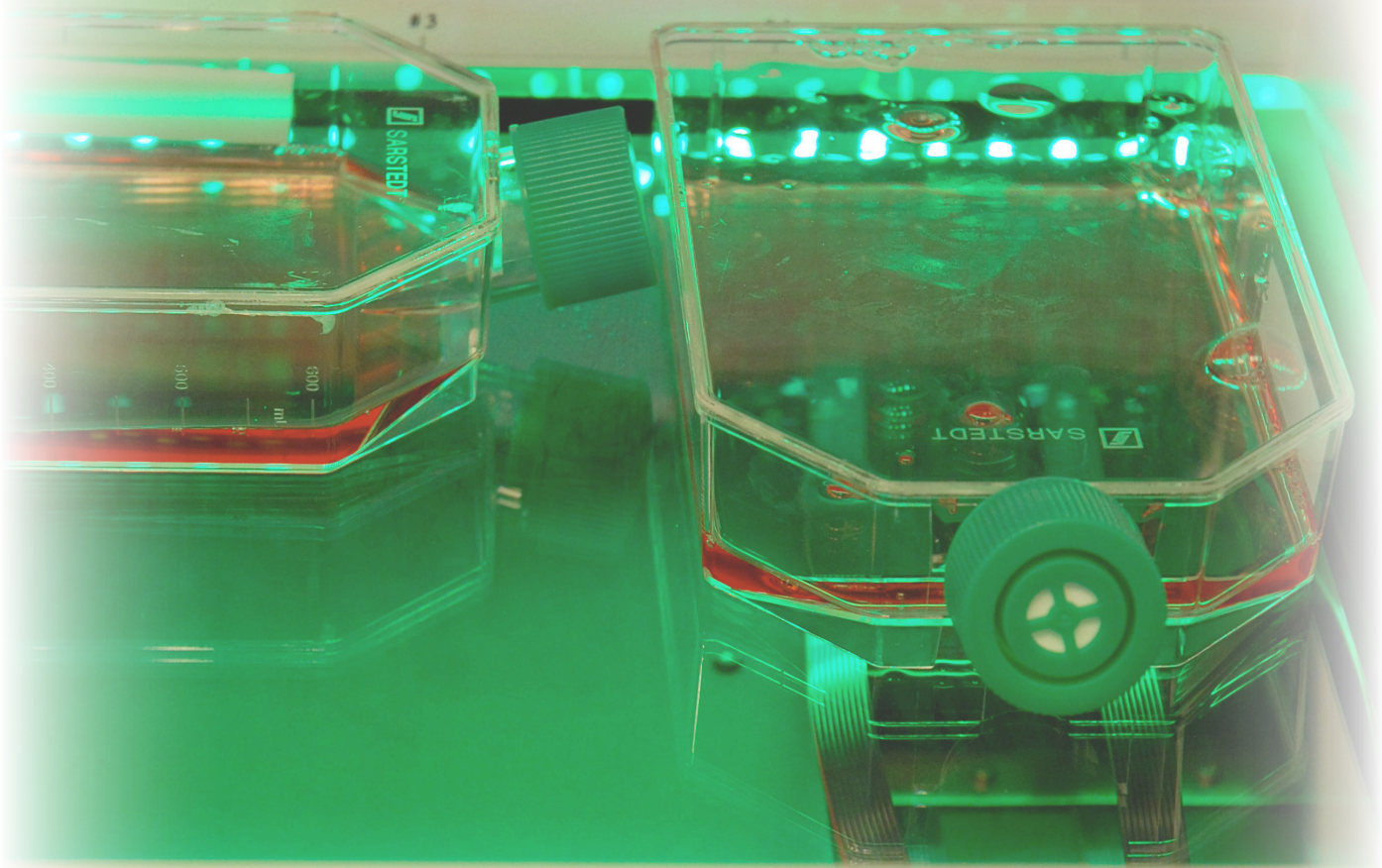
*Supervisory Board*

Mark Wegter, Chairman

Martijn Kleijwegt

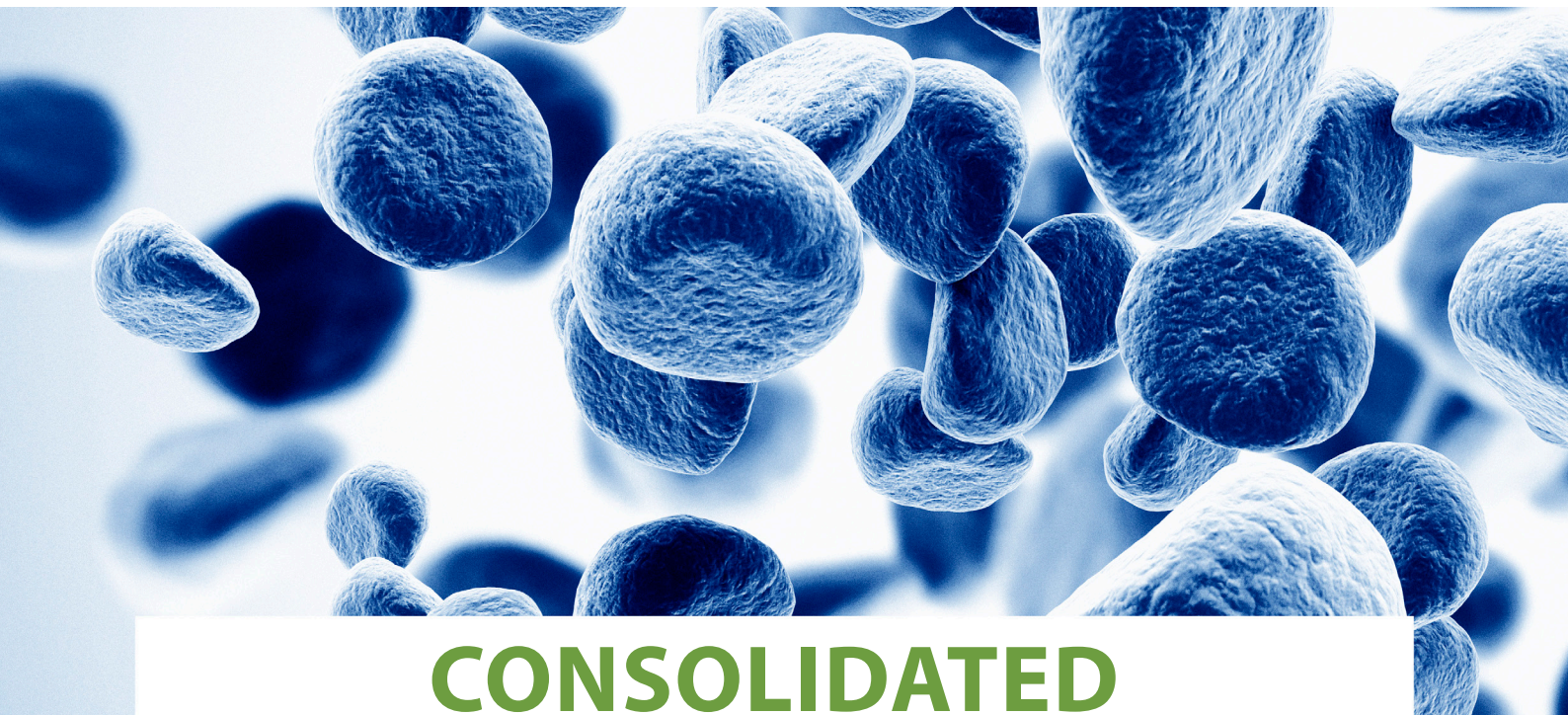
Stuart Chapman











# **CONSOLIDATED FINANCIAL STATEMENTS**

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## RESPONSIBILITY STATEMENT

The Management Board of Kiadis Pharma N.V. hereby declares that to the best of their knowledge, the consolidated financial statements for the year ended 31 December 2015, which have been prepared in accordance with International Financial Reporting Standards as adopted by the European Union, give a true and fair view of the assets, liabilities, financial position and profit or loss of the Company and the undertakings included in the consolidation taken as a whole, and the management report gives a fair view of the information required pursuant to section 5:25d(8)/(9) of the Dutch Financial Supervision Act (Wet op het financieel toezicht).

Amsterdam, 14 April 2016

### *Management Board*

Manfred Rüdiger, Chief Executive Officer

Robbert van Heekeren, Chief Financial Officer

## CONSOLIDATED STATEMENT OF FINANCIAL POSITION

		As at 31 December	
(Amounts in EUR x 1,000)	Note	2015	2014
<b>Assets</b>			
Property, plant and equipment	4	333	413
Intangible assets	5	12,714	13,687
<b>Total non-current assets</b>		<b>13,047</b>	<b>14,100</b>
Trade and other receivables	6	145	196
Deferred expenses	6	418	242
Cash and cash equivalents	7	28,666	5,674
<b>Total current assets</b>		<b>29,229</b>	<b>6,112</b>
<b>Total assets</b>		<b>42,276</b>	<b>20,212</b>
<b>Equity</b>			
Share capital		1,347	10,567
Share premium		98,137	57,243
Translation reserve		271	317
Warrant reserve		-	2,580
Accumulated deficit		(74,105)	(68,042)
<b>Equity attributable to owners of the Company</b>	8	<b>25,650</b>	<b>2,665</b>
<b>Liabilities</b>			
Loans and borrowings	10	13,713	5,090
Derivatives	11	-	3,730
<b>Total non-current liabilities</b>		<b>13,713</b>	<b>8,820</b>
Loans and borrowings	10	1,166	7,129
Trade and other payables	12	1,747	1,598
<b>Total current liabilities</b>		<b>2,913</b>	<b>8,727</b>
<b>Total liabilities</b>		<b>16,626</b>	<b>17,547</b>
<b>Total equity and liabilities</b>		<b>42,276</b>	<b>20,212</b>

## CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

		For the year ended 31 December	
(Amounts in EUR x 1,000)	Note	2015	2014
<b>Revenue</b>	13	-	-
<b>Other income</b>	14	-	-
Research and development expenses	15,16	(7,715)	(4,692)
General and administrative expenses	15,16	(8,292)	(1,476)
<b>Total operating expenses</b>		<b>(16,007)</b>	<b>(6,168)</b>
<b>Operating loss</b>		<b>(16,007)</b>	<b>(6,168)</b>
Interest income		50	28
Interest expenses		(1,394)	(1,073)
Other net finance expenses		894	(598)
<b>Net finance expenses</b>	17	<b>(450)</b>	<b>(1,643)</b>
<b>Loss before tax</b>		<b>(16,457)</b>	<b>(7,811)</b>
Income tax expense	18		(2)
<b>Loss for the period</b>		<b>(16,458)</b>	<b>(7,813)</b>
<b>Other comprehensive income</b>			
<i>Items that are or may be reclassified subsequently to profit or loss</i>			
Foreign currency translation difference for foreign operations		(46)	68
Related tax		-	-
		(46)	68
<b>Other comprehensive income for the period, net of tax</b>		<b>(46)</b>	<b>68</b>
<b>Total comprehensive income for the period</b>		<b>(16,504)</b>	<b>(7,745)</b>
<b>Loss attributable to:</b>			
Owners of the Company		(16,458)	(7,813)
		<b>(16,458)</b>	<b>(7,813)</b>
<b>Total comprehensive income attributable to:</b>			
Owners of the Company		(16,504)	(7,745)
		<b>(16,504)</b>	<b>(7,745)</b>
<b>Earnings per share</b>			
	19		
Basic earnings per share (euro)		(1,36)	(0,73)
Diluted earnings per share (euro)		(1,36)	(0,73)



## CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

		Share Capital	Share Premium	Translation Reserve	Warrant Reserve	Retained Earnings	Total Equity
(Amounts in EUR x 1,000)	Note						
<b>Balance as at 1 January 2014</b>		<b>10,896</b>	<b>51,863</b>	<b>249</b>	<b>2,580</b>	<b>(60,229)</b>	<b>5,359</b>
Loss for the period						(7,813)	(7,813)
Other comprehensive income				68			68
<b>Total comprehensive income</b>		<b>-</b>	<b>-</b>	<b>68</b>	<b>-</b>	<b>(7,813)</b>	<b>(7,745)</b>
<b>Transactions with owners, recorded directly in equity</b>							
Issue of shares	8	593	4,458				5,051
Cancellation of ordinary shares	8	(922)	922	-		-	-
<b>Balance as at 31 December 2014</b>		<b>10,567</b>	<b>57,243</b>	<b>317</b>	<b>2,580</b>	<b>(68,042)</b>	<b>2,665</b>
<b>Balance as at 1 January 2015</b>		<b>10,567</b>	<b>57,243</b>	<b>317</b>	<b>2,580</b>	<b>(68,042)</b>	<b>2,665</b>
Loss for the period						(16,458)	(16,458)
Other comprehensive income				(46)			(46)
<b>Total comprehensive income</b>		<b>-</b>	<b>-</b>	<b>(46)</b>	<b>-</b>	<b>(16,458)</b>	<b>(16,504)</b>
<b>Transactions with owners, recorded directly in equity</b>							
Issue of shares	8	278	34,436				34,714
Transaction costs	8		(3,485)				(3,485)
Business combinations	8	(9,498)	9,498				-
Equity-settled share-based payments	15					7,815	7,815
Warrants lapsed	8				(2,580)	2,580	-
Warrants exercised	8		445				445
<b>Balance as at 31 December 2015</b>		<b>1,347</b>	<b>98,137</b>	<b>271</b>	<b>-</b>	<b>(74,105)</b>	<b>25,650</b>

