Kiadis Pharma N.V.

(a public limited liability company incorporated under the laws of the Netherlands with its seat in Amsterdam, the Netherlands)

Registration Document

This registration document (the "**Registration Document**") is published in connection with an anticipated offering and/or admission to listing and trading of shares issued in the capital of Kiadis Pharma N.V. (the "**Company**", and together with its consolidated subsidiaries "**Kiadis**").

Any reference to Shares in this Registration Document comprises the ordinary shares in the capital of the Company, including any shares in the capital of the Company issued from time to time hereafter. The Shares are listed and traded on under the symbol "KDS" on Euronext Amsterdam, a regulated market operated by Euronext Amsterdam N.V. ("**Euronext Amsterdam**"), and on Euronext Brussels, a regulated market operated by Euronext Brussels NV/SA ("**Euronext Brussels**", and together with Euronext Amsterdam, "**Euronex**t") under ISIN Code NL0011323407.

This Registration Document constitutes a registration document for the purpose of article 4 of EC Regulation 809/2004 and has been prepared pursuant to article 5:2 of article 5:2 of the Dutch Financial Supervision Act (*Wet op het financieel toezicht*) (the "**Financial Supervision Act**") and the rules promulgated thereunder. This Registration Document has been approved by and filed with the Netherlands Authority for the Financial Markets (*Stichting Autoriteit Financiële Markten*, "**AFM**").

This Registration Document may only be used in connection with an offering and/or listing and trading of Shares and constitutes a prospectus in accordance with Directive 2003/71/EC, as amended from time to time, if supplemented by a securities note for the purpose of article 6 of EC Regulation 809/2004 as amended from time to time and a summary, each of which is approved by the AFM (the "**Prospectus**").

The date of this Registration Document is 12 March 2018 (the "**Registration Document Date**").

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1 Risk Factors

*The risk factors set out in this Chapter pertain to risks that are specific to Kiadis or its industry. In accordance with the Prospectus Regulation (EC Regulation 809/2004 as amended), the risk factors that are material to Shares being offered and/or admitted to listing and trading, as applicable, in order in order to assess the market risk associated with these securities, shall be set out in an AFM approved securities note and the summary which shall supplement this Registration Document (the "**Securities Note**") and collectively constitute the Prospectus.*

Any investment in the Shares involves certain risks. Accordingly, prior to investing in the Shares, prospective investors should carefully consider the risk factors described below together with all the other information contained in this Registration Document and the Securities Note. If any of the following risks actually occur, Kiadis' business, financial condition, results of operations or prospects could be materially and adversely affected. In such a case the value of the Shares could decline and investors may lose all, or part of their investment.

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

The order in which the following risks are presented is not intended to be an indication of their probability of occurrence or the magnitude of their potential effects.

Financial Risks

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

Kiadis has incurred losses in each year since its inception in 1997. Under the international financial reporting standards ("**IFRS**") as adopted by the European Union, Kiadis' net losses for the financial years ended 31 December 2016, 2015 and 2014 and the nine months ended 30 September 2017 were €14.8 million, €16.5 million, €7.8 million and €12.9 million, respectively. Currently, Kiadis does not have any products that have been approved for marketing and Kiadis continues to incur costs for research and development, pre-clinical testing and clinical development of product candidates, as well as general and administrative expenses.

Kiadis 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 product candidates and the commercialisation thereof. In addition, as Kiadis 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. Kiadis is incurring significant additional costs related to being a public company, including directors' and officers' liability insurance, increased personnel in finance and accounting, legal compliance costs, investor relations programs and increased professional fees. Kiadis' losses, among other things, have

caused and will continue to cause its working capital to decrease.

Kiadis has never generated any revenue from product sales and its ability to generate future revenues from product sales and become profitable depends significantly on its success in commercialising its product candidates.

Kiadis has not generated any revenue from product sales and has historically generated nominal revenues and other income principally from government grants and wage tax credits for employees engaged in research and development. Kiadis does not expect to receive additional grants or generate revenues from other sources in the near future. To achieve and maintain profitability, Kiadis will need to generate significant revenues from sales of products that it does not expect in the foreseeable future, if at all. Should Kiadis 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, Kiadis' business, financial condition, results of operations and prospects would be materially adversely affected. If Kiadis achieves profitability in the future, it may not be able to sustain profitability in subsequent periods. It is likely that Kiadis 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.

Kiadis requires substantial funding to continue its operations and before commercialisation of any of its products, particularly ATIR101.

At the Registration Document Date Kiadis had cash and cash equivalents of approximately €27 million. Based on its operating plans, Kiadis believes that it will be able to meet its financing needs until February 2019. Based on its present requirements, Kiadis believes its operations will require cash resources of approximately €29 million to provide it with sufficient working capital for the next twelve months following the Registration Document Date and that the current working capital shortfall amounts to approximately €2 million. Kiadis does not generate sufficient cash from product revenues to meet its current working capital requirements and is largely dependent on the issuance and sale of equity and debt securities to finance its operations and to proceed with the current plans for clinical development, including for its product candidates that provide for "Allodepleted T-cell ImmunotheRapeutics" ("**ATIR**").

Kiadis has used substantial funds to develop its product candidates and will require substantial additional funds to complete its planned development programs through commercialisation, i.e. 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 in the future, e.g. through in-licensing or acquisitions of programs or companies with synergistic or complementary technologies, products, or product candidates, and to meet its payment obligations under its loan arrangements and royalty and milestone arrangements. See also paragraphs 5.7 and 5.10 below.

The failure to raise capital when needed would adversely affect Kiadis' business, financial condition results of operations or prospects and could reduce the price of the Shares. In addition, any perceived or actual inability by Kiadis to finance its clinical development programme and other business activities, including as a result of milestone and royalty

payments to third parties, may cause the market price of the Shares to decline.

Kiadis' future funding requirements will depend on many factors, including the progress and cost of its ongoing and future clinical trials and research and development activities; the outcome, timing and cost of regulatory approvals by the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA) and the Canadian Therapeutic Products Directorate (TPD) and any other comparable regulatory authority; the growth in the number of its employees; 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 manufacturing cost of any products or product candidates; the timing, receipt and amount of any milestone, royalty and other payments, if any, from or to present and future licensors, licensees, collaborators or other third parties; the timing, receipt and amount of sales, if any, from Kiadis' products; changes in regulatory policies or laws that affect its operations or clinical development; the effects of competing products and competing technologies; and the terms and timing of establishing potential collaborations, licence agreements or other partnerships and private and government insurance reimbursement, including Medicare. If Kiadis is unable to obtain funding in a timely manner or on commercially acceptable or sensible terms, Kiadis may have to delay, scale back or stop its clinical development programs and commercialisation efforts. The failure to raise capital when needed would reduce Kiadis' business, financial condition, results of operations or prospects and could adversely affect the price of the Shares. In addition, any perceived or actual inability to finance Kiadis' clinical development program and other business activities, including as a result of milestone and royalty payments to third parties, may cause the market price of the Shares to decline.

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

Kiadis has been provided with a €15 million debt facility by Kreos Capital V (UK) Limited ("**Kreos Capital**") which it has fully drawn down (see paragraph 5.7 below), Kiadis currently does not have access to another debt or credit facility or other sources of committed capital. Kiadis intends to seek the 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 Kiadis to continue to implement its long term business strategy. If Kiadis 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 Kiadis would otherwise prefer to develop and market itself, thereby reducing their ultimate value to Kiadis. If Kiadis is unable to satisfy certain royalty payments – especially the royalty obligation to the University of Montreal (see paragraph 7.18 below) it may furthermore lose rights to certain licences or patents for its products, including to ATIR101, Kiadis' principal product. This may also result in Kiadis not being able to continue as a going concern, which could have a material impact on the carrying value of, in particular, intangible assets and property, plant and equipment. Kiadis' inability to obtain additional funds necessary to operate the business could furthermore materially and adversely affect the market price of the Shares and all or part of an investment in the Shares could be lost.

In order to finance acquisitions Kiadis 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 Kiadis.

To finance any acquisitions, Kiadis may choose to issue Shares or securities convertible into or exchangeable for Shares as consideration, which would dilute your interest in the Company. If the price of the Shares is low or volatile, Kiadis may not be able to use Shares to acquire other companies. Alternatively, it may be necessary for Kiadis to raise additional funds for acquisitions by incurring indebtedness. As a result, Kiadis' interest expense, leverage and debt service requirements could increase significantly. Additional funds may not be available on terms that are favourable to Kiadis, if at all. If Kiadis is unable to obtain the necessary financing, it may have to delay or may be unable to complete an acquisition.

The terms of any securities that Kiadis may issue could include liquidation or other preferences that adversely affect your rights or economic interests as a holder of Shares ("**Shareholder**"). To obtain debt financing, if available, lenders may require Kiadis to agree to covenants limiting or restricting its ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends, thus limiting funds available for Kiadis' business activities, or lenders could seek assignments or security rights over Kiadis' assets including patents. In relation to attracting debt financing, Kiadis needs to obtain the approval of Kreos Capital (see paragraph 5.7 below). If Kiadis raises additional funds through collaboration and licensing arrangements with third parties, it may have to relinquish valuable rights to its technologies or products, or grant licences on terms that are not favourable to it.

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

Exchange rate fluctuations could negatively affect Kiadis' financial condition.

The consolidated financial statements of the Company are presented in euro. However, since Kiadis has clinical trials in Canada and the United Kingdom and intends to have clinical trials in the United States, Sweden, Croatia and Israel, Kiadis incurs part of its expenses in Canadian dollars, British pounds, U.S. dollars, Swedish krona, Croatian kuna and Israeli sjekel. As a result, Kiadis' business and Share price will be affected by fluctuations in foreign exchange rates, primarily between the euro and the Canadian and U.S. dollar, which may have a significant impact on the reported results of operations and cash flows from period to period.

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

Kiadis is subject to income taxes in the Netherlands and other jurisdictions. Its future effective income tax rate will be impacted by a number of factors, including the geographic composition of its worldwide taxable income and its ability to allocate debt and expenses effectively. If legislators, tax authorities or government agencies in the jurisdictions in which Kiadis operates were to change applicable tax laws and regulations (for example as result of the various global, regional and local initiatives to reform the international tax framework, such as the base erosion and profit shifting project undertaken by the Organisation for Economic Co-operation and Development and anti-tax avoidance measures proposed by the European Committee) or successfully challenge the manner in which its income taxes are currently recognised or calculated or the transfer pricing polices employed by us, its effective income tax rate could increase, which would adversely impact its cash flow and profitability.

Furthermore, in many of these jurisdictions, the tax laws and regulations are very complex and are open to different interpretations and application. Although Kiadis believes its tax estimates are reasonable, the final determination of tax audits could be materially different from its tax provisions and accruals and negatively impact its financial results.

Development risks

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

ATIR101 for blood cancers, Kiadis' most advanced ATIR product in development and Kiadis' only product in clinical testing, is in Phase II with a Phase III clinical trial having recently enrolled its first patient in December 2017 after receiving regulatory approvals in various countries to start dosing patients. Kiadis' 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 Kiadis is pursuing fail, it will have to develop, acquire or license new products. Any of Kiadis' 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.

Kiadis does not expect ATIR101 to be commercially available before H2 2019, if at all, in any market. Although Kiadis applied in April 2017 for marketing authorisation for ATIR101 in the European Union, which would allow for conditional approval to be granted in Q4 2018 and ATIR101 becoming commercially available in the European Union on the basis of a conditional approval as of H2 2019 if such conditional approval is timely granted, ATIR101 may not meet applicable regulatory standards for such conditional approval, and such conditional approval may later be withdrawn if the specified conditions are not subsequently met. The results of the clinical trials to date cannot provide assurance that acceptable efficacy or safety will be shown upon completion of either of the ongoing or planned Phase II clinical or Phase III clinical trials, if any. Many products that show promise in Phase II trials fail in later clinical trials. If Kiadis is unable to make ATIR commercially available, or experiences significant delays in doing so, its business, financial condition, results of operations and prospects would be materially adversely affected.

Kiadis' product candidates provide for "Allodepleted T-cell ImmunotheRapeutics" (ATIR) and are based on its Theralux platform. Given the general applicability of Kiadis' 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 Kiadis' ability to develop other programs and would have an adverse effect on Kiadis' business, financial condition, results of operations or prospects and could reduce the price of the Shares.

Kiadis needs to complete successful clinical trials to receive regulatory approval but it may experience delays in commencing or completing, or inconclusive or negative results from, clinical trials which could harm Kiadis' ability to market a product, generate revenues and have a material adverse effect on its business, financial condition, results of operations and prospects.