## CONSOLIDATED STATEMENT OF OF CASH FLOWS

		For the year ended 31 December	
(Amounts in EUR x 1,000)	Note	2015	2014
<b>Cash flows from operating activities</b>			
<b>Loss for the period</b>		<b>(16,458)</b>	<b>(7,813)</b>
<b>Adjustments for :</b>			
Depreciation of property, plant & equipment (PPE)	4	140	126
Net interest expenses	17	1,344	1,045
Equity-settled share-based payment transactions	15	7,815	-
Net unrealised foreign exchange (gains) or losses		1,000	(361)
(Gain) or loss from derivatives	11	(3,730)	541
(Gain) or loss from restatements of loans	10	1,835	387
Income tax expense	18	1	2
<b>Cash used in operating activities</b>		<b>(8,053)</b>	<b>(6,073)</b>
<b>before changes in working capital and provisions:</b>			
Trade and other receivables		99	(143)
Deferred expenses		(175)	(16)
Trade and other payables		290	256
Other liabilities		(116)	(86)
<b>Total change in working capital</b>		<b>98</b>	<b>11</b>
Provisions		-	-
<b>Cash used in operating activities</b>		<b>(7,955)</b>	<b>(6,062)</b>
Interest paid		(141)	(13)
Income taxes paid		-	-
<b>Net cash used in operating activities</b>		<b>(8,096)</b>	<b>(6,075)</b>
<b>Cash flows from investing activities</b>			
Interest received		4	28
Acquisition of PP&E	4	(59)	(259)
<b>Net cash used in investing activities</b>		<b>(55)</b>	<b>(231)</b>
<b>Cash flows from financing activities</b>			
Proceeds from issue of shares	8	34,714	5,051
Proceeds from exercise of warrants	8	445	-
Proceeds from government loans	10	-	889
Payment for share issue costs	8	(3,485)	-
Repayment of borrowings	10	(509)	(450)
<b>Net cash from financing activities</b>		<b>31,165</b>	<b>5,490</b>
<b>Net increase (decrease) in cash and cash equivalents</b>		<b>23,014</b>	<b>(816)</b>
Cash and cash equivalents as at 1 January		5,674	6,482
Effect of exchange rate fluctuations on cash held		(22)	8
<b>Cash and cash equivalents as at 31 December</b>	7	<b>28,666</b>	<b>5,674</b>

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

### 1. CORPORATE INFORMATION

Kiadis Pharma N.V. ("the Company" or "Kiadis Pharma") and its subsidiaries (together "the Group") are engaged in the pharmaceutical development of cell-based immunotherapy products in the field of diseases of the blood building system.

The Company is a public limited liability company incorporated and domiciled in Amsterdam, The Netherlands. The address of its business office is Entrada 231-234, 1114 AA, Amsterdam-Duivendrecht, The Netherlands.

These financial statements were authorised for issue by the Management Board and Supervisory Board of the Company on 14 April 2016. The financial statements as presented in this report are subject to approval by the General Meeting of Shareholders.

### 2. SIGNIFICANT ACCOUNTING POLICIES

The principal accounting policies applied in the preparation of these consolidated financial statements are set out below. These policies have been consistently applied to all the years presented.

Certain comparative amounts in the consolidated statement of financial position, the income statement, and statement of comprehensive income have been reclassified to conform to this year's presentation.

#### 2.1 Basis of Preparation

The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards as adopted by the European Union ("EU-IFRS", hereafter also referred to as "IFRS").

The consolidated financial statements have been prepared under the historical cost convention except when otherwise stated. All financial information presented in euro has been rounded to the nearest thousands, except when otherwise indicated.

The preparation of financial statements in conformity with IFRS requires management to make judgments, estimates and assumptions that affect the application of policies and reported amounts of assets and liabilities, income and expenses. The estimates and associated assumptions are based on experience and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis of making the judgments about carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates.

The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognised in the period in which the estimate is revised if the revision affects only that period or in the period of the revision and future periods if the revision affects both current and future periods.

In particular, information about significant areas of estimation uncertainty and critical judgment in applying accounting policies, that have the most significant effect on the amounts recognised in the financial statements, are described on pages 18 – 21.

#### *Going concern assessment*

The consolidated financial statements have been prepared on a going concern basis. Management believes that in proceeding with the current plan for clinical development, the Company will be able to meet its financial obligations in the twelve months following the date of these financial statements. Therefore, management is of the opinion that the going concern assumption is justified. However, the Company will need to raise additional funds in the future to complete its development programs through commercialisation and there may be a need to raise additional funds sooner if the Company chooses to expand its development activities.

#### 2.2 New standards, amendments and interpretations not yet adopted

Kiadis Pharma is assessing the potential impact on its consolidated financial statements resulting from the application of IFRS 9 and IFRS 15. The Company is not planning to early adopt these standards.

IFRS 9, published in July 2014, replaces existing guidance in IAS 39 Financial Instruments: Recognition and Measurement. IFRS 9 includes revised guidance on classification and measurement of financial instruments, including a new expected credit loss model for calculating impairment on financial assets, and new general hedge accounting requirements. IFRS 9 is effective for annual reporting periods beginning on or after 1 January 2018, with early adoption permitted.

IFRS 15, published in May 2014 establishes a comprehensive framework for determining whether, how much and when revenue is recognised. It replaces existing revenue recognition guidance, including IAS 18 Revenue, IAS 11 Construction Contracts and IFRIC 13 Customer Loyalty Programs. IFRS 15 is effective for annual periods beginning on or after 1 January 2018. Earlier application is permitted.

IFRS 16, published in January 2016, establishes a revised framework for determining whether a lease is recognised on the (Consolidated) Statement of Financial Position. It replaces existing guidance on leases, including IAS 17. IFRS 16 is effective on or after 1 January 2019, with early adoption permitted. Kiadis Pharma will assess the potential impact on its consolidated financial statements resulting from the application of IFRS 16.

The following new or amended standards are not expected to have a significant impact on Kiadis Pharma consolidated financial statements:

- Applying the concept of materiality in practice (amendments to IAS 1 Disclosure Initiative)
- Classification of Acceptable Methods of Depreciation and Amortisation (amendments to IAS 16 and IAS 38)
- Equity method in separate financial statements (amendments to IAS 27)
- Applying the consolidation exemption (amendments to IFRS 10 & 11 and IAS 28)
- Annual Improvements to IFRSs 2012-2014 Cycle

## 2.3 Consolidation

The Company is the holding company of a group of companies. The following legal entities are subsidiaries of Kiadis Pharma N.V. and together form the Kiadis Pharma group of companies:

<u>Legal Entity</u>	<u>Registered Office</u>	<u>Investment%</u>
Kiadis Pharma B.V.	The Netherlands	100.00%
Kiadis Pharma Netherlands B.V.	The Netherlands	100.00%
Kiadis Pharma Intellectual Property B.V.	The Netherlands	100.00%
Kiadis Pharma Germany GmbH	Germany	100.00%
Kiadis Pharma Canada Inc.	Canada	100.00%
Celmed Oncology (USA) Inc. (*)	USA	100.00%

(\*) Celmed Oncology (USA) Inc. was dissolved on 31 August 2015 and has ceased to exist.

Kiadis Pharma N.V. is the parent of Kiadis Pharma B.V. The latter is the parent of all other legal entities with the exception of Celmed Oncology (USA) Inc., which was a subsidiary of Kiadis Pharma Inc. up to the date of its dissolution.

### (a) Subsidiaries

Subsidiaries are entities controlled by the Group. The Group controls an entity when it is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. The financial statements of subsidiaries are included in the consolidated financial statements from the date on which control commences until the date on which control ceases.

### (b) Business combinations

The Group accounts for business combinations using the acquisition method when control is transferred to the Group. The consideration transferred in the acquisition is generally measured at fair value, as are the identifiable net assets acquired. Any goodwill that arises is tested annually for impairment. Any gain on a bargain purchase is recognised in profit or loss immediately.

Transaction costs are expensed as incurred, except if related to the issue of debt or equity securities.

The consideration transferred does not include amounts related to the settlement of pre-existing relationships. Such amounts are generally recognised in profit or loss.

Any contingent consideration payable is measured at fair value at the acquisition date. If an obligation to pay contingent consideration that meets the definition of a financial instrument is classified as equity, then it is not re-measured and settlement is accounted for within equity. Otherwise, subsequent changes in the fair value of the contingent consideration are recognised in profit or loss.

If share-based payment awards (replacement awards) are required to be exchanged for awards held by the acquiree's employees (acquiree's awards) and relate to past services, then all or a portion of the amount of the acquirer's replacement awards is included in measuring the consideration transferred in the business combination. This determination is based on the market-based value of the replacement awards compared with the market-based value of the acquiree's awards and the extent to which the replacement awards relate to pre-combination service.

Business combinations under common control are accounted for using a predecessor value method. A predecessor value method involves accounting for the assets and liabilities of the acquired business using existing carrying values rather than at fair value. No goodwill is recognised.

## 2.4 Segment reporting

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision-maker. The chief operating decision-makers, who are responsible for allocating resources and assessing performance of the operating segments, have been identified as the Management Board.

As per 31 December 2015, the Group has one lead product under development being ATIR. This is considered to be the only reportable segment. All corporate activities can be assigned therefore to this segment as well. Therefore no additional segment analysis is disclosed.

## 2.5 Foreign Currency Translation

### *(a) Functional and presentation currency*

Items included in the financial statements of each of the Group's entities are measured using the currency of the primary economic environment in which the entity operates ("the functional currency"). The consolidated financial statements are presented in euro, which is the Company's functional and presentation currency.

### *(b) Transactions and balances*

Transactions in foreign currencies are translated to the respective functional currencies of Group entities at exchange rates at the dates of the transactions.

Monetary assets and liabilities denominated in foreign currencies are translated into the functional currency at the exchange rate at the reporting date. Non-monetary assets and liabilities denominated in foreign currencies that are measured at fair value are translated into the functional currency at the exchange rate when the fair value was determined. Non-monetary items that are measured based on historical cost in a foreign currency are translated using the exchange rate at the date of the transaction. Foreign currency differences are generally recognised in profit or loss.

### *(c) Foreign operations*

The assets and liabilities of foreign operations, including goodwill and fair value adjustments arising on acquisition, are translated into euro at exchange rates at the reporting date. The income and expenses of foreign operations are translated into euro at the exchange rates at the dates of the transactions.

Foreign currency differences are recognised in Other Comprehensive Income (OCI) and accumulated in the translation reserve, except to the extent that the translation difference is allocated to Non-Controlling Interests (NCI).

When a foreign operation is disposed of in its entirety or partially such that control, significant influence or joint control is lost, the cumulative amount in the translation reserve related to that foreign operation is reclassified to profit or loss as part of the gain or loss on disposal. If the Group disposes of part of its interest in a subsidiary but retains control, then the relevant proportion of the cumulative amount is reattributed to NCI. When the Group disposes of only part of an associate or joint venture while retaining significant influence or joint control, the relevant proportion of the cumulative amount is reclassified to profit or loss.

## 2.6 Notes to the cash flow statement

The cash flow statement has been prepared using the indirect method. The cash disclosed in the cash flow statement is comprised of cash and cash equivalents. Cash comprises cash on hand and demand deposits. Cash equivalents are short-term, highly liquid investments that are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value.

Cash flows denominated in foreign currencies have been translated at the exchange rate prevailing at the transaction date. Exchange rate differences affecting cash items are shown separately in the Cash flow statement.

Interest paid and income taxes are included in Cash from operating activities.

## 2.7 Intangible Assets

### (a) Goodwill

Goodwill represents the excess of the cost of an acquisition over the fair value of the Group's share of the net identifiable assets, liabilities and contingent liabilities of the acquired subsidiary at the date of acquisition. If the cost of acquisition is less than the fair value of the net assets of the subsidiary acquired (also after re-assessment), the difference is recognised directly in the income statement.

Separately recognised goodwill is tested annually for impairment and carried at cost less accumulated impairment losses. Impairment losses on goodwill are not reversed. Gains and losses on the disposal of an entity include the carrying amount of goodwill relating to the entity sold.

### (b) Patents (licenses, trademarks)

Patents can be acquired separately or as part of a business combination. Patents that are acquired as part of a business combination are valued at fair value. Patents that are acquired separately by the Group and have finite useful lives are measured at cost less accumulated amortisation and accumulated impairment losses. A patent is recognised as intangible asset when:

- it is probable that the future economic benefits that are attributable to the asset will flow to the entity; and
- the cost of the asset can be measured reliably.

The probability of future economic benefits must be based on reasonable and supportable assumptions about conditions that will exist over the life of the asset. The probability recognition criterion is always considered to be satisfied for intangible assets that are acquired separately or in a business combination.

Amortisation is calculated using the straight-line method to allocate the cost of patents over their estimated useful lives. Amortisation begins when an asset is available for use.

### (c1) In-process research and development acquired in a business combination

In-process research and development acquired in a business combination is capitalised as intangible assets if the assets acquired meet the definition of an intangible asset. I.e., an intangible asset lacks physical substance; is identifiable; is non-monetary; and is controlled by the entity and expected to provide future economic benefits. Intangible assets acquired in a business combination that meet the following criteria are recognised at fair value: it is probable that future economic benefits that are attributable will flow to the entity; and the fair value of the asset can be measured reliably. These intangible assets are amortised



from the moment these assets are available for use, being the commencement of the commercial introduction of the product on a straight-line basis over the term of its expected benefit.

#### *(c2) Research and development expenses*

Expenditure on research activities is recognised in profit or loss as incurred.

Development expenditure is capitalised only if the expenditure can be measured reliably, the product or process is technically and commercially feasible, future economic benefits are probable and the Group intends to and has sufficient resources to complete development and to use or sell the asset. Otherwise, it is recognised in profit or loss as incurred. Subsequent to initial recognition, development expenditure is measured at cost less accumulated amortisation and any accumulated impairment losses.

#### *(c3) Capitalised in-process research and development*

Capitalised in-process research and development costs with a finite useful life are stated at cost less accumulated amortisation and impairment losses. These costs are amortised on a straight-line basis over the term of its expected benefit from the moment these assets are available for use, being the commencement of the commercial introduction of the product.