Clinical trials are expensive and complex. Each trial can take many years to complete and have uncertain outcomes. Kiadis estimates that clinical trials of ATIR101 will continue for a significant period of time as Kiadis seeks regulatory approval for ATIR101. The results of "open-label" studies (studies in which both patient and the treating physician are aware of the treatment being used, as opposed to fully controlled or blind studies (studies in which the patient and in some cases the treating physician are unaware of the treatment being used)) used in some of the trials may not be as statistically or clinically sound as results of controlled or blind studies and may yield results that are inconclusive or unacceptable to regulatory authorities. Failure of a product can occur at any stage of the testing and Kiadis may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent commercialisation of Kiadis' current and any future product candidates. These events include, but are not limited to:

- delays in securing clinical investigators or trial sites for Kiadis' 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, which may stem from Kiadis' clinical trials being open-label, inadequately powered for statistical significance or from other factors;
- the development of unforeseen side effects in patients or unforeseen safety issues, such as graft versus host disease or encephalopathy;
- dosing issues;
- introduction of new therapies or changes in standards of practice or regulatory guidance that render Kiadis' clinical trial endpoints or the targeting of Kiadis' 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 Kiadis' future studies the safety and efficacy data obtained from a limited number of patients in Kiadis' previous and ongoing trials.

If Kiadis suffers any material delays, setbacks or negative results in its clinical trials or if Kiadis' clinical trials are put on clinical hold or 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, results of operations and prospects.

ATIR101 has been the subject of limited clinical trials and if further clinical trials reveal safety or fundamental efficacy issues, this may have a negative impact on the development path for other products that may be derived from the same platform.

The ATIR products are based on the Theralux platform and rely principally on the selectivity and photo-activation exhibited by Kiadis' photosensitizing reagent TH9402 to affect actively dividing cells such as cancer cells and immune reactive cells.

To date, the Phase I/II and Phase II clinical trials for ATIR101 have involved a discrete and small number of patients and hence provide only preliminary indications of efficacy. If ATIR101 is shown to be ineffective, unsafe or otherwise has negative or inconclusive clinical trial results, it may materially adversely affect the development and regulatory review of ATIR and other products based on the Theralux platform, if any, and Kiadis' ability to strengthen its preclinical pipeline from the Theralux platform, which could have a material adverse effect on its business, financial condition, results of operations and prospects.

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

Kiadis currently licenses some of the compounds and products used in its research programs from third parties, particularly the Theralux product portfolio, for which Kiadis has an exclusive licence (see paragraph 7.18 below). Kiadis' present development involving these compounds relies upon previous research conducted by third parties over whom Kiadis had no control. In order to receive regulatory approval for a product, Kiadis needs to present all relevant data and information obtained during its research and development, including research conducted prior to Kiadis licensing the product. Any problems that emerge from preclinical research and testing conducted prior to Kiadis' in-licensing may affect future results or Kiadis' ability to document prior research and to conduct further clinical trials, which could have a material adverse effect on its business, financial condition, results of operations and prospects.

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

Kiadis may encounter delays in the regulatory approval process if Kiadis 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 Kiadis 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, results of operations and prospects.

Risks relating to the regulatory environment

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

There is no assurance that Kiadis will be able to obtain or maintain market exclusivity for its products in indications that are important to its business. Kiadis' 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 Kiadis has rights to patents relating to the Theralux technology, these patents would likely afford only limited protection and Kiadis does not rely on them to provide it with market exclusivity for ATIR products.

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, Kiadis has been granted orphan drug designations in respect of ATIR101 in the United States and the European Union (see paragraph 7.12 below).

Once granted, exceptions to market exclusivity through orphan drug status may be granted to other applicants if Kiadis 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 Kiadis 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 Kiadis' products for different indications.

If Kiadis 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.

Kiadis' products are subject to extensive regulation, which can be costly and time-consuming to comply with, and Kiadis may not obtain approvals for performing clinical trials or for the commercialisation of any of its products.

Kiadis is not permitted to perform clinical trials with or market any product until it receives

approval from the appropriate regulatory authorities. Kiadis must obtain approval for performing clinical trials with any product and for commercialising any product, from the appropriate regulatory authority of each jurisdiction where it wishes to perform clinical trials with or market its product before it can commence clinical trials or marketing of its products in those countries. Kiadis has not received marketing approval from any regulatory authority for any of its products.

Kiadis invests substantial time and resources in preclinical studies, clinical trials and the preparation and submission of applications without any assurance that Kiadis will obtain regulatory approval or recoup its investment. The EMA, the FDA, the TPD and other regulatory authorities exercise substantial discretion in the clinical trial development phase and 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 (i) clinical trial development (i.e. placing a clinical trial under clinical hold) and (ii) 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 Kiadis' products, or challenges to their accuracy or adequacy;
- the development or observation of adverse side effects;
- conditions in Kiadis' or Kiadis' third-party manufacturers' processes or facilities;
- regulatory changes requiring new or different evidence of safety and efficacy for the product's primary indication;
- issues with adhering to industry good practice quality guidelines, regulations and requirements (GxP); or
- the inability to address questions and observations in the regulatory approval process.

Should any of these factors occur, regulatory approval of Kiadis' clinical trials or products could be denied, 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 Kiadis' business, financial condition, results of operations or prospects.

In addition, if Kiadis 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 Kiadis' 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 Kiadis' products merit such consideration.

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

If any of Kiadis' products are approved by the FDA, the EMA, the TPD or another regulatory authority, Kiadis would be subject to extensive regulatory requirements over product manufacturing, testing, labelling, packaging, storage, advertising, promotion, distribution, export, adverse event reporting and record keeping. Kiadis and its suppliers, Contract Manufacturing Organisations (CMOs) and contract testing laboratories would also be subject to inspection by the EMA, 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 Kiadis' products, which could reduce the potential market for its products. Kiadis 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. Kiadis cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, in the European Union, the United States or elsewhere. If Kiadis 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 Kiadis 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 Kiadis' operations, total or partial suspension of production and refusal to approve pending new drug applications (NDAs), supplements to approved NDAs or their equivalents in other jurisdictions and financial penalties. If Kiadis is subject to any of these sanctions, its competitive position or financial and commercial prospects could be materially adversely affected.

Operational risks

Due to Kiadis' limited resources and access to capital, Kiadis 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 Kiadis has limited resources and access to capital to fund its operations, Kiadis' management must make significant prioritisation decisions on which products to pursue and the amount of resources to allocate to each product. Kiadis' current development activities are focused primarily on the clinical development of ATIR101. To date, this trial has been postponed and Kiadis has only allocated very limited resources towards and has not yet decided when to begin clinical 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 Kiadis to miss valuable opportunities. If Kiadis 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, results of operations and prospects could be materially adversely affected.

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

Patients who are treated with Kiadis' products, whether through their participation in Kiadis' clinical trials or after (and if) such product is commercially available, may suffer adverse side effects as a result of the use of Kiadis' products. Kiadis cannot predict the possible harms or side effects that may result from these clinical trials and this use. Kiadis relies on the expertise of physicians, nurses and other associated medical personnel in administering its products to patients. If these medical personnel are not properly trained to administer, or are negligent in the administration of Kiadis' products, the therapeutic effect of Kiadis' 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 Kiadis, the sponsors of physician-initiated clinical trials involving Kiadis' 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 Kiadis' 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 Kiadis' products for indications for which the product has not been authorised or misuse of Kiadis' products may subject Kiadis to liability. Any claims against Kiadis, regardless of their merit, could be difficult and costly to defend and could materially adversely affect the market for Kiadis' products or any prospects for commercialisation of its products. Although Kiadis 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 Kiadis. Because of increasing costs of insurance coverage, Kiadis 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 Kiadis' business, financial condition, results of operations or prospects.

Kiadis may not be able to manufacture sufficient amounts of its products for the

clinical or commercial stage.

Kiadis may not be able to manufacture in time and/or sufficient amounts of its products for the clinical or commercial stage due to, for example, products not meeting specifications, lack of skilled personnel, lack of manufacturing capacity, lack of funding, lack of sufficient raw materials and manufacturing equipment fulfilling required specifications and quality standards, general management or operational issues, force majeure, failure to comply with current Good Manufacturing Practices (GMP) and other applicable regulations and quality assurance guidelines, prohibition by regulatory authorities, withdrawal from the market and import stops. Any of the aforementioned could, for example, lead to personal injury or death of patients who may already have undergone a transplantation but will then not receive the applicable Kiadis product or receive it in time. All of the above would have a material adverse effect on Kiadis' business, financial condition, results of operations or prospects.

Kiadis' manufacturing processes for its products may not fulfil requirements for clinical or commercial manufacturing.

Kiadis' manufacturing processes including its assays may not be adequately robust, effective, efficient, safe, validated and reproducible, changes to these manufacturing processes may not have been correctly made, comparability may not have been adequately established meaning that product characteristics may have changed, and Quality Assurance, GMP and other systems may not meet regulatory standards. Should any of the foregoing events occur, additional investments may be needed, new or repeat clinical studies may have to be performed and delays may be experienced, which would have a material adverse effect on Kiadis' business, financial condition, results of operations or prospects.

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

Kiadis is a party to certain agreements that contain liability or indemnification provisions under which Kiadis or the counterparty may claim damages. In the event Kiadis 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 Kiadis 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 Kiadis nevertheless could become liable to make substantial payments. If Kiadis must make substantial liability payments under an agreement, this could have a material adverse effect on Kiadis' business, results of operations, financial condition and prospects.

Kiadis may in the future acquire businesses or engage in other transactions that could disrupt its operations.

Kiadis may selectively consider acquisitions. Kiadis' valuation of any businesses or assets it acquires may prove incorrect and Kiadis cannot assure that it will realise the financial and strategic goals that were contemplated at the time of any transaction. Kiadis' 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 Kiadis may assume known and unknown contingencies related to product liability,

intellectual property, financial disclosures, accounting practices, internal controls or other liabilities. Kiadis may also have tax exposures or lose anticipated tax benefits as a result of acquisitions or integration of merged entities.

Following an acquisition, Kiadis' ongoing business may be disrupted and Kiadis' management attention may be diverted by transition or integration issues. Kiadis may have higher than anticipated costs in continuing research and development of acquired products. If Kiadis 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 Kiadis' business, results of operations, financial condition and prospects.

Kiadis' clinical development activities rely heavily on sensitive and personal information, an area which is highly regulated by privacy laws. If Kiadis 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 Kiadis' clinical development, Kiadis 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 Kiadis. 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 Kiadis. If the patient fails to execute an authorisation or the authorisation fails to contain all required provisions, then Kiadis will not be allowed access to the patient's information and Kiadis' research efforts can be substantially delayed. Furthermore, use of protected health information that is provided to Kiadis 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, Kiadis 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 Kiadis could subject Kiadis to civil and criminal penalties and adverse publicity and could harm Kiadis' 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. Kiadis 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 Kiadis from undertaking or publishing essential research, which could have a material adverse effect on Kiadis' business, results of operations, financial condition and prospects.

If Kiadis' facilities become inoperable, or if Kiadis is unable to renew its existing lease agreements, Kiadis may be unable to perform its manufacturing, clinical development or commercial activities and its business, financial condition, results of operations and prospects may be harmed.

Kiadis performs certain of its manufacturing and critical clinical development activities 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. Kiadis' lease in Amsterdam for its manufacturing facility and office space has a ten year term that is automatically extended thereafter for four years (until 31 December 2031) and thereafter for five years (until 31 December 2036), unless terminated at the end of a lease period with one year's notice. Kiadis' lease in Amsterdam for its laboratory facility has a one-year term that is automatically extended each year with a further one-year term, unless terminated with three months' notice. There is no assurance that Kiadis will be able renew its current lease agreements in the existing locations on acceptable terms upon the lapse of the current terms or extended subsequent terms. If Kiadis is unable to perform or transfer its research and clinical development activities, it may suffer delays to its clinical programs or harm to its reputation. Kiadis 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. Kiadis' insurance coverage for damage to its property and the disruption of its business may not be sufficient to cover all of Kiadis' potential losses, including the loss of time as well as the costs of lost opportunities, and may not continue to be available to Kiadis 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.

Kiadis' research and development involves the controlled use of hazardous materials, including chemicals and biological materials such as chemical solvents and human cells. Kiadis' operations also generate hazardous waste products. Kiadis 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. Kiadis may be sued for any injury or contamination that results from Kiadis' 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 Kiadis' research, development and production efforts, which could have a material adverse effect on Kiadis' business, results of operations, financial condition and prospects.

Commercialisation and market risks

The market opportunities for Kiadis' products may be smaller than currently anticipated, lowering potential revenue for Kiadis.

Kiadis makes projections of both the number of people who have the cancers and the other indications that Kiadis is targeting, as well as the number of individuals within Kiadis' target patient population 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 scientific literature and patient foundations 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, and in particular ATIR101, than Kiadis currently anticipates which would result in lower potential revenue for Kiadis.