This intangible asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount (also refer to 2.9).

#### *(d) Subsequent expenditure*

Subsequent expenditure of intangibles is capitalised only when it increases the future economic benefits embodied in the specific asset to which it relates and is amortised over the estimated useful life of the respective intangible. All other expenditure, including expenditure on internally generated goodwill, is recognised in profit or loss when incurred

## **2.8 Property, Plant and Equipment**

#### *(a) Property, plant and equipment*

Property, plant and equipment comprise laboratory equipment, hardware, furniture and leaseholds improvements. All property, plant and equipment are measured at historical cost less accumulated depreciation and impairment losses. Historical cost includes expenditures that are directly attributable to the acquisition of the asset.

When parts of an item of property, plant and equipment have different useful lives, they are accounted for as separate items (major components) of property, plant and equipment.

#### *(b) Subsequent costs*

The costs of replacing part of an item of property, plant and equipment is recognised in the carrying amount of the item if it is probable that the future economic benefits embodied within the part will flow to the Group and its cost can be measured reliably. The costs of the day-to-day servicing of property, plant and equipment are recognised in profit or loss as incurred.

#### *(c) Depreciation*

Depreciation is recognised in profit or loss on a straight-line basis over the estimated useful lives of each part of an item of property, plant and equipment.

The estimated useful lives for the current and comparative periods are as follows:

Laboratory equipment and furniture: 5 years

Hardware: 5 years

Leaseholds Improvements: Lease term

Depreciation methods, useful lives and residual values are reassessed at the reporting date.

An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount (also refer to 2.9).

Gains and losses on the sale of property, plant and equipment are included in the consolidated financial statement of income.

#### **(d) Finance leases**

Leases of property, plant and equipment where the Group has substantially all the risks and rewards of ownership are classified as finance leases. Finance leases are capitalised at the commencement of the lease at the lower of the fair value of the leased equipment and the present value of the minimum lease payments. Subsequent to initial recognition, the asset is accounted for in accordance with the accounting policy applicable to that asset.

Each lease payment is allocated between the liability and finance charges so as to achieve a constant rate on the finance balance outstanding. The corresponding rental obligations, net of finance charges, are included in "finance lease liabilities". The interest element of the finance cost is charged to the income statement over the lease term so as to produce a constant periodic rate of interest on the remaining balance of the liability for each term. Property, plant and equipment acquired under finance leases are depreciated over the shorter of the useful life of the asset or the lease term.

## **2.9 Impairment**

The carrying amounts of the Group's assets are reviewed at each reporting date to determine whether there is any indication of impairment. If any such indication exists then the asset's recoverable amount is estimated. For goodwill and intangible assets that are not yet available for use, the recoverable amount is estimated at each reporting date.

An impairment loss is recognised if the carrying amount of an asset or its cash-generating unit exceeds its recoverable amount. A cash-generating unit is the smallest identifiable asset group that generates cash flows that are largely independent from other assets and groups. Impairment losses are recognised in profit or loss. Impairment losses recognised in respect of cash-generating units are allocated first to reduce the carrying amount of any goodwill allocated to the units and then to reduce the carrying amount of the other assets in the unit (group of units) on a pro rata basis.

The recoverable amount of an asset or cash-generating unit is the greater of its value in use and its fair value less costs to sell. In assessing value in use, the estimated future cash flows are discounted to their present value using a discount rate that reflects current market assessments of the time value of money and the risks specific to the asset.

An impairment loss in respect of goodwill is not reversed. In respect of other assets, impairment losses recognised in prior periods are assessed at each reporting date for any indications that the loss has decreased or no longer exist. An impairment loss is reversed if there has been a change in the estimates used to determine the recoverable amount. An impairment loss is reversed only to the extent that the asset's carrying amount does not exceed the carrying amount that would have been determined, net of depreciation or amortisation, if no impairment loss had been recognised.

## **2.10 Financial Instruments**

A financial instrument is recognised if the Group becomes a party to the contractual provisions of the instrument. Financial assets are derecognised if the Group's contractual rights to the cash flows from the financial assets expire or if the Group transfers the financial asset to another party without retaining control or substantially all risks and rewards of the asset. Regular way purchases and sales of financial assets are accounted for at trade date, i.e. the date that the Group commits itself to purchase or sell the asset. Financial liabilities are derecognised if the Group's obligations specified in the contract expire or are discharged or cancelled.

#### **(a) Non-derivative financial instruments**

Non-derivative financial instruments comprise trade, other receivables and deferred expenses, cash and cash equivalents, loans and borrowings, and trade and other payables.

Non-derivative financial instruments are recognised initially at fair value plus, for instruments not at fair value through profit or loss, any directly attributable transaction costs, except as described below. Subsequent to initial recognition non-derivative financial instruments are measured as described below.

Investments are measured at fair value through profit and loss if held for trading purposes or designated as such upon initial

recognition. Upon initial recognition, attributable transaction costs are recognised in profit and loss when incurred. Financial instruments at fair value through profit and loss are measured at fair value, and changes therein are recognised in profit and loss. Trade receivables are recognised at amortised cost less impairment losses.

Cash and cash equivalents includes cash-in-hand, current accounts, deposits held at call with banks, other short-term highly liquid investments with original maturities of three months or less, and bank overdrafts. Bank overdrafts are shown separately within current liabilities on the statement of financial position. Bank overdrafts that are repayable on demand and form an integral part of the Group's cash management are included as a component of cash and cash equivalents for the purpose of the statement of cash flows.

Loans and borrowings are measured at fair value at initial recognition and subsequently stated at amortised cost.

Loans and borrowings are classified as "current liabilities" and "non-current liabilities" to reflect the Group's obligations to repay the loan. The portion that is due for payment within 12 months is classified as "current liabilities" while the remainder is classified as "non-current liabilities".

Trade and other payables are stated at amortised cost.

Other non-derivative financial instruments are measured at amortised cost using the effective interest method, less any impairment losses.

Accounting for finance income and expense is discussed in Note 2.15.

#### *(b) Derivative financial instruments*

Derivatives that qualify as financial liabilities are accounted for at fair value through profit and loss. At each reporting date, the fair value of derivatives is remeasured and changes are recognised in profit or loss.

Embedded derivatives are separated from the host contract and accounted for separately if the economic characteristics and risks of the host contract and the embedded derivative are not closely related, a separate instrument with the same terms as the embedded derivative would meet the definition of a derivative and the combined instrument is not measured at fair value through profit or loss. Changes in the fair value of separable embedded derivatives are recognised immediately in profit or loss.

## **2.11 Equity**

### *(a) Ordinary shares*

Incremental costs directly attributable to issue of ordinary shares and share options are recognised as a deduction from equity.

### *(b) Preference share capital*

Preference share capital is classified as equity if it is non-redeemable, or redeemable only at the Company's option, and any dividends are discretionary. Dividends thereon are recognised as distributions within equity.

Preference share capital is classified as a liability if it is redeemable on a specific date or at the option of the shareholders, or if dividend payments are not discretionary. Dividends thereon are recognised as interest expense in profit or loss.

### *(c) Treasury shares*

The cost of the Company's own equity instruments that the Company has reacquired ("treasury shares") is deducted from equity. Costs of issuing or reacquiring equity instruments (other than in a business combination) are accounted for as a deduction from equity, net of any related income tax benefit. Any consideration paid or received is recognised directly in equity.

#### **(d) Transaction costs**

Qualifying costs attributable to an equity transaction are recorded directly in equity. Only incremental costs that are attributable directly to issuing own equity instruments are recognised in equity. Qualifying costs may include, but are not limited to, fees for legal and tax advice related to the share issue, cost of preparing the prospectus, underwriting fees and fees incurred in respect of the valuation of the shares.

### **2.12 Employee Benefits**

#### **(a) Share-based payments**

For equity-settled option and bonus plans the accounting treatment is as follows: the grant date fair value of options or rights to bonus shares granted to employees is recognised as an employee expense, with a corresponding increase in equity, over the period in which the employees become unconditionally entitled to these options or rights. The amount recognised as an expense is adjusted to reflect the latest estimate of the number of rights that will vest.

For cash-settled bonus plans the expense and corresponding financial liability incurred are measured at the fair value of the liability. These cash-settled awards are subsequently re-measured at each reporting date.

#### **(b) Pension obligations**

The Group has a defined contribution plan. The Group has no legal or constructive obligations to pay further contributions if the plan does not hold sufficient assets to pay all employees the benefits relating to employee service in the current and prior periods. The contributions are recognised as employee benefit expense in profit or loss when they are due. Prepaid contributions are recognised as an asset to the extent that a cash refund or a reduction in the future payments is available.

#### **(c) Profit-sharing and bonus plans**

Short-term employee benefit obligations are measured on an undiscounted basis and are expensed as the related service is provided.

An accrual is recognised for the amount expected to be paid under short-term cash bonus or profit-sharing plans if the Group has a present legal or constructive obligation to pay this amount as a result of past service provided by the employee and the obligation can be estimated reliably.

### **2.13 Research & Development and General & Administrative Expenses**

Research expenditures, and development expenditures that do not meet the asset recognition criteria, are recognised as expenses as incurred and comprise allocated employee costs, collaboration costs, allocated office costs, license costs, amortisation costs, depreciation costs, and the cost of laboratory consumables.

General and administrative expenses comprise allocated employee costs, allocated office costs, consultancy costs, and other general and administrative costs.

### **2.14 Operating Leases**

Leases in which substantially all the risks and rewards of ownership are retained by the lessor are classified as operating leases. Payments made under operating leases (net of any incentives received from the lessor) are charged to the income statement on a straight-line basis over the term of the lease.

### **2.15 Finance Income and Expenses**

Finance income comprises interest income on funds invested, and foreign currency gains. Interest income is recognised as it accrues, using the effective interest method.

Finance expenses comprise interest expense on loans and borrowings and foreign currency losses.

## 2.16 Income Tax

Income tax expense comprises current and deferred tax. It is recognised in profit or loss except to the extent that it relates to a business combination, or items recognised directly in equity or in OCI.

### (a) Current tax

Current tax comprises the expected tax payable or receivable on the taxable income or loss for the year and any adjustment to tax payable or receivable in respect of previous years. It is measured using tax rates enacted or substantively enacted at the reporting date. Current tax also includes any tax arising from dividends.

Current tax assets and liabilities are offset only if certain criteria are met.

### (b) Deferred tax

Deferred tax is recognised in respect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for taxation purposes. Deferred tax is not recognised for:

- temporary differences on the initial recognition of assets or liabilities in a transaction that is not a business combination and that affects neither accounting nor taxable profit or loss;
- temporary differences related to investments in subsidiaries, associates and joint arrangements to the extent that the Group is able to control the timing of the reversal of the temporary differences and it is probable that they will not reverse in the foreseeable future; and
- taxable temporary differences arising on the initial recognition of goodwill.

Deferred tax assets are recognised for unused tax losses, unused tax credits and deductible temporary differences to the extent that it is probable that future taxable profits will be available against which they can be used. Deferred tax assets are reviewed at each reporting date and are reduced to the extent that it is no longer probable that the related tax benefit will be realised; such reductions are reversed when the probability of future taxable profits improves.

Unrecognised deferred tax assets are reassessed at each reporting date and recognised to the extent that it has become probable that future taxable profits will be available against which they can be used.

Deferred tax is measured at the tax rates that are expected to be applied to temporary differences when they reverse, using tax rates enacted or substantively enacted at the reporting date.

The measurement of deferred tax reflects the tax consequences that would follow from the manner in which the Group expects, at the reporting date, to recover or settle the carrying amount of its assets and liabilities.

Deferred tax assets and liabilities are offset only if certain criteria are met.

## 3. CRITICAL ACCOUNTING ESTIMATES AND JUDGEMENTS

The Group prepares its consolidated financial statements in accordance with IFRS as adopted by the EU. The preparation of financial statements requires management to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities and contingencies as of the date of the Group's financial statements, and the reported amounts of revenues and expenses for the relevant accounting periods. The Group bases these estimates on historical experience and assumptions that management believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the reported amounts of revenues and expenses that are not readily apparent from other sources. Management evaluates these estimates on an ongoing basis.

### 3.1 Critical accounting estimates and assumptions

The Group has identified the following critical accounting policies as requiring management to make the most significant estimates and judgments in the preparation of its consolidated financial statements. The Group considers an accounting policy to be critical if it requires management to make an accounting estimate based on assumptions about matters that are highly

uncertain at the time the estimate is made, and if the reasonable use of different estimates in the current period or changes in the accounting estimate that are reasonably likely to occur from period to period would have a material impact on its financial presentation. When reviewing the Group's financial statements, investors should consider the effect of estimates on its critical accounting policies, the judgments and other uncertainties affecting application of these policies and the sensitivity of the Group's reported financial results to changes in conditions and assumptions. The Group's actual results may differ materially from these estimates under different assumptions.

### **3.2 Critical judgments in applying the Company's accounting policies**

#### ***(a) Impairment of Goodwill, Patents and In-process R&D acquired in a business combination***

The Group reviews long-lived assets for impairment when events or circumstances indicate that carrying amounts may not be recoverable. In determining impairments of intangible assets and tangible fixed assets, management must make significant judgments and estimates to determine whether the cash flows generated by those assets are less than their carrying value. Determining cash flows requires the use of judgments and estimates that have been included in the Group's strategic plans and long-range forecasts. The data necessary for the execution of the impairment tests are based on management estimates of future cash flows, which require estimating revenue growth rates and profit margins.

An impairment loss is recognised if the carrying amount of an asset exceeds its recoverable amount. Impairment losses are recognised in profit or loss. The recoverable amount of an asset is the greater of its value in use and its fair value less costs to sell. In assessing value in use, in general the estimated future cash flows are discounted to their present value using a discount rate that reflects current market assessments of the time value of money and the risks specific to the asset. Goodwill and intangibles that are not yet amortised are evaluated at least annually for impairment and written down to its recoverable amount, in the case of impairment. The determination of such implied value involves significant judgment and estimates from management.

Changes in assumptions and estimates included within the impairment reviews could result in significantly different results than those recorded in the consolidated financial statements.

#### ***(b) Income Tax Expense***

The Group exercises judgment in determining the extent of the realisation of the net operating losses based upon estimates of future taxable income in the various jurisdictions in which these net operating losses exist. Where there is an expectation that on the balance of probabilities there will not be sufficient taxable profits to utilise these net operating losses, these net operating losses have not been recognised as a deferred tax asset. If actual events differ from management's estimates, or to the extent that these estimates are adjusted in the future, any changes could materially impact the Group's financial position and results of operations.

On 31 December 2015, Kiadis Pharma N.V. had deferred tax assets in respect of gross cumulative tax losses of EUR53.7 million in the Netherlands and CN\$18.6 million in Canada. These deferred tax assets have been recognised to the extent they are used to offset the deferred tax liabilities which the Group has recognised.

#### ***(c) Share-based payments***

The amount recognised as an expense for equity-settled share-based payments reflects the latest estimate of the number of rights that will vest. At each balance date, the Group revises its estimates of the number of rights which are expected to vest. The Group recognises the impact of the revision of original estimates, if any, in the income statement and a corresponding adjustment to equity.

The amount recognised as an expense for cash-settled share-based payments reflects the estimated change in fair value of the corresponding liability at the reporting date.

#### ***(d) Derivatives***

The Group exercises judgment in determining the estimated fair value of derivatives. For derivatives that are level 3 financial liabilities this means that management has to make assumptions about significant unobservable inputs used to calculate fair values, based on binomial option pricing.



#### *(e) Loans and borrowings*

The Group exercises judgment in determining which financial liabilities qualify as loans and subsequently exercises judgment in determining the estimated fair value of these loans. For level 2 financial liabilities, management has to make significant judgments and estimates about future cash flows.

### **3.3 Determination of Fair Values**

A number of the Group's accounting policies and disclosures require the determination of fair value, for both financial and non-financial assets and liabilities. Fair values have been determined for (re-)measurement and/or disclosure purposes based on the following methods. Where applicable, further information about the assumptions made in determining fair values is disclosed in the notes specific to that financial asset or liability.

#### *(a) Intangible assets*

The fair value of in-process research and development acquired in a business combination is based on the discounted cash flow method for product-related technologies (by calculating the present value of future cash flows resulting from each asset). Discount rates of 12% to 14% have been used as inputs for a risk-adjusted NPV model.

#### *(b) Property, plant and equipment*

The fair value of property, plant and equipment recognised as a result of a business combination is based on market values. The market value of property is the estimated amount for which a property could be exchanged on the date of valuation between a willing buyer and a willing seller in an arm's length transaction after proper marketing wherein the parties had each acted knowledgeably, prudently and without compulsion. The market value of items of plant, equipment, fixtures and fittings is based on the quoted market prices for similar items.

#### *(c) Trade and other receivables*

The fair value of trade and other receivables is estimated as the present value of future cash flows, discounted at the market rate of interest at the reporting date.

#### *(d) Share-based payments*

Measurement inputs to calculate the fair value of employee stock options include the (estimated) share price on the measurement date, exercise price of the instrument, expected volatility (based on weighted average historic volatility adjusted for changes expected due to publicly available information), weighted average expected life of the instruments (based on historical experience and general option holder behaviour), expected dividends, and the risk-free interest rate (based on government bonds). Service and non-market performance conditions attached to the transactions are not taken into account in determining fair value.

Measurement inputs to calculate the fair value of employee rights to equity-settled share-based payments include the estimated share price on the grant date, exercise price and the estimated vesting schedule. For cash-settled share-based payments the estimated share price at the reporting date is used as an input to calculate the fair value of the financial liability.

#### *(e) Derivatives*

The estimated fair value of derivatives of level 3 is based on a binomial model. Measurement inputs to calculate the fair value include estimated share prices, probabilities that certain scenarios will occur, discount rates, and the exercise price of the financial instrument.

#### *(f) Loan from Hospira Inc.*

The Group exercises judgment in determining the estimated value of the financial liability towards Hospira Inc. that has been judged as a loan. For this financial liability, management has to make significant judgments and estimates about future cash flows towards Hospira Inc.

#### 4. PROPERTY, PLANT AND EQUIPMENT

(Amounts in EUR x 1,000)	Laboratory Equipment	Furniture & Hardware	Leasehold Improvements	Total
<b>Balance as at 1 January 2014</b>				
Cost of acquisition	568	295	41	904
Depreciation / impairment	(356)	(227)	(41)	(624)
<b>Book value as at 1 January 2014</b>	<b>212</b>	<b>68</b>	<b>-</b>	<b>280</b>
<b>Changes in book value 2014</b>				
Additions	250	9	-	259
Depreciation	(96)	(30)	-	(126)
<b>Total changes in book value 2014</b>	<b>154</b>	<b>(21)</b>	<b>-</b>	<b>133</b>
<b>Balance as at 31 December 2014</b>				
Cost of acquisition	818	182	41	1.041
Depreciation / impairment	(452)	(135)	(41)	(628)
<b>Book value as at 31 December 2014</b>	<b>366</b>	<b>47</b>	<b>-</b>	<b>413</b>
<b>Changes in book value 2015</b>				
Additions	38	22	-	60
Depreciation	(124)	(16)	-	(140)
<b>Total changes in book value 2015</b>	<b>(86)</b>	<b>6</b>	<b>-</b>	<b>(80)</b>
<b>Balance as at 31 December 2015</b>				
Cost of acquisition	856	204	41	1.101
Depreciation / impairment	(576)	(151)	(41)	(768)
<b>Book value as at 31 December 2015</b>	<b>280</b>	<b>53</b>	<b>-</b>	<b>333</b>

## 5. INTANGIBLE ASSETS

(Amounts in EUR x 1,000)	Goodwill	In-process Research & Development	Patents	Total
<b>Balance as at 1 January 2014</b>				
Cost	4,160	8,988	80	13,228
Amortization / Impairment	-	-	(80)	(80)
<b>Book value as at 1 January 2014</b>	<b>4,160</b>	<b>8,988</b>	<b>-</b>	<b>13,148</b>
<b>Changes in book value 2014</b>				
Effect of movement in foreign exchange rates	170	369	-	539
<b>Total changes in book value 2014</b>	<b>170</b>	<b>369</b>	<b>-</b>	<b>539</b>
<b>Balance as at 31 December 2014</b>				
Cost	4,330	9,357	80	13,767
Amortization / Impairment	-	-	(80)	(80)
<b>Book value as at 31 December 2014</b>	<b>4,330</b>	<b>9,357</b>	<b>-</b>	<b>13,687</b>
<b>Changes in book value 2015</b>				
Effect of movement in foreign exchange rates	(308)	(665)	-	(973)
<b>Total changes in book value 2015</b>	<b>(308)</b>	<b>(665)</b>	<b>-</b>	<b>(973)</b>
<b>Balance as at 31 December 2015</b>				
Cost	4,022	8,692	80	12,794
Amortization / Impairment	-	-	(80)	(80)
<b>Book value as at 31 December 2015</b>	<b>4,022</b>	<b>8,692</b>	<b>-</b>	<b>12,714</b>

### Goodwill

Goodwill recognised relates to the acquisition of Celmed BioSciences Inc.

### In-process research and development acquired in a business combination

The business combination effected in 2006 (acquisition of Celmed BioSciences Inc.) has been accounted for in accordance with IFRS 3, Business Combinations. Based on IFRS 3, the acquirer shall, at the acquisition date, allocate the cost of a business combination by recognizing the acquiree's identifiable assets, liabilities and contingent liabilities that satisfy the recognition criteria, at their fair values at that date. These intangible assets are amortised from the commencement of the commercial production of the product on a straight-line basis over the term of its expected benefit. The useful live is estimated to be 10 years at minimum from the date of market introduction.

### Impairment test of goodwill and in-process research and development

For the purpose of the impairment testing, goodwill and in-process research and development have been allocated to the total Group because no lower cash-generating units can be identified which generate cash inflows that are largely independent of those from other assets. The recoverable amount is determined based on a value-in-use calculation (i.e. the present value of the future cash flows expected to be derived from the products, of which positive cash flows are not expected till the development period has successfully completed and a product has been launched, the commencement of the commercial sale of the product). The calculation is executed by applying an income approach which involves calculating the present value of future

cash flows (over an estimable period) resulting from each asset. Estimated risk-adjusted future net cash flows are used, which are a.o. based on probabilities of reaching the market with an estimated potential product introduction date (estimated in 2020), possible revenues resulting from estimated market shares and product pricing, estimated gross margins and estimated operating expenditures. A discount rate of 12% had been used for a risk-adjusted NPV model. Reasonable possible changes in key assumptions will not lead to a materially different outcome. However, a scenario of not being able to reach commercialisation of the related products will probably result in impairment.

## 6. TRADE, OTHER RECEIVABLES AND DEFERRED EXPENSES

(Amounts in EUR x 1,000)	2015	2014
VAT receivables	80	122
Deferred expenses	418	242
Deposits (lease of buildings)	-	58
Interest receivable	46	-
Other amounts receivable	19	16
	<b>563</b>	<b>438</b>

## 7. CASH AND CASH EQUIVALENTS

(Amounts in EUR x 1,000)	2015	2014
Cash at bank and in hand	9,013	5,643
Short-term bank deposits	19,653	31
<b>Cash and cash equivalents</b>	<b>28,666</b>	<b>5,674</b>
Bank overdrafts used for cash management purposes	-	-
<b>Net cash as per statement of cash flows</b>	<b>28,666</b>	<b>5,674</b>

All amounts reported as cash or cash equivalents are at the free disposal of the company with the exception of a call deposit having a carrying value of EUR73 thousand that is pledged against certain bank guarantees provided as security for the lease of buildings.

## 8. SHAREHOLDERS' EQUITY

### Shares issued

	Number of Issued Shares		
	Ordinary Shares	Preference Shares Class AA	Preference Shares Class BB
<b>Balance as at 1 January 2014</b>	<b>9,706,917</b>	<b>1,188,841</b>	-
New shares issued for cash	-	-	593,577
Cancellation of ordinary shares	(921,998)	-	-
<b>Balance as at 31 December 2014</b>	<b>8,784,919</b>	<b>1,188,841</b>	<b>593,577</b>
New shares issued for cash	2,777,136	-	-
Business combinations	1,909,589	(1,188,841)	(593,577)
<b>Balance as at 31 December 2015</b>	<b>13,471,644</b>	-	-

On 31 December 2015, the total number of ordinary shares issued by the Company was 13,471,644 (2014: 8,784,919) with a nominal value of EUR0.10 (2014: EUR1.00) per share. Ordinary shares hold the right to one vote per share.

## Share capital

(Amounts in EUR x 1,000)	Issued Share Capital			
	Ordinary Shares	Preference Shares Class AA	Preference Shares Class BB	Total
<b>Balance as at 1 January 2014</b>	<b>9,707</b>	<b>1,189</b>	<b>-</b>	<b>10,896</b>
New shares issued for cash	-	-	593	593
Cancellation of ordinary shares	(922)	-	-	(922)
<b>Balance as at 31 December 2014</b>	<b>8,785</b>	<b>1,189</b>	<b>593</b>	<b>10,567</b>
New shares issued for cash	278	-	-	278
Business combinations	(7,716)	(1,189)	(593)	(9,498)
<b>Balance as at 31 December 2015</b>	<b>1,347</b>	<b>-</b>	<b>-</b>	<b>1,347</b>

On 12 June 2015 a restructuring took place that has been accounted for as a business combination under common control. Kiadis Pharma N.V. was incorporated and issued 10,694,508 ordinary shares to existing preference shareholders of Kiadis Pharma B.V. who in turn surrendered all shares they were holding in Kiadis Pharma B.V. immediately prior to the incorporation of Kiadis Pharma N.V. Consequently, Kiadis Pharma N.V. became the new parent of the Kiadis Pharma group of companies.

On 3 July 2015 the Company successfully completed an Initial Public Offering (IPO) and 2,613,636 ordinary shares were issued at a price of EUR12.50 per share. On 4 August 2015 an additional 163,500 ordinary shares were issued at a price of EUR12.50 under the over-allotment option (also known as Greenshoe-option), a special provision in the Company's IPO prospectus which allowed underwriters to sell more shares than originally planned based on higher than expected demand from investors. The gross proceeds of the IPO amounted to EUR34.7 million.

Upon completion of the IPO on 3 July 2015, all common shareholders of Kiadis Pharma B.V. were required to surrender their common shares to the former preferred shareholders of Kiadis Pharma B.V. in alignment with the shareholders agreement. On 31 December 2015, not all legal documentation with respect to the transfer of common shares had been completed for common shareholders who represented a stake of approximately 2.5% in Kiadis Pharma B.V. However, these shareholders had no legally enforceable rights to hold on to their shares and therefore no interest in the results and net assets of Kiadis Pharma B.V. Consequently, management has determined that the economic substance of this non-controlling interest in Kiadis Pharma B.V. is nil. On 6 January 2016, Kiadis Pharma B.V. merged into Kiadis Pharma N.V. by way of a legal merger and ceased to exist.

## Treasury shares

At 31 December 2015 the Group did not hold any of its own shares (2014: nil).