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

Kiadis incurs and will incur substantial research and clinical development costs before it can confirm the scientific validity or commercial viability of a product. Even if the EMA, the FDA, the TPD or any other regulatory authority approves the marketing of ATIR101, or any other products that Kiadis may develop, physicians, healthcare providers, patients or the medical community may not accept or use them. The degree of market acceptance of ATIR101 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;
- Kiadis' 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 ATIR101 or any other products that Kiadis may develop fails to achieve market acceptance, Kiadis may not be able to generate sufficient revenue. As a result, Kiadis may be required to seek additional financing.

In addition, Kiadis targets specific indications with discrete patient populations. Kiadis therefore may have to achieve significant market penetration in each target market and obtain relatively high prices for its products to achieve profitability. Kiadis 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 Kiadis is unable to do so, its business, financial condition, results of operations and prospects would be materially adversely affected.

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

See paragraph 7.8 below for information on Kiadis' current competitive position. Kiadis 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. Kiadis 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. Kiadis' competitors have developed or may be developing alternative products for cancer and other indications into which Kiadis may expand, such as inborn diseases of the blood building system. Kiadis' competitors may have substantially greater financial, technological, manufacturing, marketing, managerial, regulatory and research and development resources

and experience. Kiadis' competitors may also:

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

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

The commercial success of Kiadis' products, including ATIR101, 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 Kiadis' 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 Kiadis may develop. If public perception is influenced by claims that cell-based therapy is unsafe, ineffective or prohibitively expensive, Kiadis' 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 Kiadis' products. Any increased scrutiny could delay or increase the costs of obtaining regulatory approval for Kiadis' products, which could have a material adverse effect on Kiadis' business, results of operations, financial condition and prospects.

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

If Kiadis 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. Kiadis' ability to realise its commercialisation strategy and manage any growth will require Kiadis to continue to recruit and train additional qualified personnel and make appropriate changes to its operational, financial and management controls. Kiadis 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 Kiadis' management and Kiadis' business development resources. Any inability to manage

anticipated growth and expanding operations, including as a result of failing to realise Kiadis' commercialisation strategy for ATIR101, could adversely affect its business, financial condition, results of operations or prospects.

Governments, especially in the European Union and Canada, often impose strict price controls, which may adversely affect Kiadis' 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, Kiadis may be required to conduct a post-authorisation clinical trial that compares the cost-effectiveness of Kiadis' product to other available therapies. If reimbursement of Kiadis' products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels or the pricing negotiation is considerably delayed, Kiadis may be unable to achieve or sustain profitability.

Governments in some of the Member States of the European Union are developing strategies regarding joint negotiations in relation to pricing and reimbursement conditions (reimbursement is discussed further below).

Kiadis expects future pricing negotiations in the EU to be based upon improvements with ATIR101 over the Baltimore protocol (see paragraph 6.5 below), for which analysis of the Phase III data should provide the requisite input. However, until the moment that Phase III data becomes available, Kiadis will start pricing discussions with hospitals, payors and reimbursement agencies on the basis of more limited Phase II data, the outcome of which is uncertain.

If Kiadis 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.

The commercial success of Kiadis' 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 Kiadis' products. In the European Union and other markets, Kiadis' 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 Kiadis' products as cost-effective, reimbursement may not be available to patients or may be insufficient to allow Kiadis' 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 Kiadis' products. Any of these factors could impair the development of a commercial market for Kiadis' products and its business, financial condition, results of operations and prospects could be materially adversely affected.

Risks relating to Kiadis' dependence on third parties and key personnel

Kiadis relies on third parties who exclusively license intellectual property rights

relating to the Theralux platform to it. If any such exclusive licence is terminated, Kiadis may be unable to commercialise and market the ATIR products.

Kiadis 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, Kiadis is required to, among other things, develop, obtain regulatory approval of, seek intellectual property protection for and commercialise products based on the Theralux technology. Kiadis' 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, Kiadis would be prevented from continuing its use of this technology in clinical trials or, if Kiadis' products are approved for marketing, in commercial sales. The loss of rights under this licence could preclude Kiadis from further developing, commercialising and marketing ATIR101 and other products, which would have a material adverse effect on Kiadis' business, financial condition, results of operations and prospects.

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

Kiadis 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, Kiadis 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 Kiadis will be able to enter into strategic alliances on terms favourable to it, or at all. Potential partners may require royalty or milestone payments, rights to current or after-developed intellectual property, exclusivity rights, limitations on liabilities, indemnities or other provisions that are in itself adverse to Kiadis. Potential partners may fail to diligently fund, develop or commercialise Kiadis products.

Kiadis relies on third-party support to manufacture certain of its products and technologies. If Kiadis is unable to enter into or maintain its arrangements with third party manufacturers under favourable terms, Kiadis' ability to develop its products or generate sufficient product revenues could be harmed.

The manufacturing of ATIR and the TH9402 compound has been historically outsourced to CMOs. Although Kiadis has recently entered into a lease agreement for commercial manufacturing space in the Netherlands for ATIR, until that facility is fully functional, CMOs remain essential to Kiadis' current manufacturing processes. Kiadis is currently negotiating additional CMO arrangements to secure sufficient (back-up) capacity for the Phase III trial with ATIR101 but does not yet have such arrangements in place. Kiadis' reliance on a small number of suppliers, CMOs and contract testing laboratories limits Kiadis' control over quality assurance, quality control, transport and delivery schedules and Kiadis cannot assure that any third parties will perform to Kiadis' standards.

If Kiadis were to experience an unexpected loss of supply of, or if any CMO or supplier were unable to meet Kiadis' demand for, any of its products, it could experience delays in its research and development activities, planned clinical studies or commercialisation of approved products. Kiadis could be unable to find alternative CMOs or suppliers of acceptable quality who can deliver appropriate volumes at acceptable cost. Moreover, Kiadis'

CMOs and 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 CMOs and suppliers, if necessary, would significantly delay Kiadis' clinical studies and the commercialisation of its products. In addition, Kiadis may not be able to successfully transfer manufacturing from one CMO to another CMO or to in-house production.

Kiadis also needs to work with CMOs and 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 Kiadis and its CMOs and 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 CMOs and suppliers and Kiadis also may be subject to audits by the appropriate regulatory authorities. If any of Kiadis' CMOs or suppliers fails to comply with applicable GMP or other applicable manufacturing regulations, Kiadis' ability to develop and commercialise its products or product candidates could suffer significant interruptions.

Kiadis faces risks inherent in relying on a limited number of CMOs as any disruption, such as a fire, natural hazards or vandalism at a CMO could significantly interrupt Kiadis' manufacturing capability. Business interruption insurance may not adequately compensate Kiadis for any losses that may occur and Kiadis would have to bear the additional cost of any disruption.

If Kiadis achieves regulatory approval for any of its products, Kiadis' CMOs and suppliers may not be able to increase production to suitable commercial levels. Any failure to achieve and maintain high quality manufacturing standards and fulfil applicable regulatory requirements could result in patient injury or death, product recalls or withdrawals, regulatory censure or lawsuits. In addition, in case of failure to comply with applicable requirements the data generated in Kiadis' clinical trials may be deemed unreliable and the FDA, the EMA, the TPD or other comparable foreign regulatory authorities may require Kiadis to extend, repeat or perform additional clinical trials which would delay the regulatory approval process. Kiadis cannot assure that upon inspection by a given regulatory authority, such regulatory authority will determine that the manufacturing process complies with such requirements. Manufacturing errors, disruptions and difficulties in obtaining export and import approvals could contribute to cost overruns, impair Kiadis' ability to manage production, cause delays in shipments and cancellation of orders that may adversely affect its relationships with future customers and potentially allow competitors to penetrate Kiadis' customer accounts. In addition, CMOs, suppliers and contract testing laboratories may prioritise capacity for Kiadis' competitors or increase prices charged to Kiadis, which could harm Kiadis' ability to generate sufficient product revenues.

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

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

Kiadis relies and may rely on contract research organisations (CROs), clinical data management organisations, consultants and other service firms to design, conduct, supervise and monitor clinical studies. Kiadis and these third parties are required to comply with various regulations, including GCP, which are enforced by the guidelines of the competent authorities of the member states of the European Economic Area (the "**EEA**"), the FDA, 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 Kiadis or any of these third parties fail to comply with applicable requirements, the clinical data generated in Kiadis' clinical trials may be deemed unreliable and the EMA, the FDA, the TPD or other comparable foreign regulatory authorities may require Kiadis to perform additional clinical trials before approving its marketing applications. Kiadis 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, Kiadis' clinical trials must be conducted with products that are GMP produced. Failure to comply with these regulations may require Kiadis to repeat pre-clinical and clinical trials, which would delay the regulatory approval process.

Third party staff are not Kiadis employees and, except for remedies available to Kiadis under its agreements with such third parties, Kiadis cannot control whether or not they devote sufficient time and resources to its ongoing clinical and pre-clinical programs. If these third parties 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 Kiadis' clinical protocols, regulatory requirements or for other reasons, Kiadis' clinical trials may be extended, delayed or terminated and Kiadis may not be able to obtain regulatory approval for or successfully commercialise its products in development. As a result, Kiadis' 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 Kiadis 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 Kiadis' 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 Kiadis to disclose its proprietary information to these parties, which could increase the risk that this information will be misappropriated. Kiadis 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 Kiadis is unable to identify and successfully manage the performance of third-party service providers in the future, its business may be adversely affected. Though Kiadis carefully manages the relationships with third parties, there can be no assurance that Kiadis will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on Kiadis' business, financial condition, results of operation and prospects.

If Kiadis 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, Kiadis' clinical development programs could be delayed and otherwise adversely affected. Kiadis 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 EMA, the FDA, and other regulatory authorities require clinical trials to be conducted in

accordance with good clinical practices (GCP), including for conducting, recording and reporting the results of pre-clinical 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. Kiadis' 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 Kiadis' business, financial condition, results of operations and prospects.

The failure to attract and retain senior management and skilled personnel could impair Kiadis' development and commercialisation efforts.

Kiadis is highly dependent on the members of the Company's board of managing directors (the "**Management Board**"), its senior management that supports the Management Board in the day-to-day management of the Company consisting of Dr. A. Sandler, Mr. J. Feijen, Ms. M. Hoppe and Mr. Hård ("**Senior Management**") and various key scientific and technical personnel, being the Vice President CMC, the Head of Technology and Development, the Head of Project Management, the Head of Manufacturing, the Head of Analytics and Validation, the Head of Regulatory Affairs, the Head of Clinical Operations and the Head of Quality Affairs. 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 Kiadis' business, financial condition, results of operations and prospects. If Kiadis does not have sufficient numbers of skilled employees to support its research, development, manufacturing, commercialisation, regulatory compliance or management functions, or if its employees lack the skills necessary for the development of its operations, Kiadis 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 Kiadis. If Kiadis is unable to attract and retain sufficient scientific, technical and managerial personnel, Kiadis will be unable to advance its clinical programs, commercialise any approved products or expand its business, which may have a material adverse effect on Kiadis' business, financial condition, results of operations and prospects.

Risks relating to intellectual property and know-how

The duration and scope of Kiadis' 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 Kiadis' product candidates are obtained, the expiration of a patent may leave Kiadis

more vulnerable to competition from biosimilar or generic alternatives. Certain of Kiadis' issued patents relevant for ATIR or other aspects of Kiadis' technology have already expired, and others will expire in the coming years (see the table in paragraph 7.14.2 below which does not take into account extensions that could become available in the future).

Moreover, patents have a limited scope of protection. Kiadis' 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, Kiadis' 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 Kiadis' 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, Kiadis 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.

Kiadis' 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 Kiadis' existing patents or future patents, if issued, could result in a ruling adverse to Kiadis 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 Kiadis' patents, and claims in these patents were consequently narrowed or invalidated, Kiadis' 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 Kiadis 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 Kiadis has rights may not issue or concur with the scope of claims sought by Kiadis, if at all, or the scope of claims Kiadis or its licensors are seeking may not be sufficiently broad to protect Kiadis' products. If Kiadis' patents expire or if a challenge to an existing patent is successful, there could be a material adverse effect on Kiadis' business, financial condition, results of operations and prospects.

Kiadis 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 U.S. 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.

Kiadis' competitors would be able to offer and sell products based on Kiadis' compounds so long as they do not infringe any valid patents or other proprietary rights that Kiadis or others, including Kiadis' licensors, may have. Such risks for Kiadis will increase if Kiadis 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 Kiadis 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 Kiadis fails to enforce adequately or protect its intellectual property rights its business may be harmed.

Kiadis' 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 Kiadis' ability to compete.

Kiadis' 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 Kiadis' 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 Kiadis' intellectual property or narrow the scope of its patent protection.

Patents also will not adequately protect Kiadis' products if competitors devise ways of making or using these products without legally infringing Kiadis' 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 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, Kiadis may challenge a competitor based on Kiadis' 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 Kiadis 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.

Kiadis 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. Kiadis 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 Kiadis, in order to protect its rights, Kiadis may have to participate in an expensive and time-consuming opposition proceeding before the European Patent Office, the U.S. 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 Kiadis' business, financial condition, results of operations and prospects.

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

Competitors may use Kiadis' technologies in jurisdictions where Kiadis has not obtained patent protection to develop their own products such as China and may export otherwise infringing products to territories where Kiadis 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 Kiadis' products in jurisdictions where Kiadis 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 Kiadis to stop the infringement of its patents or marketing of competing products in violation of its proprietary rights generally. Proceedings to enforce Kiadis' patent rights in foreign jurisdictions could result in substantial cost and divert Kiadis' efforts and attention from other aspects of its business. The inability of Kiadis to protect or enforce its intellectual property rights throughout the world could have a material adverse effect on its business, prospects, financial condition, results of operations and prospects.

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.

Kiadis considers proprietary trade secrets and confidential know-how and unpatented know-how to be important to its business. Kiadis relies on trade secrets and confidential know-how to protect its technology, especially where Kiadis does not believe that patent protection is appropriate or obtainable. However, trade secrets and confidential know-how are difficult to protect. Kiadis' current or former employees, consultants, contractors, outside scientific collaborators and other advisers may have access to and unintentionally or wilfully disclose Kiadis' confidential information, including to competitors, and confidentiality agreements may not be in place with all of these parties or if in place 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 Kiadis' competitive business position. Moreover, Kiadis' 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, Kiadis'

competitors could limit how Kiadis uses its trade secrets and confidential know-how, which may have a material adverse effect on Kiadis' business, financial condition, results of operations and prospects.

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

There is a risk that Kiadis or the licensors of intellectual property that Kiadis 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 in which Kiadis' research is conducted. Because patent applications take several years to complete, there may be currently pending applications, unknown to Kiadis, which may later result in issued patents that cover the production, manufacture, commercialisation or use of Kiadis' products. Many of Kiadis' employees were previously employed at universities or other biotechnology or pharmaceutical companies. Although no claims are currently pending, Kiadis may be subject to claims that these employees or Kiadis 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 Kiadis fails in defending such claims, in addition to paying monetary damages, Kiadis 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, Kiadis might:

- be prohibited from selling or licensing any product that it may develop unless the patent holder licenses the patent to Kiadis, 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 Kiadis' 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 Kiadis' ability to commercialise its products.

If patents issued to third parties contain valid claims that cover Kiadis' compounds or their manufacture or uses or assays relevant to Kiadis' development plans, Kiadis may be required to obtain licences to these patents or to develop or obtain alternative technology. If a patent is issued that covers Kiadis' compounds or their manufacture or uses or assays related to Kiadis' development plans then Kiadis 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. Kiadis 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, Kiadis' business prospects could be materially adversely affected.

2 Important Information

2.1 General

You should rely only on the information contained in, or incorporated by reference into, this Registration Document and any supplement to this Registration Document within the meaning of article 5:23 of the Financial Supervision Act, should such supplement be published. No person is or has been authorised to give any information or to make any representations other than those contained in this Registration Document and, if given or made, such information or representations must not be relied upon as having been authorised by Kiadis or any of its affiliates or agents. The delivery of this Registration Document shall not under any circumstances, create any implication that there has been no change in Kiadis affairs or that information contained herein is correct as of any time subsequent to the date hereof.

2.2 Responsibility statement

Kiadis Pharma N.V., with its registered seat in Amsterdam and with its registered office at Paasheuvelweg 25A, 1105 BP Amsterdam, the Netherlands, accepts responsibility for the information contained in this Registration Document. To the best of Kiadis Pharma N.V.'s knowledge (having taken all reasonable care to ensure that such is the case), the information contained in this Registration Document is in accordance with the facts and contains no omission likely to affect its import.

The information included in this Registration Document reflects Kiadis' position as at the Registration Document Date and under no circumstances should the issue and distribution of this Registration Document after the Registration Document Date be interpreted as implying that the information included herein will continue to be correct and complete at any later date.

This Registration Document is to be read in conjunction with all the documents which are incorporated herein by reference (see paragraph 2.4 below).

The distribution of this Registration Document may be restricted by law in certain jurisdictions. This Registration Document may not be used for the purpose of, or in connection with, any offer or solicitation of any offer by anyone. This Registration Document does not constitute an offer of, a solicitation of, or an invitation to purchase any Shares. Persons who obtain this Registration Document must inform themselves about and observe all such restrictions. The Company does not accept any legal responsibility for any violation by any person, of any such restrictions.

2.3 Presentation of financial and other information

2.3.1 Financial information

The Company was incorporated on 12 June 2015, in the context of a capital restructuring (the "**Capital Restructuring**") in connection with Kiadis' initial public offering ("**IPO**") in 2015 and in which Capital Restructuring the shares in Kiadis Pharma B.V. were transferred to the Company in exchange for Shares, as a consequence whereof the Company became the holding company of the Kiadis corporate group and the direct holder of 97.52% of the shares of Kiadis Pharma B.V. On 6 January 2016, Kiadis Pharma B.V., as disappearing entity, merged into the Company and consequently ceased to exist.

The Company's consolidated financial statements for the financial years ended 31 December 2016 and 2015, Kiadis Pharma B.V.'s consolidated financial statements for the financial year ended 31 December 2014, and the Company's consolidated interim financial statements for the six months ended 30 June 2017 have been incorporated by reference in this Registration Document (see also paragraph 2.4 below), and its consolidated interim financial statements for the nine months ended 30 September 2017 have been included in this Registration Document beginning on page F-1. Due to the immaterial nature of the differences between the financial statements of the Company and Kiadis Pharma B.V. for the financial year ending 31 December 2014, the Management Board is of the view that the financial statements of Kiadis Pharma B.V. for the financial year ending 31 December 2014 provide the information required to be presented herein over the financial year ending 31 December 2014 in accordance with Item 20.1 of Annex I of Commission Regulation (EC) No 809/2004 and pursuant to the Financial Supervision Act, which is designed to ensure that investors and potential investors in the Shares are aware of all information that, according to the particular nature of the Company and of the Shares, is necessary to enable investors and potential investors to make an informed assessment of the assets and liabilities, financial position, profit and losses and prospects of the Company and of the rights attaching to the Shares.

The consolidated financial statements for the financial years ended 31 December 2016, 2015 and 2014 incorporated by reference in this Registration Document have been audited by KPMG Accountants N.V. ("**KPMG**"), independent auditors, as stated in its independent auditor's reports which are also incorporated by reference in this Registration Document.

2.3.2 Rounding

Certain figures contained in this Registration Document have been subject to rounding adjustments. Accordingly, in certain instances the sum of the numbers in a column or a row in tables contained in this Registration Document may not conform exactly to the total figure given for that column or row.

2.3.3 Currencies

Unless otherwise indicated, all references in this Registration Document to "€", "euro", "Eur", "EUR" or "cents" are to the currency introduced at the start of the third stage of the European Economic and Monetary Union pursuant to the treaty establishing the European Community, as amended. All references to "$", "US$" or "U.S. dollars" are to the lawful currency of the United States. All references to "Canadian dollar" or "CN$" are to the lawful currency of Canada.

2.3.4 Exchange rate information

The exchange rates below are provided solely for information and convenience. The tables below show, for the periods indicated, the high, low, average and period end. No representation is made that euros could have been, or could be, converted into U.S. dollars or Canadian dollars at any particular rate indicated or any other rate.

***Year ended 31 December**	**High**	**Low**	**Average**	**End of Period**
		U.S. Dollars per 1 euro		
2014	1.39	1.21	1.33	1.21
2015	1.21	1.05	1.11	1.09

2016	1.15	1.04	1.11	1.05
2017	1.20	1.04	1.13	1.20

On 9 March 2018 the exchange rate of U.S. dollar per 1 euro was 1.23*.

***Year ended 31 December**	**High**	**Low**	**Average**	**End of Period**
		Canadian Dollars per 1 Euro		
2014	1.55	1.39	1.47	1.41
2015	1.53	1.31	1.42	1.50
2016	1.59	1.39	1.47	1.41
2017	1.53	1.38	1.47	1.51

On 9 March 2018 the exchange rate of Canadian dollars per 1 euro was 1.58*.

*Source: Bloomberg.

2.3.5 Gender references

Words in a particular gender shall include all genders – and accordingly a reference to "he" or "his" shall also refer to "she" and "her", unless the context requires otherwise.

2.4 Documents incorporated by reference

The Company's articles of association (*statuten*) as they read on the Registration Document Date (the "**Articles of Association**") (the Dutch version and an English translation thereof) are incorporated by reference in the Registration Document. In addition, the following parts of the Company's consolidated financial statements for the financial years ended 31 December 2016 and 2015, as well as Kiadis Pharma B.V.'s consolidated financial statements for the financial year ended 31 December 2014 are incorporated by reference in this Registration Document:

The Company's consolidated financial statements for the financial year ended 31 December 2016:

- Consolidated statement of financial position - page 43
- Consolidated statement of comprehensive income - page 44
- Consolidated statement of changes in equity - page 45
- Consolidated statement of cash flows - page 46
- Notes to the consolidated financial statements - pages 47-73
- Independent auditor's report - pages 85-89

The Company's consolidated financial statements for the financial year ended 31 December 2015:

- Consolidated statement of financial position - page 51
- Consolidated statement of comprehensive income - page 52
- Consolidated statement of changes in equity - page 53
- Consolidated statement of cash flows - page 54
- Notes to the consolidated financial statements - pages 55-83
- Independent auditor's report - pages 94-99

Kiadis Pharma B.V.'s consolidated financial statements for the financial year ended 31 December 2014:

- Consolidated statement of financial position - page 5
- Consolidated statement of comprehensive income - page 6
- Consolidated statement of changes in equity - page 7
- Consolidated statement of cash flows - page 8
- Notes to the consolidated financial statements - pages 9-45
- Other information - pages 55 and 56

Also, the following parts of the Company's interim report for the six months ended 30 June 2017 are incorporated by reference in this Registration Document.

- Consolidated statement of financial position - page 8
- Consolidated statement of comprehensive income - page 9
- Consolidated statement of changes in equity - page 10
- Consolidated statement of cash flow - page 11
- Notes to the consolidated interim financial statements - pages 12-21

Any statement contained in a document which is incorporated by reference herein shall be deemed to be modified or superseded for the purpose of this Registration Document to the extent that a statement contained herein (or in a later document which is incorporated by reference herein) modifies or supersedes such earlier statement (whether expressly, by implication or otherwise). Any statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute part of this Registration Document.

Where the documents incorporated by reference themselves incorporate information by reference, such information does not form part of this Registration Document.

Copies of the documents incorporated by reference in this Registration Document may be obtained from the Company's website at http://www.kiadis.com. No documents or information

other than the information incorporated by reference, including the content of Kiadis' website – www.kiadis.com - or of websites accessible from hyperlinks on that website, form part of, or are incorporated by reference into, this Registration Document.

2.5 Available information

Copies of this Registration Document, the Company's consolidated financial statements for the financial years ended 31 December 2016 and 2015, Kiadis Pharma B.V.'s consolidated financial statements for the financial year ended 31 December 2014, the Company's consolidated interim financial statements for the six months ended 30 June 2017 and the Articles of Association may be obtained free of charge for a period of twelve months following the Registration Document Date by sending a request in writing to the Company at Paasheuvelweg 25A, 1105 BP Amsterdam, the Netherlands.

2.6 Enforceability of judgments

The ability of Shareholders in certain countries other than the Netherlands, in particular in the United States, to bring an action against the Company may be limited under law. The Company is a public limited liability company (*naamloze vennootschap*) incorporated under the laws of the Netherlands and has its statutory seat (*statutaire zetel*) in Amsterdam, the Netherlands.

All but one of the members of the Management Board and the Company's board of supervisory directors (the "**Supervisory Board**") are resident of countries other than the United States. All or a substantial proportion of the assets of these individuals are located outside the United States. Kiadis' assets are predominantly located outside the United States. As a result, it may not be possible or it may be difficult for investors to effect service of process within the United States upon Kiadis or such persons, or to enforce against them in U.S. courts a judgment obtained in such courts, including judgments predicated on the civil liability provisions of U.S. federal securities laws or the securities laws of any state or territory within the United States.

The United States and the Netherlands do not currently have a treaty providing for reciprocal recognition and enforcement of judgments, other than arbitration awards, in civil and commercial matters. Accordingly, a judgment rendered by a court in the United States will not be recognised and enforced by the Dutch courts. However, if a person has obtained a final and conclusive judgment for the payment of money rendered by a court in the United States which is enforceable in the United States and files his claim with the competent Dutch court, the Dutch court will generally give binding effect to such foreign judgment insofar as it finds that (i) the jurisdiction of the U.S. court has been based on a ground of jurisdiction that is generally acceptable according to international standards, (ii) the judgment by the U.S. court was rendered in legal proceedings that comply with the standards of the proper administration of justice that includes sufficient safeguards (*behoorlijke rechtspleging*) and (iii) the judgment by the U.S. court is not incompatible with a decision rendered between the same parties by a Dutch court, or with a previous decision rendered between the same parties by a foreign court in a dispute that concerns the same subject and is based on the same cause, provided that the previous decision qualifies for acknowledgement in the Netherlands and except to the extent that the foreign judgment contravenes Dutch public policy (*openbare orde*).