## Share premium

(Amounts in EUR x 1,000)	2015	2014
<b>Balance as at 1 January</b>	<b>57,243</b>	<b>51,863</b>
Share premium on new shares issued	34,436	4,458
Transaction costs	(3,485)	-
Cancellation of ordinary shares	-	922
Business combinations	9,498	-
Warrants exercised	445	-
<b>Balance as at 31 December</b>	<b>98,137</b>	<b>57,243</b>

Transaction costs relate to the Initial Public Offering of an aggregate number of 2,777,136 new shares issued by the Company and include legal fees, underwriting fees and costs of preparing the prospectus.

In June 2015, the Group received a notification from Kreos Capital III Ltd ("Kreos") to exercise its warrants. See also Note 11. Subsequently, the shareholders of the Company agreed with Kreos that the Group would be discharged of its obligation to issue new shares to Kreos upon exercise of the warrants. Instead, the shareholders would surrender a pro rata number of their shares to Kreos. Subsequently, the Company has recorded the amount received from Kreos for the exercise of 52,271 warrants with an exercise price of EUR8.51 as share premium.

#### *Translation reserve*

The translation reserve comprises all foreign currency differences arising from translation of the financial statements of foreign operations as well as from the translation of liabilities that hedge the Company's net investment in a foreign subsidiary.

#### *Warrant reserve*

All warrants issued in connection with the 2009 and 2010 convertible bridge loans, which were still outstanding as at 30 June 2015, lapsed on 3 July 2015, the date of completion of the Initial Public Offering of the Company's shares. The Company did not receive any exercise notices on or before 30 June 2015, the last day of the shortened exercise period of the warrants. The warrant reserve of EUR2,580 thousand in total has been reclassified to retained earnings.

## 9. DEFERRED TAX ASSETS AND LIABILITIES

Management has considered that (i) its main group companies have no history of taxable profits in recent years, and (ii) there is no convincing evidence that these companies will be able to generate taxable profits in the near-term future. Therefore, it is uncertain how the Group may recover or settle its deferred tax assets and liabilities in the next few years. However, management has come to the conclusion that the Group's deferred tax assets exceed its deferred tax liabilities and may be used to offset its deferred tax liabilities in the different tax jurisdictions in which the Group operates. Hence the Group has recognised its deferred tax assets relating to unused tax losses only to the extent that they may be used to offset its deferred tax liabilities. The Group has not recognised a deferred tax asset for the remaining part of its unused tax losses.

#### *Tax loss carry forwards*

(Amounts in EUR x 1,000)	2015	2014
Kiadis Pharma N.V. (*)	4,944	-
Kiadis Pharma B.V. (*)	48,725	43,317
Kiadis Pharma Canada Inc. (**)	12,269	12,926
Celmed Oncology (USA) Inc. (***)	-	26,351
	<b>65,938</b>	<b>82,594</b>

(\*) The tax loss carry forwards in The Netherlands can only be utilised if the business carried on after the change of control is similar to the business carried on before the change in control.

(\*\*) The tax loss carry forwards in Canada can only be utilised to the extent that the business carried on prior to the change of control is carried on after the change in control with a reasonable expectation of profit and only to the extent of the profit of that business or a similar business.

(\*\*\*) Celmed Oncology (USA) Inc. was dissolved on 31 August 2015. The tax loss carry forwards related to a discontinued business and were not available to offset taxes on future profits from the Company's current product portfolio.



## 10. LOANS AND BORROWINGS

(Amounts in EUR x 1,000)	2015	2014
<b>Non current liabilities</b>		
Government loans (RVO NL)	6,093	-
Loan from Hospira Inc.	6,803	4,382
Loan from University of Montreal	817	708
Finance lease liabilities	-	-
	<b>13,713</b>	<b>5,090</b>

(Amounts in EUR x 1,000)	2015	2014
<b>Current liabilities</b>		
Government loans (RVO NL)	1,166	7,129
	<b>1,166</b>	<b>7,129</b>

### Terms and debt repayment schedule

	Nominal interest rate	Year of maturity	Carrying amount	
(Amounts in EUR x 1,000)			2015	2014
Government Loan I (RVO NL)	11,40%	2015-2020	4,580	4,693
Government Loan II (RVO NL)	10,00%	2016-2020	2,679	2,436
Loan from Hospira Inc.	1,50%	undefined	6,803	4,382
Loan from University of Montreal	3,50%	undefined	817	708
			<b>14,879</b>	<b>12,219</b>

### Loan from RVO NL

The Company has two loans from Rijksdienst voor Ondernemend Nederland (RVO NL), a Dutch governmental agency. These types of loans have as purpose to stimulate innovation. In 2015, the Company agreed on a repayment schedule for both loans with RVO NL.

### Loan from Hospira Inc.

In December 2011, the Company entered into an agreement with Hospira Inc. for which an amount of US\$24.5 million had been judged as a loan. The loan bears a contractual interest rate of 1.5% per annum and the conditional payment obligations regarding this loan are as follows:

- (a) a milestone payment of US\$3 million upon the earlier of (i) the execution of a sub-license on the Theralux platform, or (ii) the first commercial sale of a product derived from the Theralux platform; and
- (b) a 5% royalty on worldwide net-sales of products derived from the Theralux product platform until the loan amount has been fully paid.

After initial recognition at fair value, the carrying amount of the loan is re-measured at each reporting date, should there have been a change in the (estimated) underlying cash flows. In such cases, the carrying amount of the loan is re-measured to the net present value of the expected underlying cash flows discounted at the original effective interest rate of 11%.

### Covenants

The Company is not subject to any debt covenants.

## 11. DERIVATIVES

(Amounts in EUR x 1,000)	2015	2014
<b>Balance as at 1 January</b>	<b>3,730</b>	<b>3,189</b>
Gain included in 'finance income':		
- Exercise of warrants	(4,589)	-
Loss included in 'finance expenses':		
- Net change in fair value (unrealised)	859	541
<b>Balance as at 31 December</b>	<b>-</b>	<b>3,730</b>

In 2010, the Company signed a warrant agreement with Kreos Capital III Ltd ("Kreos"), in connection with a loan agreement. At the time of issuance, the number of warrants was not fixed. As a result, the warrants did not meet the criteria of an equity instrument and were classified as a financial liability (see also Note 20).

The fair value of the warrants has been determined by making use of binomial option pricing, taking into account potential scenarios of exercising or lapsing during the exercise period until the expiry date of November 2020. The warrants entitle the holder to buy shares of any existing or future class of shares of the Group. Input parameters that have been used are amongst others potential future equity values at moment of exercise and probabilities of occurring of these equity values. A risk-adjusted discount rate of 12% has been used in these calculations.

Derivatives are re-measured at each reporting date. The Company issued special purpose interim financial statements for the first 3 months of 2015 for inclusion in its prospectus published on 16 June 2015. The fair value of derivatives on 31 March 2015 was calculated at EUR4,589 thousand and the change in fair value compared to 31 December 2014 of EUR859 was charged to profit or loss.

In June 2015, Kreos notified the Group of its intention to exercise its rights under the warrant agreement anticipating the Company's Initial Public Offering to be completed by 3 July 2015. Subsequently, the shareholders of the Company agreed with Kreos that the Group would be discharged of its obligation to issue new shares to Kreos upon exercise of the warrants. Instead, the shareholders would surrender a pro rata number of their shares to Kreos. Subsequently, the Group has derecognised the financial liability and recorded an extinguishment gain of EUR4,589 thousand.

## 12. TRADE AND OTHER PAYABLES

(Amounts in EUR x 1,000)	2015	2014
Suppliers	596	396
Salaries, bonuses and vacation	162	119
Payroll tax and social premium contributions	95	107
Accrued clinical costs	479	249
Accrued manufacturing costs	226	79
Accrued audit fees	81	58
Accrued R&D contracts	-	441
Other	108	149
	<b>1,747</b>	<b>1,598</b>

### 13. REVENUE

No revenues were recorded in 2015 and 2014.

### 14. OTHER INCOME

No other income was recorded in 2015 and 2014.

### 15. EMPLOYEE BENEFITS

(Amounts in EUR x 1,000)	2015	2014
Wages and salaries	2,200	1,855
Compulsory social security contributions	197	176
Contributions to defined contribution plans	87	81
Share-based payments	7,815	-
Company cars	5	18
Other employee benefits	39	27
<b>Total</b>	<b>10,343</b>	<b>2,157</b>

#### Number of employees (headcount) as at 31 December

Research & development positions	22	16
General & administrative positions	5	5
	<b>27</b>	<b>21</b>

#### Share-based payments

The Group had a share option program that entitled key management personnel and senior employees to purchase shares in the Company. All options issued under the Kiadis stock option plan that had vested and were outstanding as at 31 December 2014, have lapsed on 3 July 2015.

Kiadis Pharma had implemented a bonus plan to provide incentives to certain executives and key employees of the Company. Several participants had joined this plan over the years. The potential bonus to be received by each participant, if any, would be depending on the value of an exit to be realised. Potential scenarios of a qualifying exit would be a trade-sale, an asset deal, a licensing deal or an Initial Public Offering (IPO) of the company. During 2015 one of the potential scenarios with regard to an exit became probable, being an IPO, and on 3 July 2015 (settlement-date) this exit scenario became official. In line with this scenario, it became clear that bonus shares would have to be issued. The expenditures for this plan with equity-settled share-based payments have been included for 2015, taking into account for these bonus instruments the original grant dates, with related fair values. (Before, it had been mentioned under the contingencies). Currently with a vesting period till 27 June 2016, being 360 days after the IPO settlement-date, in line with lock-up provisions (which can only be changed with consent of the bank consortium which had co-ordinated the IPO), management expects that all of these potential bonus shares will be issued. The total number of potential bonus shares to be issued has been calculated at 696,338.

## 16. EXPENSES

(Amounts in EUR x 1,000)	2015	2014
Employee benefits (see Note 15)	10,343	2,157
Depreciation expense	140	126
Facilities	325	314
Consultancy	1,462	594
Telecom & IT	139	73
Travel	257	230
Insurance	67	62
Clinical costs	785	545
Manufacturing	2,147	1,794
Royalty settlement - Industry Canada	232	232
Royalty settlement - University of Montréal, Canada	(225)	(225)
Other	342	273
<b>Total operating expenses</b>	<b>16,007</b>	<b>6,168</b>

The research and development expenses comprise allocated employee costs, clinical development costs, collaboration costs, laboratory supplies, consumables costs and allocated depreciation costs. General and administrative expenses comprise allocated employee costs, office costs and other administrative costs.

The research and development and general and administrative expenses can be summarised as follows:

(Amounts in EUR x 1,000)	2015	2014
Research and development expenses	7,715	4,692
General and administrative expenses	8,292	1,476
<b>Total operating expenses</b>	<b>16,007</b>	<b>6,168</b>

### Auditor's fees

The following fees were charged by KPMG Accountants N.V. to the Company, its subsidiaries and other consolidated companies, as referred to in Section 2:382a(1) and (2) of the Netherlands Civil Code.

(Amounts in EUR x 1,000)	KPMG Accountants N.V.	Other KPMG network	Total KPMG
<b>2015</b>			
Audit of the financial statements	106		106
Other audit engagements	239		239
Tax-related advisory services		105	105
Other non-audit services			-
	<b>345</b>	<b>105</b>	<b>450</b>
<b>2014</b>			
Audit of the financial statements	45		45
Other audit engagements			-
Tax-related advisory services		28	28
Other non-audit services			-
	<b>45</b>	<b>28</b>	<b>73</b>

In 2015, fees for Other audit engagements of EUR239 thousand include EUR190 thousand in fees for audit services in connection with the Initial Public Offering (IPO) completed on 3 July 2015. This amount is included in the transaction costs of the IPO and charged directly to equity.

## 17. FINANCE INCOME AND EXPENSES

(Amounts in EUR x 1,000)	2015	2014
<b>Finance income</b>		
- Interest income	50	28
- Net foreign exchange gain	-	330
- Gain from exercise of derivatives	4,589	-
	<b>4,639</b>	<b>358</b>
<b>Finance expenses</b>		
- Bank borrowings, and other debt	(1,394)	(1,073)
- Net foreign exchange loss	(1,001)	-
- Loss from restatements of loans	(1,835)	(387)
- Loss from change in fair value of derivatives	(859)	(541)
	<b>(5,089)</b>	<b>(2,001)</b>

The Company recorded an extinguishment gain of EUR4.6 million following the exercise of warrants classified as a financial liability. See also Note 11.

Finance expenses for bank borrowings and other debt include interest on third party loans for EUR613 thousand (2014: EUR418 thousand) and interest on government loans for EUR780 thousand (2014: EUR644 thousand).

## 18. INCOME TAX EXPENSE IN THE INCOME STATEMENT

(Amounts in EUR x 1,000)	2015	2014
<b>Current tax expense</b>		
Current year	1	2
	1	2
<b>Deferred tax expense</b>		
	-	-
<b>Tax expense</b>	<b>1</b>	<b>2</b>

Current year tax expense relates to the subsidiary in Germany that charges its expenses with a mark-up to other group companies.

(Amounts in EUR x 1,000)	2015	2014
<b>Reconciliation of effective tax rate</b>		
Loss before income taxes	(16,458)	(7,813)
Tax using the Company's domestic tax rate (25.0% for all years)	4,115	1,953
Effect of tax rates in foreign jurisdictions	11	38
Tax exempt income	933	128
Non-deductible expenses	(1,881)	(881)
Tax incentives	4	1
Current year losses for which no deferred tax asset is recognised	(3,181)	(1,237)
	<b>1</b>	<b>2</b>

## 19. EARNINGS PER SHARE

### Basic earnings per share

(Amounts in EUR x 1,000)	2015	2014
Loss attributable to ordinary shareholders	(16,458)	(7,813)
Issued ordinary shares at 1 January	10,694,508	10,694,508
Effect of shares issued in July 2015	1,296,077	-
Effect of shares issued in August 2015	66,744	-
Weighted-average number of ordinary shares at 31 December	12,057,329	10,694,508
Basic earnings per share (EUR)	(1,36)	(0,73)

The calculation of basic earnings per share for the year ended 31 December 2015 has been based on the loss attributable to ordinary shareholders of EUR16,458 thousand and a weighted-average number of ordinary shares outstanding during the year of 12,057 thousand.