2.7 Market data and other information from third parties

The information in this Registration Document that has been sourced from third parties has been accurately reproduced and, as far as Kiadis is aware and able to ascertain from the information published by that third party, no facts have been omitted that would render the reproduced information inaccurate or misleading. Industry publications generally state that their information is obtained from sources they believe reliable but that the accuracy and completeness of such information is not guaranteed and that the projections they contain are based on a number of significant assumptions. Although Kiadis believes these sources to be reliable, as Kiadis does not have access to the information, methodology and other bases for such information, Kiadis has not independently verified the information. Kiadis is not aware of any exhaustive industry or market reports that cover or address its specific markets.

In this Registration Document, Kiadis makes certain statements regarding the markets and the competitive position in the sectors and geographies in which Kiadis competes. Kiadis believes these statements to be true based on market data and industry statistics which are in the public domain, but has not independently verified the information.

2.8 Forward-looking statements

This document contains certain statements that are or may be forward-looking statements with respect to Kiadis' financial condition, results of operations and/or business achievements, including, without limitation, statements containing the words "believe", "anticipate", "expect", "estimate", "may", "could", "should", "would", "will", "intend" and similar expressions. Such forward-looking statements involve unknown risks, uncertainties and other factors which may cause Kiadis' actual results, financial condition, performance or achievements, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed described in Chapter 1 (Risk Factors). Given these uncertainties, prospective investors are cautioned not to place any undue reliance on such forward-looking statements. Kiadis disclaims any obligation to update any such forward-looking statements in this Registration Document to reflect future events or developments.

2.9 References to defined terms and incorporation of terms

Certain terms used in this Registration Document, including capitalised terms and certain technical and other terms are explained in Chapter 14 (Definitions and Glossary).

3 Dividend Policy

3.1 Dividend history

The Company has never declared or paid any dividends on its Shares.

3.2 Dividend policy

The Company expects to retain all earnings, if any, generated by Kiadis' operations for the development and growth of its business and does not anticipate paying any dividends to the Shareholders in the near future. Also, pursuant to the facility agreement that Kiadis entered into with Kreos Capital on 17 August 2017 (the "**Kreos Capital Facility Agreement**"), as long as any of the loans provided by Kreos Capital remains outstanding, the Company is not entitled to make any dividend or other distributions to Shareholders (see also paragraph 5.7 below).

The Company's reserves and dividends policy will be reviewed from time to time and distribution of any dividends will be based upon a proposal thereto by the Management Board after taking into account Kiadis' earnings, cash flow, financial condition, capital investment requirements and other factors considered important by the Management Board.

4 Selected Consolidated Historical Financial Information

The selected consolidated financial information set forth below should be read in conjunction with paragraph 2.3 above, Chapter 5 (Operating and Financial Review) the audited consolidated financial statements and notes thereto for the financial years ended 31 December 2016, 2015 and 2014 (relating to Kiadis Pharma B.V.) and the unaudited consolidated interim financial statements and the notes thereto for the six-month period ended 30 June 2017 incorporated by reference in this Registration Document, and the unaudited consolidated interim financial statements and the notes thereto for the nine-month period ended 30 September 2017 included in this Registration Document beginning on page F-1.

The selected consolidated financial information has been extracted from the audited consolidated financial statements and notes thereto for the financial years ended 31 December 2016, 2015 and 2014 (in the tables in this Chapter 4 marked "Audited") and the unaudited consolidated interim financial statements and the notes thereto for the six-month period ended 30 June 2017 and the nine-month period ending 30 September 2017 (in the tables in this Chapter 4 marked "Unaudited").

The financial statements and interim financial statements from which the selected consolidated financial information set forth below has been derived, were prepared in accordance with IFRS as adopted by the European Union. The unaudited consolidated interim financial information has been stated on a basis consistent with the audited Financial Statements and should be read in conjunction with the Company's audited consolidated financial statements and notes thereto for the financial year ended 31 December 2016.

4.1 Selected consolidated balance sheet data

(in € thousands)	As of 31 December		
	2016	**2015**	**2014**
	Audited		
ASSETS			
Property, plant and equipment	536	333	413
Intangible assets	13,540	12,714	13,687
Total non-current assets	**14,076**	**13,047**	**14,100**
Trade and other receivables	230	145	196
Deferred expenses	351	418	242
Cash and cash equivalents	14,559	28,666	5,674
Total current assets	**15,140**	**29,229**	**6,112**
Total assets	**29,216**	**42,276**	**20,212**
EQUITY			
Share capital	1,397	1,347	10,567
Share premium	103,200	98,137	57,243
Translation reserve	307	271	317
Warrant reserve	-	-	2,580
Accumulated deficit	(95,463)	(74,105)	(68,042)
Equity attributable to owners of the Company	**9,441**	**25,650**	**2,665**
LIABILITIES			
Loans and borrowings	15,605	13,713	5,090
Derivatives & employee benefits	-	-	3,730
Total non-current liabilities	**15,605**	**13,713**	**8,820**

Loans and borrowings	1,555	1,166	7,129
Trade and other payables	2,615	1,747	1,598
Total current liabilities	**4,170**	**2,913**	**8,727**
Total liabilities	**19,775**	**16,626**	**17,547**
Total equity and liabilities	**29,216**	**42,276**	**20,212**

(in € thousands)	**As of 30 September 2017**	**As of 30 June 2017**	**As of 31 December 2016**
	Unaudited	Unaudited	Audited
ASSETS			
Property, plant and equipment	467	493	536
Intangible assets	13,134	13,017	13,540
Total non-current assets	**13,601**	**13,510**	**14,076**
Trade and other receivables	243	168	230
Deferred expenses	397	385	351
Cash and cash equivalents	13,215	10,733	14,559
Total current assets	**13,855**	**11,286**	**15,140**
Total assets	**27,456**	**24,796**	**29,216**
EQUITY			
Share capital	1,504	1,471	1,397
Share premium	108,405	105,212	103,200
Translation reserve	294	295	307
Warrant reserve	1,274	167	-
Accumulated deficit	(107,874)	(103,621)	(95,463)
Equity attributable to owners of the Company	**3,603**	**3,524**	**9,441**
LIABILITIES			
Loans and borrowings	18,081	14,636	15,605
Derivatives & employee benefits	2,033	2,023	-
Total non-current liabilities	**20,114**	**16,659**	**15,605**
Loans and borrowings	1,280	1,682	1,555
Trade and other payables	2,459	2,931	2,615
Total current liabilities	**3,739**	**4,613**	**4,170**
Total liabilities	**23,853**	**21,272**	**19,775**
Total equity and liabilities	**27,456**	**24,796**	**29,216**

4.2 Selected consolidated income statement data

(in € thousands)	**Year ended 31 December**		
	2016	**2015**	**2014**
	Audited		
Revenues	**-**	**-**	**-**
Other income	**-**	**-**	**-**
Research and development expenses	(8,206)	(7,715)	(4,692)
General and administrative expenses	(3,202)	(8,292)	(1,476)
Total operating expenses	**(11,408)**	**(16,007)**	**(6,168)**
Operating loss	**(11,408)**	**(16,007)**	**(6,168)**
Interest income	13	50	28
Interest expenses	(1,571)	(1,394)	(1,073)
Other net finance (expenses) income	(1,827)	894	(598)
Net finance expenses	**(3,385)**	**(450)**	**(1,643)**
Loss before tax	(14,793)	(16,457)	(7,811)
Income tax expenses	(1)	(1)	(2)
Loss for the period	**(14,794)**	**(16,458)**	**(7,813)**

(in € thousands)	Nine months ended 30 September		Six months ended 30 June	
	2017	**2016**	**2017**	**2016**
	Unaudited		Unaudited	
Revenues	-	-	-	**-**
Other income	-	-	-	**-**
Research and development expenses	(8,096)	(5,647)	(5,882)	(3,803)
General and administrative expenses	(3,607)	(2,172)	(2,276)	(1,252)
Total operating expenses	**(11,703)**	**(7,819)**	**(8,158)**	**(5,055)**
Operating loss	**(11,703)**	**(7,819)**	**(8,158)**	**(5,055)**
Interest income	-	29	-	25
Interest expenses	(1,439)	(1,167)	(880)	(754)
Other net finance (expenses) income	260	(936)	516	(662)
Net finance expenses	**(1,179)**	**(2,074)**	**(364)**	**(1,392)**
Loss before tax	(12,882)	(9,893)	(8,522)	(6,446)
Income tax expenses	-	-	-	-
Loss for the period	**(12,882)**	**(9,893)**	**(8,522)**	**(6,446)**

4.3 Selected consolidated cash flow data

(in € thousands)	Year ended 31 December		
	2016	**2015**	**2014**
	Audited		
Net cash used in operating activities	(14,311)	(8,096)	(6,075)
Net cash used in investing activities	(242)	(55)	(231)
Net cash from financing activities	426	31,165	5,490
Net cash flow	**(14,127)**	**23,014**	**(816)**
Cash and cash equivalents at beginning of period	**28,666**	**5,674**	**6,482**
Effect of exchange rate fluctuations on cash held	20	(22)	8
Cash and cash equivalents at end of period	**14,559**	**28,666**	**5,674**

(in € thousands)	Nine months ended 30 September		Six months ended 30 June	
	2017	**2016**	**2017**	**2016**
	Unaudited		Unaudited	
Net cash used in operating activities	(11,517)	(11,494)	(7,560)	(5,258)
Net cash used in investing activities	(45)	(134)	(30)	(56)
Net cash from financing activities	10,229	718	3,778	331
Net (decrease) increase in cash and cash equivalents	**(1,333)**	**(10,910)**	**(3,812)**	**(4,983)**
Cash and cash equivalents at beginning of period	**14,559**	**28,666**	**14,559**	**28,666**
Effect of exchange rate fluctuations on cash held	(11)	7	(14)	15
Cash and cash equivalents at end of period	**13,215**	**17,763**	**10,733**	**23,698**

5 Operating and Financial Review

The following discussion and analysis of Kiadis' financial condition and results of operations should be read in conjunction with paragraph 2.3 above, the audited consolidated financial statements and notes thereto for the financial years ended 31 December 2016, 2015 and 2014 (relating to Kiadis Pharma B.V.), and the unaudited consolidated interim financial statements and the notes thereto for the six-month period ended 30 June 2017 incorporated by reference in this Registration Document, the unaudited consolidated interim financial statements and the notes thereto for the nine-month period ended 30 September 2017 included in this Registration Document beginning on page F-1 and the rest of this Registration Document. The unaudited financial information for the interim periods ended 30 June 2017 and 2016 and the audited consolidated financial statements for the years ended 31 December 2016, 2015 and 2014 have been prepared in accordance with IFRS as adopted by the European Union.

This discussion and analysis contains forward-looking statements based on the Company's current expectations and assumptions about Kiadis' future business that are subject to known and unknown risks and uncertainties. Kiadis' actual results and the timing of events could differ materially from those expressed or implied by such forward-looking statements as a result of various factors, including those discussed below and elsewhere in this Registration Document, particularly in Chapter 1 (Risk Factors) and in paragraph 2.8 above.

5.1 Overview

Kiadis is a clinical stage biopharmaceutical company focused on research, development and future commercialisation of cell-based immunotherapy products as an adjunctive treatment for hematopoietic stem cell transplantations (HSCT) in patients suffering from blood cancers and inherited blood disorders. Kiadis believes that it has identified an important and significant unmet need for its innovative products which have the potential to make HSCT safer and more effective, improving patient survival and quality of life.

Kiadis' product candidates for HSCT provide for "Allodepleted T-cell ImmunotheRapeutics" (ATIR). ATIR is a cell-based, personalised immunotherapeutic product manufactured on an individual patient basis. ATIR is a donor-derived T-lymphocyte enriched leukocyte preparation depleted *ex vivo* of host-alloreactive T-cells. Kiadis' product candidates focus on two therapeutic indications:

- ATIR101: Kiadis' lead product candidate, for haploidentical HSCT treatments in blood cancers.

- ATIR201: Kiadis' second product candidate, for haploidentical HSCT for inherited blood disorders, with an initial focus on thalassaemia.

Based on the positive results from its completed single dose Phase II trial with ATIR101 in patients with blood cancer (CR-AIR-007), Kiadis submitted a Marketing Authorisation Application (MAA) to the EMA in April 2017, for approval of ATIR101 across the European Union. In addition, Kiadis has received regulatory approval in various countries to start dosing patients in a Phase III trial with ATIR101 that will be performed across Europe and North America and for which Kiadis enrolled the first patient in December 2017. An additional Phase II clinical trial (CR-AIR-008) is ongoing to test the safety of a second dose of ATIR101. In relation to ATIR201, Kiadis has received approval for the clinical protocol for a Phase I/II trial in beta-thalassaemia (β-thalassaemia) major patients (CR-BD-001) by the national

regulatory authorities of the United Kingdom and Germany. This trial has been postponed. Kiadis has not yet decided when to begin the trial and patients have not yet been enrolled.

Since its inception, Kiadis has not generated any revenues or net cash flows from sales of its products. ATIR101, Kiadis' most advanced product candidate, has not yet been approved for marketing. To date, Kiadis has relied principally on the issuance and sale of equity and debt securities to finance its operations, internal growth and selective acquisitions of businesses, technologies and other assets. In 2014, Kiadis raised €5.1 million in equity and in 2015, it raised, through its IPO, €31.2 million as net proceeds (€34.7 million as gross proceeds) in equity. In 2016, it raised an additional €1.6 million in equity, and in June 2017 a further €4.6 million as net proceeds (€5.0 million as gross proceeds) in equity. In the period from 2009 until 2014, Kiadis received an investment loan (*innovatiekrediet*) in the amount of €4.1 million from the Netherlands Enterprise Agency (*Rijksdienst voor Ondernemend Nederland*) ("**RVO Nederland**"), a division of the Dutch Ministry of Economic Affairs. In 2014, Kiadis received an additional investment loan from RVO Nederland in the amount of €0.9 million to support the clinical development of ATIR101. In August 2017, Kiadis obtained up to €15 million debt financing from Kreos Capital by way of a loan consisting of two tranches, with the first tranche of €10 million immediately drawn down, and which first tranche was partly used to fully repay the investment loans from RVO Nederland (see also paragraph 5.7 below). In September 2017 Kiadis issued shares upon the exercise of warrants and received €2.4 million in cash. In October 2017, Kiadis raised another €16.2 million as net proceeds (€18.0 million as gross proceeds) in equity and it drew down the second tranche of €5 million of the debt financing from Kreos Capital.

Kiadis has incurred significant losses in each year of operations, as it has devoted a significant amount of its resources to clinical development and research. During the years ended 31 December 2014, 2015 and 2016 and the first nine months of 2017, Kiadis incurred aggregate losses of approximately €51.9 million. Kiadis expects to continue to incur substantial operating losses in the future as it continues to develop and seek regulatory approval for its product candidates. Kiadis will not receive any revenues or net cash flows from sales of its product candidates unless they have been approved by the EMA, the FDA or similar regulatory authorities in other countries and commercialised successfully, which Kiadis does not expect to be before 2019, if at all.

5.2 Material factors affecting results of operations and financial condition

Kiadis believes that the following factors have had and will continue to have a material effect on its results of operations and financial condition.

5.2.1 Revenues and other income

Kiadis did not record any revenues during the period covered by the historical financial information included in this Registration Document.

5.2.2 Research and development expenses

Kiadis is focused on the clinical development of its lead product candidate ATIR101. To date, Kiadis has devoted substantially all of its resources to research and development efforts relating to its product candidates. It anticipates that research and development expenses will continue to increase as it advances the clinical development of ATIR101 and ATIR201 and potentially adds new programs.

Kiadis believes that as its programs advance, research and development expenses may be expected to comprise the following:

- the costs of conducting and managing its sponsored clinical trials, including clinical investigator cost, payments of patient expenses and costs, and payments to CROs assisting with Kiadis' clinical development programs;
- salary and benefit costs allocated to research and development employees;
- regulatory activities, including testing and collecting data, preparing and submitting filings, communicating with regulatory authorities and reviewing the design and conduct of clinical trials for compliance with applicable requirements;
- depreciation of laboratory and other equipment;
- payments of costs in connection with physician-initiated clinical trials and evaluations;
- payments to suppliers of active pharmaceutical ingredients and manufacturers of the products used in Kiadis' clinical trials and research and development activities;
- licence costs; and
- costs of preclinical studies, including toxicology studies.

Clinical development timelines and associated costs may vary significantly depending on how Kiadis chooses to allocate the expenditures among its clinical and product discovery programs. Kiadis expects research and development expenses to continue to increase for the foreseeable future as it seeks to complete the development of and achieve regulatory approval for its product candidates ATIR101 and ATIR201. Kiadis is currently focused on advancing its product candidates through clinical trials, including with an international Phase III trial for ATIR101 for which Kiadis recently received regulatory approval in various countries. See also paragraph 7.7 below for further information.

Kiadis anticipates, however, that it will make further decisions on the continued development and funding of existing and future clinical programs in response to the scientific and clinical success of its product candidates in clinical development, as well as an ongoing assessment of market opportunities. Kiadis also anticipates that research and development expenses will increase in future periods if it proceeds to dose additional patients in its ATIR101 Phase III clinical trial. There is a risk that any clinical development or product discovery program may not result in marketing approval. To the extent that Kiadis fails to obtain approval to market any of its product candidates in a timely manner and have to continue clinical trials over a longer period of time, its research and development expenses may further increase. Kiadis cannot assure that it will be able to successfully develop and commercialise any of its products in development, if approved for marketing, due to risks and uncertainties including those factors described in Chapter 1 (Risk Factors).

5.2.3 Selling and distribution expenses

Historically, Kiadis has not incurred any selling and distribution expense. If any of its products were to be approved for marketing, Kiadis may incur substantial selling and distribution

expenses in future periods, in order to establish an infrastructure for independent marketing, direct sales and distribution to specialised transplantation centres, obtain supplies of active pharmaceutical ingredients and manufacture commercial quantities of Kiadis' products. Kiadis would also be subject to certain milestone and royalty payment obligations if its products were to be approved for marketing and successfully commercialised. See paragraph 7.18 below.

5.2.4 General and administrative expenses

Kiadis anticipates that its general and administrative expenses will increase as it seeks to further expand its business. Kiadis expects that as it advances its programs and prepares for the commercialisation of its products in development, if approved for marketing, general and administrative expenses will continue to comprise the following:

- employee benefits, including salaries, pensions, profit-sharing plans, share-based compensation expenses, and bonus plans and other related costs for employees in executive and operational functions;
- advisers' fees, including accounting, legal, intellectual property and consulting services; and
- rental expenses, facilities expenses and other general expenses relating to the operations.

Kiadis has adopted an employee share option plan and an employee stock appreciation rights plan under which key management personnel and employees may be granted share options and/or stock appreciation rights. The fair value of these instruments will be recognised as an employee expense. These employee compensation expenses may contribute to the increase in Kiadis' general and administrative expenses.

Kiadis also anticipates that the continuing development of its business, the establishment of an investor relations program and the expense of maintaining directors' and officers' liability insurance, will contribute to the expected future increase in general and administrative expenses.

5.3 Consolidated income statement

The following discussion and analysis of Kiadis' results of operations and financial condition is based on its historical results.

The following table sets forth the consolidated income statement for the periods indicated:

	Nine months ended 30 September		**Year ended 31 December**		
(in € thousands)	**2017**	**2016**	**2016**	**2015**	**2014**
	Unaudited		Audited		
Revenues			**-**	**-**	**-**
Other income			**-**	**-**	**-**
Research and development expenses	(8,096)	(5,647)	(8,206)	(7,715)	(4,692)
General and administrative expenses	(3,607)	(2,172)	(3,202)	(8,292)	(1,476)

Total operating expenses	**(11,703)**	**(7,819)**	**(11,408)**	**(16,007)**	**(6,168)**
Operating loss	**(11,703)**	**(7,819)**	**(11,408)**	**(16,007)**	**(6,168)**
Interest income		29	13	50	28
Interest expenses	(1,439)	(1,167)	(1,571)	(1,394)	(1,073)
Other net finance (expenses) income	260	(936)	(1,827)	894	(598)
Net finance expenses	**(1,179)**	**(2,074)**	**(3,385)**	**(450)**	**(1,643)**
Loss before tax	(12,882)	(9,893)	(14,793)	(16,457)	(7,811)
Income tax expenses	-	-	(1)	(1)	(2)
Loss for the period	**(12,882)**	**(9,893)**	**(14,794)**	**(16,458)**	**(7,813)**

5.3.1 Comparison of the nine months ended 30 September 2017 and 2016

Revenues

During the entire period covered by the historical financial information included in this Registration Document, no revenues have been generated.

Other income

During the entire period covered by the historical financial information included in this Registration Document, no other income has been generated.

Research and development expenses

Research and development expenses for the nine months ended 30 September 2017 increased to €8.1 million from €5.6 million for the nine months ended 30 September 2016. This increase is mainly due due to the expansion of the work force in Kiadis' research and development departments and start-up costs for the Phase III clinical trial with ATIR101, and higher consultancy expenses mainly for the Marketing Authorisation Application submission.

General and administrative expenses

General and administrative expenses increased from €2.2 million for the nine months ended 30 September 2016 to €3.6 million for the nine months ended 30 September 2017. This increase was primarily due to higher consultancy expenses related to funding activities, severance pay to Kiadis' former CEO, and increased share-based payments as a result of share options and stock appreciation rights granted to employees and management in 2017.

Results from operating activities

As a result of the above factors, operating loss increased from €7.8 million for the nine months ended 30 September 2016 to €11.7 million for the nine months ended 30 September 2017, an increase of 50%.

Net finance expenses

Net finance expenses came in at €1.2 million for the nine months ended 30 September 2017 compared to net finance expenses of €2.1 million for the nine months ended 30 September 2016. This was primarily due to a loss of €1.5 million from adjusting the carrying value of Kiadis' obligations under the Hospira Termination and Royalty Agreement that are regarded as a loan (see paragraph 5.7 below) in the first nine months of 2016 compared to a loss of

€0.3 million from adjusting the carrying value of this loan for the nine months ended 30 September 2017.

Profit (loss) for the period

As a result of the above factors, the loss for the period increased from €9.9 million for the nine months ended 30 September 2016 to €12.9 million for the nine months ended 30 September 2017, an increase of 30%.

5.3.2 Comparison of years ended 31 December 2016 and 2015

Revenues

During the entire period covered by the historical financial information included in this Registration Document, no revenues have been generated.

Other income

During the entire period covered by the historical financial information included in this Registration Document, no other income has been generated.

Research and development expenses

Research and development expenses increased from €7.7 million for the year ended 31 December 2015 to €8.2 million for the year ended 31 December 2016, an increase of 6%. Research and development expenses represented 72% of Kiadis' total operating expenses for the year ended 31 December 2016, compared to 48% for the year ended 31 December 2015.

The above comparisons are distorted by the costs related to share-based payments allocated to personnel in the research and development departments incurred in 2015. Excluding these share-based payments, research and development expenses increased from €5.5 million for the year ended 31 December 2015 to €8.2 million for the year ended 31 December 2016, an increase of approximately 50%. This increase was primarily attributable to the expansion of the workforce in research and development departments to accommodate the required increase in development activities and costs related to procuring a new North American manufacturer for the ATIR101 Phase III clinical trial. Research and development expenses excluding share-based payments represented 75% of Kiadis' total operating expenses for the year ended 31 December 2016, compared to 67% for the year ended 31 December 2015.

General and administrative expenses

General and administrative expenses decreased from €8.3 million for the year ended 31 December 2015 to €3.2 million for the year ended 31 December 2016, a decrease of 61%, excluding share-based payments.

The above comparison is distorted by the costs related to share-based payments allocated to staff and management incurred in 2015 and 2016. Excluding these share-based payments, general and administrative expenses increased due to increased activity-levels, from €2.7 million for the year ended 31 December 2015 to €2.8 million for the year ended 31 December

2016, an increase of 1%.

Results from operating activities

As a result of the above factors, operating loss decreased from €16.0 million for the year ended 31 December 2015 to €11.4 million for the year ended 31 December 2016, a decrease of 29%.

Net finance expenses

Net finance expenses increased from €0.5 million for the year ended 31 December 2015 to €3.4 million for the year ended 31 December 2016, an increase of 652%. This increase was mainly attributable to an extinguishment gain of €4.6 million related to previously issued warrants recorded in 2015 partially offset by net foreign exchange rate losses of €1.5 million in 2015. The foreign exchange rate losses were mainly driven by €0.8 million of unrealized Canadian dollar/euro exchange loss on intra-group loans and €0.5 million of unrealized U.S. Dollar/euro exchange rate loss on the loan from Hospira Inc.

Profit (loss) for the period

As a result of the above factors, Kiadis' loss for the period decreased from €16.5 million for the year ended 31 December 2015 to €14.8 million for the year ended 31 December 2016, a decrease of 11%.