For the years presented in these consolidated financial statements, the number of issued ordinary shares at 1 January has been adjusted for the business combination that took place on 12 June 2015. See also Note 8. Shares have been included in the weighted average number of shares from their issuance date.



### *Diluted earnings per share*

(Amounts in EUR x 1,000)	2015	2014
Weighted average number of ordinary shares (basic)	12,057,329	10,694,508
Effect of share-based payments (bonus shares)	-	-
Weighted-average number of ordinary shares (diluted) at 31 December	12,057,329	10,694,508
Diluted earnings per share (EUR)	(1,36)	(0,73)

The calculation of diluted earnings per share for the year ended 31 December 2015 has been based on the loss attributable to ordinary shareholders of EUR16,458 thousand and a weighted-average number of ordinary shares outstanding after adjustment for the effects of all dilutive potential ordinary shares.

At 31 December 2015, an aggregate number of 696,338 dilutive potential ordinary shares awarded as employee bonuses (see also Note 15) were excluded from the diluted weighted-average of ordinary shares calculation because their effect would have been anti-dilutive. As a result, diluted earnings per share equals basic earnings per share.

## **20. FINANCIAL INSTRUMENTS**

As a result of our operating and financing activities, we are exposed to market risks that may affect our financial position and results of operations. Market risk is the potential to incur economic losses on risk sensitive financial instruments arising from adverse changes in factors such as foreign exchange rate fluctuations.

Management is responsible for implementing and evaluating policies which govern our funding, investments and any use of derivative financial instruments. Management monitors risk exposure on an ongoing basis.

### *Capital management*

The Company does not have an explicit return on capital policy. There have been no changes in the capital management policies during the year. Capital is considered by the Company to be equity and debt as shown in the statement of financial position.

### *Credit risk*

Credit risk is the risk of financial loss if a customer or counterparty to a financial instrument fails to meet its contractual obligations.

Kiadis Pharma currently has no regular sales and therefore no substantial amounts outstanding with customers. As such, customer related credit risks are not considered to be of significant influence to the Company.

The Company limits its exposure to credit risk by maintaining its bank accounts and short term deposits with well established bank institutions.

### *Liquidity risk analysis*

Liquidity risk is the risk that the Company will not be able to meet its financial obligations as they fall due. The Company's approach to managing liquidity is to ensure, as far as possible, that it will always have sufficient liquidity to meet liabilities when due, under both normal and stressed conditions, without incurring unacceptable losses or risking damage to the Company's reputation.

As at 31 December 2015, the Company has adequate funds available to settle its payment obligations from its ongoing business operations.

A debt repayment schedule is included in Note 10. Also refer to the Going concern assessment in Note 2.1 for an explanation of how the Company assessed its short-term obligations.

### *Exposure to interest rate risks*

The effective interest rate on short-term bank deposits was 0.4% on average for 2015 (2014: 0.9%). An increase of 50 basis points in interest rates would have increased equity and profit by EUR59 thousand.

### *Exposure to foreign currency risk*

The Company's functional currency is the euro. It operates via its Dutch entities, but it also conduct business in North America. The Company has therefore expenses denominated in the Canadian dollar and the US dollar in connection with, among other things, its sponsored trials, process development, loans, and the maintenance of its intellectual property portfolio. The Company also has intercompany financing between Company companies and has US dollar loans.

Upon preparing consolidated financial statements, the Company's euro-denominated consolidated reported financial results can be affected by changes in the relative values of the Canadian dollar and the US dollar against the euro. Fluctuations in currency values also distort period-to-period comparisons of financial performance. Also given the high volatility of currency exchange rates, there can be no assurance that the Company will be able to effectively manage its currency risk to minimize its impact on its business. The Company's exposure to foreign currency translation gains and losses may change over time if it expands its operations and could have a material adverse effect on the Company's business, results of operations or financial condition. The Company does not currently engage in any hedging activities to limit its exposure to exchange rate fluctuations.

A strengthening of the Canadian and US dollar against the euro at 31 December 2015 of 6% would have increased equity by EUR60 thousand and decreased the loss for the year by EUR257 thousand. This analysis is based on foreign currency exchange rates that the company considered to be reasonably possible at the end of the reporting period. All other variables are considered to remain unchanged.

The analysis is performed on the same basis for 2014. A strengthening of the Canadian dollar and US dollar against the euro at 31 December 2014 of 6% would have increased equity by EUR131 thousand and decreased the loss for the year by EUR396 thousand.

## Fair values

The following tables show the carrying amounts and fair values of financial assets and liabilities, including their levels in the fair value. It does not include fair value information for financial assets and liabilities not measured at fair value if the carrying amount is a reasonable approximation of fair value.

(Amounts in EUR x 1,000)	Carrying amount			Fair value			
	Non-current assets		Current assets	Total	Level 1	Level 2	Level 3
			Trade and other receivables				

### 31 December 2015

#### Financial assets not measured at fair value

Trade and other receivables			145	145			
Cash and cash equivalents				28,666			
			<b>145</b>	<b>28,666</b>			

### 31 December 2014

#### Financial assets not measured at fair value

Trade and other receivables			196	196			
Cash and cash equivalents				5,674			
			<b>196</b>	<b>5,674</b>			

(Amounts in EUR x 1,000)	Carrying amount					Fair value			
	Non-current liabilities		Current liabilities		Total	Level 1	Level 2	Level 3	Total
	Derivatives	Loans and borrowings	Trade and other payables	Loans and borrowings					

### 31 December 2015

#### Financial liabilities measured at fair value

Derivatives	-				-			-	-
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#### Financial liabilities not measured at fair value

Government Loans (RVO NL)		6,093		1,166	7,259		7,259		7,259
Government Loans (Industry Canada)		-		-	-		-		-
Secured bank loans		-		-	-		-		-
Loan from Hospira Inc.		6,803			6,803		6,803		6,803
Loan from University of Montreal		817			817		817		817
Trade and other payables			1,747		1,747				
		<b>-</b>	<b>13,713</b>	<b>1,747</b>	<b>1,166</b>		<b>16,626</b>		

### 31 December 2014

#### Financial liabilities measured at fair value

Derivatives	3,730				3,730			3,730	3,730
-------------	-------	--	--	--	-------	--	--	-------	-------

#### Financial liabilities not measured at fair value

Government Loans (RVO NL)		-		7,129	7,129		7,129		7,129
Government Loans (Industry Canada)		-		-	-		-		-
Secured bank loans		-		-	-		-		-
Loan from Hospira Inc.		4,382			4,382		4,382		4,382
Loan from University of Montreal		708			708		708		708
Trade and other payables			1,598		1,598				
		<b>3,730</b>	<b>5,090</b>	<b>1,598</b>	<b>7,129</b>		<b>17,547</b>		

## 21. CONTINGENCIES

### Milestone payments

#### *Celmed Founding Shareholders*

The Group is party to agreements with certain former shareholders of Celmed BioSciences Inc., including Theratechnologies Inc., Fonds de Solidarité des Travailleurs du Quebec and Investissements Santé Inc. Under these agreements, the Group is obligated to pay such shareholders CN\$3.4 million, if and when all approvals required to market Rhito1™ in the United States have been granted by the FDA and CN\$6.9 million, if and when all approvals required to market NB1011 in the United States have been granted by the FDA. These obligations are secured by a hypothecation of certain rights to Theralux and NB1011 patents under Quebec laws and a security interest under California law.

#### *University of Montreal*

Between 1991 and 1997, Kiadis Pharma Canada Inc. and/or its predecessors entered into a series of licensing agreements with the University of Montreal which obligates the Group to pay royalties of 5% of net sales of all products derived from the Theralux product platform for the term of our commercialisation of such products. The same rate of royalties applies to receipts related to sub-licenses.

#### *Hospira Inc.*

If the loan (see Note 10) has been repaid, Hospira is able to receive thereafter royalties of 3% on net sales of products derived from the Theralux product platform in a specified territory (total world minus North & South America and China) for an unlimited period of time.

## 22. COMMITMENTS

### Operating lease commitments

The future aggregate minimum lease payments under non-cancellable operating leases are as follows:

(Amounts in EUR x 1,000)	2015	2014
Less than one year	275	196
Between one and five years	57	-
More than 5 year	-	-
	<b>332</b>	<b>196</b>

#### *(a) Rental of premises:*

The Company has rental commitments regarding office and laboratory space located in Amsterdam with a total liability as of December 31, 2015 of EUR330 thousand (2014: EUR192 thousand). The remaining lease terms are 8 months for office space and 16 months for laboratory space.

#### *(b) Laboratory equipment:*

The Company has undersigned one operational lease contract (2014: 1) in The Netherlands regarding laboratory equipment. The liability as of December 31, 2015 amounted to EUR2 thousand (2014: EUR4). The terms of the contract will end in 2016.

#### *(c) Capital commitments*

At the reporting date 31 December 2015 there were no capital expenditures contracted for, but not yet incurred.

## 23. BUSINESS COMBINATIONS

On 12 June 2015 a restructuring took place that qualified as a business combination under common control. Kiadis Pharma N.V. was incorporated and issued new shares to existing preference shareholders of Kiadis Pharma B.V. in exchange for the shares they held in Kiadis Pharma B.V. immediately prior to the incorporation of Kiadis Pharma N.V. As a result, Kiadis Pharma N.V. became the new parent of the Kiadis Pharma group of companies.

## 24. RELATED PARTIES

### Transactions with related parties with a significant influence over the Company

The transactions with shareholders that have a significant impact over the Company during the years presented are described below. Other than this, there were no transactions or business activities with related parties.

### Management Board and Supervisory Board

#### (a) Management Board salary, bonus and other emoluments

In addition to salaries, the Group also provides non-cash benefits. The Management Board included in the table below relates to 2 members (Chief Executive Officer (CEO) and Chief Financial Officer (CFO)) that were in office during the years 2015 and 2014.

(Amounts in EUR x 1,000)	2015	2014
Salaries and other short-term employee benefits	498	536
Pensions	9	11
Share-based payments	3,731	-
Social securities	30	27
Other emoluments	5	5
<b>Total</b>	<b>4,273</b>	<b>579</b>

The table below shows the remuneration received by the individual members of the Management Board for the year ended 31 December 2015.

(Amounts in EUR)	Base salary	Cash bonus	Share-based payments	Pension contributions	Social security costs	Other benefits	Total remuneration
Mr. Manfred Rüdiger	315,000	-	2,848,815	1,418	21,697	5,331	3,192,261
Mr. Robbert van Heekeren	172,711	10,000	882,561	6,966	8,624	-	1,080,862
	<b>487,711</b>	<b>10,000</b>	<b>3,731,376</b>	<b>8,384</b>	<b>30,321</b>	<b>5,331</b>	<b>4,273,123</b>

Currently with a vesting period till 27 June 2016, being 360 days after the IPO settlement-date, in line with lock-up provisions (which can only be changed with consent of the bank consortium which had co-ordinated the IPO), a potential number of 319,708 bonus shares will be issued for Mr. Rüdiger and 78,620 for Mr. van Heekeren. The expenditures for this plan with these equity-settled share-based payments have already been included for 2015, taking into account for these bonus instruments the original grant dates, with related fair values.

The remuneration of the Supervisory Board members included in the table below relates to the compensation for 4 members in 2015 (2014: 3).

(Amounts in EUR x 1,000)	2015	2014
Remuneration	25	50
Share-based payments	61	-
<b>Total</b>	<b>86</b>	<b>50</b>

The table below shows the remuneration received by the individual members of the Supervisory Board for the year ended 31 December 2015.

(Amounts in EUR)	Base salary	Cash bonus	Share-based payments	Pension contributions	Social security costs	Other benefits	Total remuneration
Mr. Mark Wegter	-	-	-	-	-	-	-
Mr. Martijn Kleijwegt	-	-	-	-	-	-	-
Mr. Stuart Chapman	15,000	-	-	-	-	-	15,000
Mr. Vincent Brichard	10,000	-	60,841	-	-	-	70,841
	25,000	-	60,841	-	-	-	85,841

Currently with a vesting period till 27 June 2016, being 360 days after the IPO settlement-date, in line with lock-up provisions (which can only be changed with consent of the bank consortium which had co-ordinated the IPO), a potential number of 5,054 bonus shares will be issued for Mr. Brichard. The expenditures for this plan with these equity-settled share-based payments have already been included for 2015, taking into account for these bonus instruments the original grant dates, with related fair values.

#### *(b) Transactions of shares in the Company*

In 2015 the Company raised EUR34.7 million in gross proceeds by issuing 2,777,136 new shares priced at EUR12.50 per share in an Initial Public Offering (IPO). As of 2 July 2015, the Company's shares are listed on the Euronext stock markets in Amsterdam, the Netherlands and Brussels, Belgium.

Most of the existing major shareholders subscribed to the IPO. These shareholders acquired the additional shares at identical conditions as the other participants.

LSP I, a major shareholder acquired 138,238 shares at EUR12.50 per share. LSP II, a major shareholder acquired 103,512 shares at EUR12.50 per share. Mr. Kleijwegt, a member of the Company's supervisory board, acquired (through Pro-Ventures I B.V.) 21,978 shares at EUR12.50 per share. Draper Esprit, Lenildis and Alta Partners, acquired 269,597, 163,074 and 81,473 shares respectively, at a price of EUR12.50 per share.

#### *(c) Options held in the Company*

All options held by Management Board and Supervisory Board members lapsed upon the successful completion of the IPO on 3 July 2015.