5.3.3 Comparison of years ended 31 December 2015 and 2014

Revenues

During the entire period covered by the historical financial information included in this Registration Document, no revenues have been generated.

Other income

During the entire period covered by the historical financial information included in this Registration Document, no other income has been generated.

Research and development expenses

Research and development expenses increased from €4.7 million for the year ended 31 December 2014 to €7.7 million for the year ended 31 December 2015, an increase of 64%. Research and development expenses represented 48% of Kiadis' total operating expenses for the year ended 31 December 2015, compared to 76% for the year ended 31 December 2014.

The above comparisons are distorted by the costs related to share-based payments allocated to personnel in the research and development departments incurred in 2015. Excluding these share-based payments, research and development expenses increased from €4.7 million for the year ended 31 December 2014 to €5.5 million for the year ended 31 December 2015, an increase of 17%. This increase was primarily attributable to the expansion of the workforce in research and development departments due to increased activity-levels and higher expenses related to the Phase II trial with ATIR101 than in the prior year as a result of a higher number of patients treated in the CR-AIR-007 trial in 2015 and

patients treated in the CR-AIR-008 trial that started in 2015. Research and development expenses represented 67% of Kiadis' total operating expenses for the year ended 31 December 2015, compared to 76% for the year ended 31 December 2014.

General and administrative expenses

General and administrative expenses increased from €1.5 million for the year ended 31 December 2014 to €8.3 million for the year ended 31 December 2015, an increase of 462%.

The above comparison is distorted by the costs related to share-based payments allocated to staff and management incurred in 2015. Excluding these share-based payments, general and administrative expenses increased from €1.5 million for the year ended 31 December 2014 to €2.7 million for the year ended 31 December 2015, an increase of 84%. This increase was primarily attributable to the costs incurred in relation to Kiadis' IPO in 2015.

Results from operating activities

As a result of the above factors, operating loss from operating activities increased from €6.2 million for the year ended 31 December 2014 to €16.0 million for the year ended 31 December 2015.

Net finance expenses

Net finance expenses decreased from €1.6 million for the year ended 31 December 2014 to €0.5 million for the year ended 31 December 2015, a decrease of 73%. This decrease was attributable to an extinguishment gain on previously issued warrants of €4.6 million recorded in 2015. This positive effect was offset by a loan restatement of €1.8 million and net exchange rate losses of €1.5 million in 2015.

Profit (loss) for the period

As a result of the above factors, the loss for the period increased from a level of €7.8 million for the year ended 31 December 2014 to €16.5 million for the year ended 31 December 2015, an increase of 111%.

5.4 Significant change in Kiadis' financial or trading position since 30 September 2017

In October 2017, Kiadis raised €16.2 million as net proceeds (€18.0 million as gross proceeds) in equity and it drew down the second tranche of €5 million of the debt financing from Kreos Capital. In the context of this draw down, 42,269 warrants were issued to Kreos Capital V (Expert Fund) LP ("**Kreos Expert**"). See also paragraphs 5.5 and 10.3.2 below.

5.5 Liquidity and capital resources

Kiadis has incurred aggregate losses of approximately €39.1 million during the years ended 31 December 2016, 2015 and 2014. Kiadis will not receive any revenues or net cash flows from sales of its products until they have been approved by regulatory authorities and commercialised successfully. Kiadis does not anticipate commercialising any of its product candidates before 2019, if at all.

Since its inception, Kiadis has not generated any revenues or net cash flows from sales of its

products. ATIR101, Kiadis' most advanced product candidate, has not yet been approved for marketing. To date, Kiadis has relied principally on the issuance and sale of equity and debt securities to finance its operations, internal growth and selective acquisitions of businesses, technologies and other assets. In 2014, Kiadis raised €5.1 million in equity and in 2015 it raised, through its IPO, €31.2 million as net proceeds (€34.7 million as gross proceeds) in equity. In 2016, it raised an additional €1.6 million in equity. In June 2017 Kiadis raised a further €4.6 million as net proceeds (€5.0 million as gross proceeds) in equity, and in September 2017 Kiadis issued shares upon the exercise of warrants and received €2.4 million in cash. In October 2017 Kiadis raised another €16.2 million as net proceeds (€18.0 million as gross proceeds) in equity. In the period from 2009 until 2012, Kiadis received an investment loan (*innovatiekrediet*) in the amount of €2.8 million from RVO Nederland. In 2013 and 2014, Kiadis received an additional investment loan from RVO Nederland in the amount of €2.2 million to support the clinical development of ATIR101. In August 2017, Kiadis obtained a debt facility of up to €15 million from Kreos Capital. The first tranche of €10 million of this facility was drawn down in August 2017 and the second tranche of €5 million in October 2017.

As of 30 September 2017, Kiadis had cash and cash equivalents of approximately €13 million, and at the Registration Document Date it had cash and cash equivalents of approximately €27 million. Based on its operating plans, Kiadis believes that it will be able to meet its financing needs until February 2019. Based on its present requirements, Kiadis believes its operations will require cash resources of approximately €29 million to provide it with sufficient working capital for the next twelve months following the Registration Document Date and that the current working capital shortfall amounts to approximately €2 million. Kiadis may require additional capital resources due to significant uncertainty associated with and time required to complete the clinical trials. However, it may also need to raise additional funds more quickly if Kiadis chooses to expand its development activities or if it considers acquisitions. Factors that could influence Kiadis' future capital requirements and the timing thereof include:

- the progress and cost of Kiadis' clinical trials, including payments of patient cost, clinical investigator cost and payments to CROs that are assisting with its sponsored clinical trials, and other research and development activities;
- the cost and timing of obtaining regulatory approval to commence further clinical trials;
- the costs associated with physician-initiated clinical trials;
- the cost of filing, prosecuting, defending and enforcing any patent applications, claims, patents and other intellectual property rights;
- the cost and timing of securing active pharmaceutical ingredients from suppliers;
- the cost and timing of establishing production capacities and obtaining sufficient quantities of Kiadis' products for clinical trials;
- the costs associated with process optimisations;
- the repayment obligations under the Kreos Capital Facility Agreement and the loan provided by the University of Montreal (see paragraph 5.7);

- the royalty and milestone obligations to Hospira, Inc. ("**Hospira**") and the University of Montreal (see paragraph 7.18 below);
- the terms and timing of any collaborative, licensing and other arrangements that Kiadis may establish;
- the cost of acquiring or licensing additional products, if any;
- the amount and timing of further investments in preclinical research, if any; and
- the cost of preparing for launch and commercialisation of its product candidates.

Kiadis may raise additional capital through public or private equity offerings, debt financings, convertible loans, warrants, collaborations or other means. It may consider raising additional capital to take advantage of favourable market conditions or other strategic considerations even if Kiadis has sufficient funds for planned operations.

To the extent that Kiadis raises additional funds by issuance and sale of equity or equity linked securities, Shareholders will experience dilution. Debt financings, if available, may subject Kiadis to financial and other restrictive covenants that limit Kiadis' ability to engage in activities that it may believe to be in its long-term best interests. Additional financing may not be available on acceptable terms, if at all. Capital may become difficult or impossible to obtain due to poor market or other conditions outside of Kiadis' control.

5.6 Capital expenditures and principal investments

The following table sets forth Kiadis' capital expenditures for the years ended 31 December 2016, 2015 and 2014, as well as the nine-month periods ended 30 June 2017 and 2016.

	Nine months ended 30 September		**Year ended 31 December**		
(in € thousands)	**2017**	**2016**	**2016**	**2015**	**2014**
	Unaudited		Audited		
Laboratory equipment	6	166	250	38	250
Other tangible assets	47	19	103	22	9
Capital expenditure	53	185	**353**	**60**	**259**

The principal investments in the period covered by the historical financial information included in this Registration Document are primarily related to investments in the Netherlands for laboratory equipment, office equipment and information technology. Other tangible assets (2016:103k) are IT equipment and furniture & fittings (2016: €65k) and leasehold improvements (2016: €38k) There have not been significant investments in the period from 30 September 2017 up to the Registration Document Date.

Based on its current operations, Kiadis expects that its future capital expenditures will relate primarily to further investments in the Netherlands for manufacturing facilities and equipment, laboratory equipment, office equipment and information technology. No firm commitments in relation to such investments have been made.

5.7 Indebtedness

RVO Nederland

In the period 2009 through 2011 Kiadis obtained investment loans for the development of ATIR granted by RVO Nederland. As per 30 June 2017, a total amount of €5.3 million was recorded as a loan from RVO Nederland. This amount, including accrued interest, consisted of two parts: a €3.3 million loan, bearing interest of 11.4% per annum, and a €2.0 million loan, bearing interest of 10.0% per annum. Kiadis has repaid these two loans in full in August 2017, by using €5.3 million of the €10 million loan received from Kreos Capital, being the first tranche of the debt facility Kiadis entered into with Kreos Capital – see below in this paragraph.

Kreos Capital Facility Agreement

On 17 August 2017, Kiadis entered into a debt facility of up to €15 million with Kreos Capital (the "**Kreos Capital Facility Agreemen**t").

The Kreos Capital Facility Agreement regards a loan consisting of two tranches. The first tranche of €10 million – Tranche A – was drawn down immediately after execution of the Kreos Capital Facility Agreement. Of the €10 million received, Kiadis used €5.3 million to fully repay the loans from RVO Nederland. The second tranche of up to €5 million – Tranche B – was conditional upon Kiadis raising at least €20 million of additional funds before 1 July 2018. It was drawn down in October 2017, following the October 2017 equity raise (see paragraph 5.5).

Tranche A has a 45-month term from draw down and an implied 10% annual fixed interest rate. Interest payments are to be made during the first 9 months, with the remaining 36 months amortising in equal monthly instalments comprising principal and interest. Tranche B has a 48-month term from draw down and an implied 10% annual fixed interest rate. Interest payments are to be made during the first 12 months, with the remaining 36 months amortising in equal monthly instalments comprising principal and interest. In relation to both tranches, an end of loan payment equal to 5% of the amount drawn down is due.

Kiadis' obligations under the Kreos Capital Facility Agreement are secured for the benefit of Kreos Capital by means security rights over Kiadis' assets, including its intellectual property, through a first ranking Dutch law governed pledge of receivables, movable assets and intellectual property rights, and a movable hypothec on movable property including receivables, movable assets and intellectual property rights governed by the laws of Quebec, Canada.

The Kreos Capital Facility Agreement also includes customary undertakings and restrictions. These include a negative pledge undertaking, a restriction on the disposals of assets outside of the ordinary course of business, a restriction on attracting further borrowings and debt except for certain categories of permitted indebtedness such as fully subordinated and unsecured debt, a working capital facility at terms reasonably approved by Kreos Capital, operational leases and financial leases up to a certain threshold amount, a restriction on entering into joint ventures, mergers and similar transactions and restructurings, an undertaking to continue the business in the ordinary course of business, a restriction on the granting of guarantees in respect of the obligation of any person, a restriction to make a substantial change to the general nature or scope of Kiadis' current business and an undertaking to maintain adequate risk protection through insurances. Also, as long as any of

the loans under the Kreos Capital Facility Agreement remains outstanding, the Company is not entitled to make any dividend payments or other distributions to Shareholders.

The loans provided under the Kreos Capital Facility Agreement shall become immediately due and payable in the event that a person or group of persons acting in concert gains direct or indirect control over Kiadis, by (a) obtaining the power to (i) to cast or control the casting of more than half the votes that can be cast at a General Meeting, (ii) appoint or remove all or the majority of the directors, or (iii) give binding directions with respect to Kiadis' operating and financial policies, or (b) beneficially holding more than 50% of the Company's issued share capital.

In connection with the Kreos Capital Facility Agreement, 253,617 warrants have been issued to Kreos Expert, of which 211,348 were issued at closing of the debt facility in August 2017, and 42,269 were issued following the drawdown of Tranche B in October 2017. On the warrants issued to Kreos Expert, see also paragraph 10.3.2.

Hospira

In December 2010, Kiadis entered into a licence agreement with Hospira, to develop and commercialise ATIR in certain territories (the "**Hospira Licence Agreement**"). This agreement was terminated as of January 2012, when Hospira and Kiadis agreed to terminate both the exclusive licence Kiadis had granted to Hospira related to products derived from the Theralux platform, and Hospira's obligations with respect to such products (the "**Hospira Termination and Royalty Agreement**"). Notwithstanding termination, pursuant to the Hospira Termination and Royalty Agreement Kiadis has agreed to make payments to Hospira as follows:

(a) a milestone payment of US$ 3 million upon the earlier of (i) the execution of a sub-licence on the Theralux platform, or (ii) the first commercial sale of a product derived from the Theralux platform by Kiadis; and

(b) a 5% royalty on worldwide net-sales of products derived from the Theralux platform until a threshold-amount has been paid, after which a 3% royalty on net sales of products derived from the Theralux platform in all countries except those in North America, South America, China, Mongolia, Tibet, Hong Kong, Macau and Antarctica applies. This threshold amount as at 30 September 2017 is US$ 26.7 million plus 1.5% interest compounded annually, which is reduced by US$ 3 million, in the event the potential milestone referred to in (a) above has been paid.