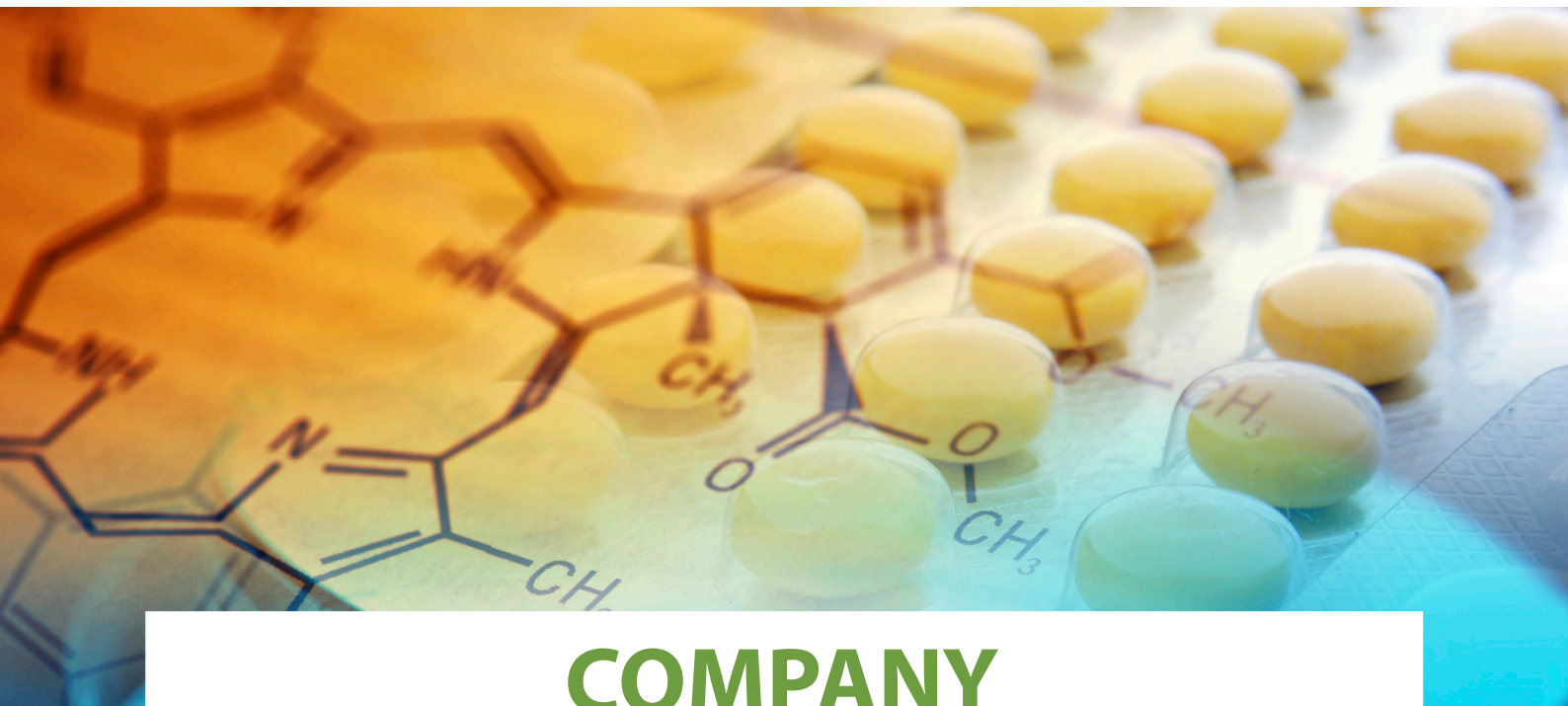
## 25. SUBSEQUENT EVENTS

On 6 January 2016 a legal merger took place and Kiadis Pharma B.V. merged into Kiadis Pharma N.V., with the latter being the surviving company.

On 29 January 2016 the Company entered into an equity investment agreement with The Leukemia & Lymphoma Society (LLS) for an amount of US\$1 million. On 5 February 2016 the Company issued 89,308 ordinary shares to LLS for a subscription price of EUR10.235 per share. The subscription price was established at the lowest of 3 average closing prices of the Company's listed ordinary shares. The 3 average closing prices were calculated using the closing prices of (i) the last five days, (ii) the last 15 days and (iii) the last 30 days prior to the effective date of the agreement.

On 4 April 2016, Kiadis Pharma presented positive data on the primary endpoint of its single-dose Phase II trial with ATIR101.





# **COMPANY FINANCIAL STATEMENTS**

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## COMPANY BALANCE SHEET

		As at 31 December	
(Amounts in EUR x 1,000)	Note	2015	2014
<b>Assets</b>			
Financial non-current assets	1	2,939	-
<b>Total non-current assets</b>		<b>2,939</b>	<b>-</b>
Trade, other receivables and prepayments	2	3,320	-
Cash and cash equivalents	3	20,441	-
<b>Total current assets</b>		<b>23,761</b>	<b>-</b>
<b>Total assets</b>		<b>26,700</b>	<b>-</b>
<b>Equity</b>			
Share capital		1,347	-
Share premium		31,827	-
Translation reserve		(46)	-
Accumulated deficit		(7,478)	-
<b>Equity attributable to owners of the Company</b>	4	<b>25,650</b>	<b>-</b>
<b>Liabilities</b>			
Loans and borrowings		-	-
<b>Total non-current liabilities</b>		<b>-</b>	<b>-</b>
<b>Loans and borrowings</b>		<b>-</b>	<b>-</b>
Trade and other payables	5	1,050	-
<b>Total current liabilities</b>		<b>1,050</b>	<b>-</b>
<b>Total liabilities</b>		<b>1,050</b>	<b>-</b>
<b>Total equity and liabilities</b>		<b>26,700</b>	<b>-</b>

## COMPANY INCOME STATEMENT

	For the year ended 31 December	
(Amounts in EUR x 1,000)	2015	2014
Share in results from participating interests, after taxation	(9,234)	-
Other results, after taxation	(6,059)	-
<b>Loss for the period</b>	<b>(15,293)</b>	<b>-</b>

### GENERAL INFORMATION

On 12 June 2015, Kiadis Pharma N.V. was incorporated and became the parent of the Kiadis Pharma group of companies. The company financial statements cover the period from the date of incorporation through 31 December 2015. The description of the Group's activities and the Group structure as included in the notes to the consolidated financial statements also apply to the Company financial statements.

### BASIS OF PREPARATION

The company financial statements have been prepared in accordance with the provisions of Part 9, Book 2, of the Netherlands Civil Code. The Company uses the option of Article 8:362 of Part 9, Book 2, of the Netherlands Civil Code to prepare the Company financial statements, using the same accounting policies as in the consolidated financial statements. Valuation is based on recognition and measurement requirements of accounting standards adopted by the EU as explained further in the notes of the consolidated financial statements.

In accordance with the exemption in Article 2:402 of Part 9 Book 2 of the Netherlands Civil Code the Company income statement is presented in abbreviated form.

### FINANCIAL NON-CURRENT ASSETS

Participating interests are measured on the basis of the equity method, and are reported net of non-current group receivables and intangible assets related to investments in subsidiaries. Participating interests with negative equity are reported under provisions.

#### *Result from participating interests*

The share of profit of participating interests consists of the share of the Company in the results of these participating interests.

### GOING CONCERN

See Note 2.1 of the consolidated financial statements.



## 1. FINANCIAL NON-CURRENT ASSETS

(Amounts in EUR x 1,000)	2015	2014
<b>Participating interests in group companies</b>	<b>2,939</b>	<b>-</b>

The movements can be shown as follows:

(Amounts in EUR x 1,000)	Kiadis Pharma B.V.	Total
<b>Changes in 2015</b>		
Business combinations	1,500	1,500
Investments	10,719	10,719
Share in result	(9,234)	(9,234)
Effect of changes in foreign exchange rates	(46)	(46)
<b>Total changes in 2015</b>	<b>2,939</b>	<b>2,939</b>
<b>Balance as at 31 December 2015</b>	<b>2,939</b>	<b>2,939</b>

## 2. TRADE, OTHER RECEIVABLES AND DEFERRED EXPENSES

(Amounts in EUR x 1,000)	2015	2014
Receivable from group companies	3,195	-
Interest receivable	32	-
VAT receivable	19	-
Deferred expenses	74	-
	<b>3,320</b>	<b>-</b>

## 3. CASH AND CASH EQUIVALENTS

(Amounts in EUR x 1,000)	2015	2014
Cash at bank and in hand	7,939	-
Short-term bank deposits	12,502	-
<b>Cash and cash equivalents</b>	<b>20,441</b>	<b>-</b>
Bank overdrafts used for cash management purposes	-	-
<b>Net cash as per balance sheet</b>	<b>20,441</b>	<b>-</b>

#### 4. EQUITY

(Amounts in EUR x 1,000)	Share Capital	Share Premium	Translation Reserve	Warrant Reserve	Retained Earnings	Total Equity
<b>Balance as at 1 January 2015</b>	-	-	-	-	-	-
<b>Changes in 2015</b>						
Profit (loss) for the period	-	-	-	-	(15,293)	(15,293)
Issue of shares - incorporation	1,069	431	-	-	-	1,500
Issue of shares - IPO	278	34,436	-	-	-	34,714
Transaction costs	-	(3,485)	-	-	-	(3,485)
Exercise of warrants	-	445	-	-	-	445
Share based payments	-	-	-	-	7,815	7,815
Translation difference	-	-	(46)	-	-	(46)
<b>Balance as at 31 December 2015</b>	<b>1,347</b>	<b>31,827</b>	<b>(46)</b>	<b>-</b>	<b>(7,478)</b>	<b>25,650</b>

#### 5. TRADE AND OTHER PAYABLES

(Amounts in EUR x 1,000)	2015	2014
Suppliers	95	-
Salaries, bonuses and vacation	47	-
Debts to subsidiaries	776	-
Accrued audit fees	81	-
Other	51	-
	<b>1,050</b>	<b>-</b>

#### 6. FINANCIAL INSTRUMENTS

See Note 20 of the consolidated financial statements.

#### 7. COMMITMENTS

As of 1 January 2016 the Company is the parent of the fiscal unity Kiadis Pharma N.V., and therefore liable for the liabilities of the fiscal unity as a whole.

## 8. REMUNERATION OF SENIOR MANAGEMENT

See Note 24 of the consolidated financial statements.

14 April 2016

### *Management Board*

Manfred Rüdiger, Chief Executive Officer

Robbert van Heekeren, Chief Financial Officer

### *Supervisory Board*

Mark Wegter, Chairman

Martijn Kleijwegt

Stuart Chapman

## OTHER INFORMATION

### *Provisions of article of association in respect of profit appropriation*

As per Article 21 of the Company's articles of association, the Management Board shall determine, subject to prior approval of the Supervisory Board, which part of the profits shall be added to the Company's reserves. The remaining profits are at the disposition of the shareholders' meeting.

### *Proposed appropriation of the net loss for the year*

The Management Board proposes that the loss for the year of EUR15,293 thousand will be charged to the retained earnings. This proposal is reflected in the financial statements.

## INDEPENDENT AUDITOR'S REPORT

Please find attached the independent auditor's report from KPMG.

# Independent auditor's report

To: the Annual General Meeting of Shareholders and Supervisory Board of Kiadis Pharma N.V.

## Report on the audit of the annual financial statements 2015

### Opinion

In our opinion:

- the consolidated financial statements give a true and fair view of the financial position of Kiadis Pharma N.V. as at 31 December 2015, and of its result and its cash flows for the year 2015 in accordance with International Financial Reporting Standards as adopted by the European Union (EU-IFRS) and with Part 9 of Book 2 of the Netherlands Civil Code;
- the company financial statements give a true and fair view of the financial position of Kiadis Pharma N.V. as at 31 December 2015, and of its result for 2015 in accordance with Part 9 of Book 2 of the Netherlands Civil Code.

### What we have audited

We have audited the financial statements 2015 of Kiadis Pharma N.V., based in Amsterdam. The financial statements include the consolidated financial statements and the company financial statements.

The consolidated financial statements comprise:

- 1 the consolidated statement of financial position as at 31 December 2015;
- 2 the following consolidated statements for 2015: the statements of comprehensive income, changes in equity and cash flows; and
- 3 the notes comprising a summary of the significant accounting policies and other explanatory information.

The company financial statements comprise:

- 1 the company balance sheet as at 31 December 2015;
- 2 the company income statement for 2015; and
- 3 the notes comprising a summary of the significant accounting policies and other explanatory information.

### Basis for our opinion

We conducted our audit in accordance with Dutch law, including the Dutch Standards on Auditing. Our responsibilities under those standards are further described in the 'Our responsibilities for the audit of the financial statements' section of our report.

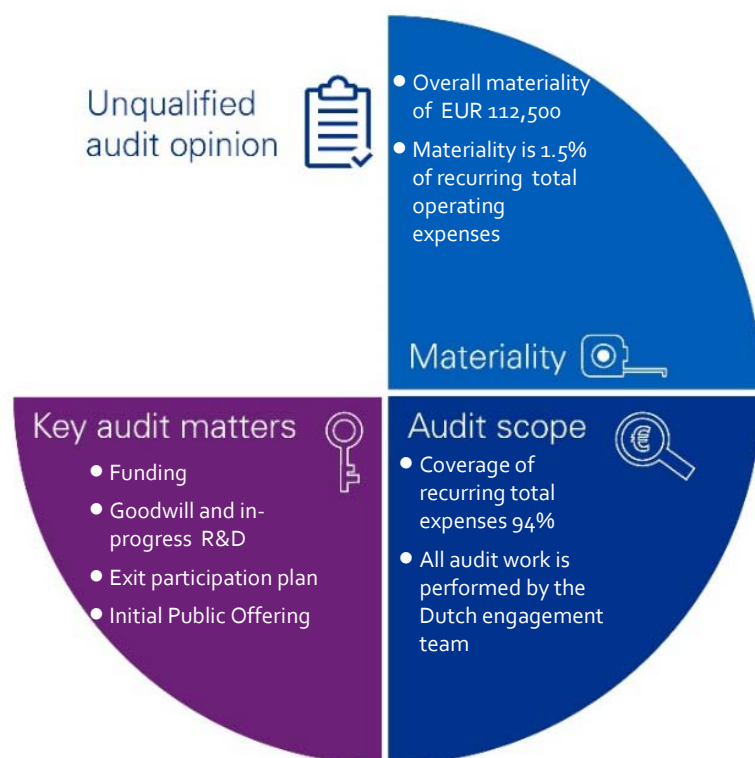
We are independent of Kiadis Pharma N.V. in accordance with the Verordening inzake de onafhankelijkheid van accountants bij assurance-opdrachten (ViO) and other relevant independence regulations in the Netherlands. Furthermore, we have complied with the Verordening gedrags- en beroepsregels accountants (VGBA).

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



## Audit approach

### Summary



### Materiality

Misstatements can arise from fraud or error and are considered material if, individually or in aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements. The materiality affects the nature, timing and extent of our audit procedures and the evaluation of the effect of identified misstatements on our opinion.

Based on our professional judgement we determined the materiality for the financial statements as a whole at EUR 112,500 (2014: EUR 125,000). The materiality is determined with reference to recurring total operating expenses (1,5%). We consider recurring total operating expenses as the most appropriate benchmark as this best reflects the nature of the entity, being in the stage of developing a medicine. We have also taken into account misstatements and/or possible misstatements that in our opinion are material for qualitative reasons for the users of the financial statements.

We agreed with the Supervisory Board that misstatements in excess of EUR 6,000, which are identified during the audit, would be reported to them, as well as smaller misstatements that in our view must be reported on qualitative grounds.

### Scope of the group audit

Kiadis Pharma N.V. is head of a group of entities. The financial information of this group is included in the financial statements of Kiadis Pharma N.V.

Because we are ultimately responsible for the opinion, we are also responsible for directing, supervising and performing the group audit. In this respect we have determined the nature and extent of the audit procedures to be carried out for group entities. Decisive were the size and/or the risk profile of the group entities or operations. On this basis, we selected group entities for which an audit or review had to be carried out on the complete set of financial information or specific items.

Our group audit mainly focused on the significant entity Kiadis Pharma Netherlands B.V., considering its activities, performing a full scope audit. In addition we have performed specified audit procedures on the financial information of Kiadis Pharma Intellectual Property B.V., Kiadis Pharma Germany GmbH, Kiadis Pharma Canada Inc. and Celmed Oncology (USA) Inc. Accounting for the Group's activities takes place at the headquarters in Amsterdam, the Netherlands. As a consequence, we were able to perform all of the audit work

for the Group at group level. This resulted in a coverage of the recurring total operating expenses of 94%. By performing the procedures mentioned above at group entities, together with additional procedures at group level, we have been able to obtain sufficient and appropriate audit evidence about the group's financial information to provide an opinion about the financial statements.

### Our key audit matters

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the financial statements. We have communicated the key audit matters to the Supervisory Board. The key audit matters are not a comprehensive reflection of all matters discussed.

Key audit matters were addressed in the context of our audit of the financial statements as a whole and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

## Funding

### Description

The company is active in the pharmaceutical development of cell-based immunotherapy products in the field of diseases of the blood building system. Given the stage of development of such medicines, the company incurred large research and development costs over the years and anticipates to spend more in the future before its products are being ready for sale. As a consequence, from time to time the company is required to obtain funding in order to be able to continue the development activities to support the clinical studies. In order to obtain additional funding, the company completed an Initial Public Offering (IPO), collecting EUR 34,7 million. Reference is made to the related key audit matter. As described in Note 7 to the financial statements, management expects the 2015 year-end cash balance of EUR 28.7 million to be sufficient to fund the company for at least one year from the date on which the financial statements are signed by the Management Board and the date of our opinion.

As future funding is not guaranteed, the company is highly dependent on the progress and results of the study, other strategic partners, grants, co-funding and the capital markets appetite for such investments, an inherent risk for the company as a going concern exists on the long term, as described in Note 2.1 to the financial statements and the financial risk paragraph of the Report of the Management Board.

### Our response

We evaluated and challenged the company's future business plans and related cash flow forecasts and the process in which these were prepared. We tested the underlying key assumptions, such as expected cash outflow for R&D expenses and other operating expenses. We evaluated management's worst-case scenario to assess the risk that a change in the assumptions either individually or collectively would lead to different conclusions. As included in our responses of 'Valuation Goodwill and In-progress research and development' we included in our team a valuation specialist to assist us in the audit activities related to the business enterprise value and future business plans. In order to corroborate management's future business plans and to identify potential contradictory information we, among others, read the board minutes and supervisory board minutes. On a sample basis, we verified that the study results used by management are directly retrieved from external independent sources.

### Our observation

We consider management assumptions regarding business planning and related cash flow forecast balanced. The disclosure regarding going concern, as included in Note 2.1 to the financial statements as well as the financial risk paragraph of the Report of the Management Board is sufficient.

## Valuation Goodwill and In-progress research and development

### Description

There is a risk that the carrying value of goodwill and in-progress research and development may not be recovered from future cash flows if e.g. study results do not meet the current expectations. As explained in Note 2.7 to the financial statements, an impairment trigger analyses is performed at each reporting date and a full impairment analyses is performed on a yearly basis. There is inherent uncertainty involved in forecasts and significant judgements are made to the assumptions used in the company's impairment model, as disclosed by management in Note 5 to the financial statements, making this a key matter for our audit.

### Our response

Our audit procedures included, among others, testing the company's impairment model and evaluating the assumptions and methodologies used by the company. In particular, the expected market introduction date, the likelihood of market introduction of the product, expected sales volume, price and margins as well as discount rates

## Valuation Goodwill and In-progress research and development

were assessed. We compared the business enterprise value derived from the market share price with the carrying amount of goodwill and intangible fixed assets. We included in our team a valuation specialist to assist us in these audit activities. We made an assessment of the business enterprise value with externally derived data and compared it with the market capitalisation based on the stock price at year-end 2015.

We also assessed the adequacy of the disclosures in Note 5 to the financial statements about the assumptions to which the outcome of the impairment test is most sensitive.

### Our observation

In our view, the assumptions used in the impairment model are balanced and as a consequence the valuation is appropriate. The disclosure in Note 5 about the assumptions of the impairments test is sufficient.



## Exit participation plan

### Description

In 2012 and later, certain individuals were granted benefits under the exit participation plan. The exit participation plan defined several exit scenarios that would give rise to a benefit to eligible employees. In previous years, the scenarios and distribution of benefits were uncertain. Therefore the exit participation plan was not recognized on balance, but disclosed as a contingent liability. Resulting from the initial public offering (IPO) in July 2015, the uncertainty disappeared and the granted benefits were accounted through equity-settled bonus shares. Management has calculated for the equity-settled share-based payment a fair value at original grant dates of EUR 7.8 million as disclosed in Note 8 to the financial statements. In accordance with IFRS 2 management calculated the estimated fair values of the equity instruments under the exit participation plan back to the original grant dates. The fair value of equity is based on the business enterprise model, as described in 'Valuation Goodwill and In-progress research and development'. For the IPO, extra non-vesting conditions for the participants have been introduced. A lock-up period of one year exists to be eligible to receive the shares. As described in IFRS 2 the modifications do not have to be accounted for if these are not beneficial for the participants. As the fair value determination requires management to make judgments and the calculation is rather complex, we consider this a key matter of our audit.



### Our response

In previous years the assumptions in the business enterprise model, made by management, have been reviewed by our valuation specialist. We reassessed the assumptions to verify consistent application of the model by management and reconciled the calculation with the underlying contracts and other documentation.

We also assessed the adequacy of the disclosures in Note 8 to the financial statements about the fair value calculation of the equity-settled share-based payment.



### Our observation

In our view, the assumptions used in the model are balanced and as a consequence the valuation of the equity-settled share-based payment is appropriate. We consider the disclosure in Note 8 on the exit participation plan to be sufficient.



## Initial Public Offering

### Description

On 3 July 2015 the company completed an Initial Public Offering (IPO) and 2,613,636 ordinary shares were issued at a price of EUR 12.50 per share. On 4 August 2015 an additional 163,500 ordinary shares were issued at a price of EUR 12.50 under the over-allotment option, a special provision which allowed underwriters to sell more shares than originally planned based on higher than expected demand from investors. The gross proceeds of the IPO amounted to EUR 34.7 million.

As a result of the IPO we identified the following complex accounting topics which require our additional attention and therefore we consider this a key matter of our audit.

Transaction cost relating to the Initial Public Offering of an aggregate number of 2,777,136 new shares issued by the company which includes legal fees, underwriting fees and costs of preparing the prospectus. The transaction cost directly attributable to equity amounts to EUR 3.5 million. In accordance with IAS 32 management made a judgement to qualify costs attributable to the IPO directly in equity. Only incremental costs that are attributable directly to issuing own equity instruments have been recognised in equity. Qualifying costs include fees for legal and tax advice related to the share



## Initial Public Offering

issue, cost of preparing the prospectus, underwriting fees and fees incurred in respect of the valuation of the shares.

In June 2015, the company received a notification from Kreos Capital III Ltd ('Kreos') to exercise its warrants. On 30 June 2015, shares were redistributed pro rata from the current shareholders to Kreos. Management has recognized the fair value of the warrants at EUR 4.6 million before the IPO event and change in fair value compared to 31 December 2014 of EUR 0.9 million charged to profit or loss. Subsequently, the Company has derecognised the financial liability and recorded an extinguishment gain of EUR 4.6 million. The company has recorded the amount received from Kreos for the execution of 52,271 warrants with an exercise price of EUR 8.51 as share premium. As the fair value determination requires management to make judgments and the calculation is rather complex, we consider this a key matter of our audit.

### Our response

Our audit procedures included, among others, an assessment of the analysis of attributable costs to equity as prepared by management. We compared the attributable costs to equity analysis with IAS 32.

We also assessed the adequacy of the disclosures in Note 8 to the financial statements on the transaction cost.

For the extinguishment of the warrants we have included audit procedures for the calculation of the warrants and redistribution of shares as prepared by management. In previous years the assumptions in the model of the calculation of the warrants, made by management, have been reviewed by our valuation specialists. We reassessed the assumptions to verify consistent application of the model by management and assessed the assumptions with the underlying documentation, such as contracts and related correspondence with shareholders and Kreos.

We also assessed the adequacy of the disclosures in Notes 11 and 17 to the financial statements on the warrants.



### Our observation

In our view, management's assessment and calculation of the IPO and transactions costs directly attributable to equity complies with applicable accounting principles.

For the extinguishment of the warrants, in our view, the assumptions used by management are balanced and as a consequence the valuation of the extinguishment gain is appropriate. We consider the disclosure in Note 11 and 17 about the Kreos warrants to be sufficient.



## Responsibilities of the Management Board and Supervisory Board for the financial statements

The Management Board is responsible for the preparation and fair presentation of the financial statements in accordance with EU-IFRS and with Part 9 of Book 2 of the Netherlands Civil Code and for the preparation of the Report of Management Directors in accordance with Part 9 of Book 2 of the Netherlands Civil Code.

Furthermore, the Management Board is responsible for such internal control as it determines is necessary to enable the preparation of the financial statements that are free from material misstatement, whether due to errors or fraud.

As part of the preparation of the financial statements, the Management Board is responsible for assessing the company's ability to continue as a going concern. Based on the financial reporting framework mentioned, they should prepare the financial statements using the going concern basis of accounting unless they either intend to liquidate the company or to cease operations, or have no realistic alternative but to do so. The Management Board should disclose events and circumstances that may cast significant doubt on the company's ability to continue as a going concern in the financial statements.

The Supervisory Board is responsible for overseeing the company's financial reporting process.

### Our responsibilities for the audit of financial statements

Our objective is to plan and perform the audit to obtain sufficient and appropriate audit evidence for our opinion. Our audit has been performed with a high, but not absolute, level of assurance, which means we may not have detected all errors and fraud. For a further description of our responsibilities in respect of an audit of financial statements we refer to the website of the professional body for auditors in the Netherlands (NBA)

[www.nba.nl/standardtexts-auditorsreport](http://www.nba.nl/standardtexts-auditorsreport).

## Report on other legal and regulatory requirements

### Report on the Report of Management Board and the other information

Pursuant to legal requirements of Part 9 of Book 2 of the Netherlands Civil Code (concerning our obligation to report about the Report of Management Board and other information):

- We have no deficiencies to report as a result of our examination whether the Report of Management Board, to the extent we can assess, has been prepared in accordance with Part 9 of Book 2 of the Netherlands Civil Code, and whether the information as required by Part 9 of Book 2 of the Netherlands Civil Code has been annexed.
- We report that the Report of Management Board, to the extent we can assess, is consistent with the financial statements.

### Engagement

We have operated as statutory auditor of Kiadis Pharma N.V., and its legal predecessors, since 2011. We were engaged by the General Meeting of Shareholders as auditor of Kiadis Pharma N.V. on 9 December 2015, for the audit of 2015.

Amstelveen, 14 April 2016

KPMG Accountants N.V.

H.A.P.M. van Meel RA



A microscopic image showing numerous cells, likely cancer cells, in shades of blue and white. The cells are irregular in shape and size, with some showing prominent nuclei and others appearing more rounded or elongated. They are scattered across the frame, creating a dense, textured background.

## **SAVING LIVES WITH INNOVATIVE CELL-BASED THERAPY**

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