Kiadis' obligations under the Hospira Termination and Royalty Agreement with regard to the threshold amount have been judged as a loan. After initial recognition at fair value, the carrying amount of the loan is restated at each reporting date, should there have been a change in the (estimated) underlying cash flows. In the statement of financial position as of 30 September 2017, the carrying amount of the loan is €10.2 million. The 3% royalty obligations for ATIR as mentioned above are not presented in the statement of financial position.

University of Montreal

Kiadis has been granted a loan from the University of Montreal. As of 30 September 2017, an amount of €0.8 million is recorded as loan, including accrued interest. The loan bears

interest of 3.5% per annum, to be added to the loan. The repayment schedule of the loan is as follows: (i) 50% of the loan upon the execution of a sublicence on a product based on the Theralux platform provided (a) that the sublicence includes an upfront fee and (b) that the granting of an option to a sublicence will not trigger the repayment obligation, or (ii) 100% of the loan in the case of a trade sale of Kiadis, or (iii) the future royalty on worldwide net sales of a product based on the Theralux platform, as part of the current licensing contract with the University of Montreal, will increase by 2.5%, on top of the current 5% licence fee, until the loan has been repaid. In case the above mentioned repayment schedule will not result in repayment in full, Kiadis is still obliged to make repayments in full.

5.8 Cash flows

The following table summarises the principal components of Kiadis' consolidated cash flows for the periods indicated;

	Nine months ended 30 September		Year ended 31 December		
(in € thousands)	**2017**	**2016**	**2016**	**2015**	**2014**
	Unaudited		Audited		
Net cash used in operating activities	(11,517)	(11,494)	(14,311)	(8,096)	(6,075)
Net cash used in investing activities	(45)	(134)	(242)	(55)	(231)
Net cash from financing activities	10,229	718	426	31,165	5,490
Net (decrease) increase in cash and cash equivalents	(1,333)	(10,910)	**(14,127)**	**23,014**	**(816)**
Cash and cash equivalents at beginning of period	14,559	28,666	**28,666**	**5,674**	**6,482**
Effect of exchange rate fluctuations on cash held	(11)	7	20	(22)	8
Cash and cash equivalents at end of period	13,215	17,763	**14,559**	**28,666**	**5,674**

5.8.1 Net cash used in operating activities

Net cash used in operating activities reflects Kiadis' results for the period adjusted for, among other things, depreciation, unrealised foreign exchange results, share-based payments, changes in working capital and interest accruals and payments.

Net cash used in operating activities was €11.5 million for the nine months ended 30 September 2017, compared to €11.5 million for the nine months ended 30 September 2016.

Net cash used in operating activities was €14.3 million for the year ended 31 December 2016, an increase of €6.2 million compared to €8.1 million for the year ended 31 December 2015, primarily reflecting the increase in operating losses.

Net cash used in operating activities of €8.1 million for the year ended 31 December 2015 was €2.0 million higher compared to €6.1 million for the year ended 31 December 2014. This increase primarily reflects the increase in operating losses.

5.8.2 Net cash used in investing activities

Net cash from (or used in) investing activities reflects, among other things, proceeds or expenses related to capital expenditures, divestments and interest received.

Net cash used in investing activities for the nine months ended 30 September 2017 was €45 thousand compared to €134 thousand for the nine months ended 30 September 2016, mainly due to lower capital expenditures related to laboratory equipment.

Net cash used in investing activities was €242 thousand for the year ended 31 December 2016, compared to €55 thousand for the year ended 31 December 2015, an increase of €187 thousand, primarily as a result of higher purchases of laboratory equipment.

Net cash used in investing activities of €55 thousand for the year ended 31 December 2015 reflects a decrease of €176 thousand compared to €231 thousand for the year ended 31 December 2014, primarily as a result of higher purchases of laboratory equipment in 2014.

5.8.3 Net cash from financing activities

Net cash from (or used in) financing activities reflects proceeds from the issue and sale of share capital, changes in borrowings and changes in lease contracts.

For the nine months ended 30 September 2017, cash from financing activities amounted to €10.2 million compared to cash from financing activities of €0.7 million for the nine months ended 30 September 2016. In the first nine months of 2016, the Company issued new Shares for cash and raised €1.6 million in gross proceeds, and in the first nine months of 2017 the Company issued new Shares for cash and raised €5.0 million in gross proceeds. In the third quarter of 2017, the Company issued new Shares for cash upon the exercise of warrants and raised €2.4 million. In addition, in August 2017 the Company restructured its debt and entered into the Kreos Capital Facility Agreement with Kreos Capital, which regards a loan consisting of two tranches. The first tranche of €10 million – Tranche A – was drawn down immediately after execution of the Kreos Capital Facility Agreement. Of the amount of €10 million received, Kiadis used €5.3 million to fully repay the loans from RVO Nederland. See also paragraph 5.5 above.

Net cash from financing activities was €0.4 million for the year ended 31 December 2016, compared to €31.2 million for the year ended 31 December 2015, when the Company successfully completed the IPO of its Shares. For the year ended 31 December 2014 the net cash from financing activities of €5.5 million was primarily the result of proceeds from the issue of Shares for cash in an amount of €5.1 million.

5.9 Off balance sheet arrangements

As of 30 September 2017, Kiadis did not have any off-balance sheet arrangements other than operating leases of approximately €180 thousand which are summarised in paragraph 5.10 below. In December 2017, Kiadis signed a new lease contract for an existing commercial manufacturing facility in Amsterdam in order to relocate its head offices and laboratories and expand its activities. The lease term is 10 years starting 1 January 2018. Lease payments over this 10-year period total €9.2 million and payments for lease related services amount to €5.1 million.

5.10 Contractual obligations and commercial commitments

The following of the Company's contractual obligations and commercial commitments are expected to have an impact on liquidity and cash flow in future periods:

- its debt obligations under the Kreos Capital Facility Agreement and under the loan from the University of Montreal (see paragraph 5.7 above);
- its obligations under the Hospira Termination and Royalty Agreement (see paragraph 5.7 above); and
- operating lease obligations consisting of a lease contract for manufacturing and office space and a lease contract for laboratory facilities.

In addition to these contractual obligations and commercial commitments described above, Kiadis is subject to certain royalty and milestone payment obligations, which are contingent on its products achieving regulatory approval for marketing or their commercialisation or realising sub-licensing contracts. In particular, Kiadis is committed to pay to the University of Montreal royalties of 5% of revenues to be received by it as a result of the commercialisation of products derived from the Theralux platform, including commercialisation via sub-licensing. For a description of Kiadis' obligations to Hospira under the Hospira Termination and Royalty Agreement, see paragraph 5.7 above.

For a description of Kiadis' contingent liability for milestone payments to the original shareholders of Celmed BioSciences Inc. ("**Celmed**") in relation to Rhitol and NB1011 – two product candidates which Kiadis ceased to further develop in 2008 – and certain security rights that have been vested in relation thereto, see note 22 to the Company's audited consolidated financial statements for the years ended 31 December 2016, 2015 and 2014 incorporated by reference.

For more on these royalty and milestone payments, see also paragraph 7.18 below.

5.11 Critical accounting policies

Kiadis prepares its consolidated financial statements in accordance with IFRS as adopted by the European Union. The preparation of financial statements requires senior management to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities and contingencies as of the date of Kiadis' financial statements, as well as reported amounts of revenues and expenses for the relevant accounting periods. Kiadis 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 carrying values of assets and liabilities and reported amounts of revenues and expenses that are not readily apparent from other sources. Management evaluates these estimates on an ongoing basis.

Kiadis 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. Kiadis 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 Kiadis' 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 Kiadis' reported financial results to changes in conditions and assumptions. Kiadis' actual results may differ materially from these estimates under different assumptions.

5.11.1 Impairment of goodwill, patents and in-process R&D acquired in a business combination

Kiadis 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 Kiadis' strategic plans and long term forecasts. The data necessary for the execution of the impairment tests are based on management's estimates of future cash flows, which require an estimation of 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, estimated future cash flows generally are discounted to their present value using a discount rate that reflects current market assessments of the time value of money and risks specific to the asset. Goodwill and intangibles that are not yet amortised are evaluated at least annually for impairment and written down to their recoverable amount, in the case of impairment. 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.

5.11.2 Income tax expense

Kiadis exercises judgment in determining the extent of realisation of 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 to the valuation allowance could materially impact Kiadis' financial position and results of operations.

On 31 December 2016, the Company had unrecognised deferred tax assets in respect of gross cumulative tax losses of €57.4 million in the Netherlands and €15 million in Canada.

5.11.3 Share-based payments

For equity-settled option plans the accounting treatment is as follows. The estimated grant date fair value of options 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 the options. The amount is recognised as an expense will be adjusted to reflect the latest estimate of the number of options that will vest. At each balance

date, Kiadis will revise its estimates of the number of options which are expected to vest. Kiadis recognises the impact of the revision of original estimates, if any, in the income statement and makes a corresponding adjustment to equity. For cash-settled bonus plans, such as stock appreciation rights plans, the expense and corresponding liability incurred are measured at the fair value of the liability. These cash-settled awards are subsequently re-measured at each reporting date. 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. Kiadis has adopted an employee share option plan and an employee stock appreciation rights plan under which key management personnel and employees may be granted share options and/or stock appreciation rights.

5.11.4 Derivatives

Kiadis exercises judgment in determining the estimated value of derivatives. For derivatives that are level 3 financial liabilities - inputs not based on observable market data -, this means that management has to make assumptions about significant unobservable inputs used to calculate fair values, based on binomial option pricing.

5.11.5 Loans and borrowings

Kiadis exercises judgment in determining which financial liabilities qualify as loans and subsequently exercises judgment in determining the estimated value of these loans. For level 3 financial liabilities, management has to make significant judgments and estimates about future cash flows.

5.11.6 Qualitative disclosure about market risk

As a result of its operating and financing activities, Kiadis is exposed to market risks that may affect its financial position and results of operations. Market risk is the risk that changes in market prices, such as foreign exchange rates, interest rates and equity prices will potentially cause economic losses to Kiadis.

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

5.11.7 Foreign currency risk

Kiadis' functional currency is the euro. It operates via its Dutch entities, but it also conducts business in North America. Kiadis therefore has expenses denominated in Canadian dollars and U.S. dollars in connection with, among other things, its sponsored clinical trials, process development, loans, and the maintenance of its intellectual property portfolio. Kiadis also has intercompany financing between companies within the Kiadis corporate group and has U.S. dollar denominated loans.

Upon preparing consolidated financial statements, Kiadis' euro-denominated consolidated reported financial results can be affected by changes in the relative values of the Canadian dollars and the U.S. dollars 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 Kiadis will be able to effectively manage its currency risk to minimise its impact on its business. Kiadis' 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 Kiadis' business, results of operations or financial condition. Kiadis does not currently engage in any hedging activities to limit its exposure to exchange rate fluctuations.

5.11.8 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 attempts to limit its exposure to credit risk by maintaining its bank accounts and short term deposits with well-established banks.

5.11.9 Liquidity risk

Liquidity risk is the risk that Kiadis will not be able to meet its financial obligations as they fall due. Kiadis' 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 its reputation.

6 Industry

6.1 Haematopoietic Stem Cell Transplantations

Bone marrow transplantation is used for the treatment of diseases of the immune or blood forming system in bone marrow and involves replacing diseased bone marrow with new, healthy bone marrow. Bone marrow transplantations are performed for blood cancers (i.e. leukaemia, lymphoma, Non Hodgkins Lymphoma (NHL) and Multiple Melanoma (MM)), inherited blood disorders (i.e. sickle cell anaemia and thalassaemia) and inherited immune disorders (i.e. Severe Combined Immune Deficiency (SCID)).

Although clinical practice for donor-derived (allogeneic) haematopoietic stem cell transplantations (HSCT), as these bone marrow transplantations are now commonly called, has improved over the years, it is still associated with significant risks and side effects. Newly emerging cell-based immunotherapies, including Kiadis' own product candidates, aim to make HSCT safer and more effective.

The objective of an allogeneic HSCT is to completely restore the blood and immune system of the patient with transplanted cells from a healthy donor. Haematopoietic stem cells can be obtained from bone marrow, peripheral blood or umbilical cord blood, with peripheral blood now being the most common source (*Passweg et al., Bone Marrow Transplantation (2015); 50: 476-482*).

Over the past decades, the use of allogeneic stem cell transplantation has increased significantly, as shown in Figure 6.1 below.

Actual number of HSCT recipients in the U.S. by transplant type

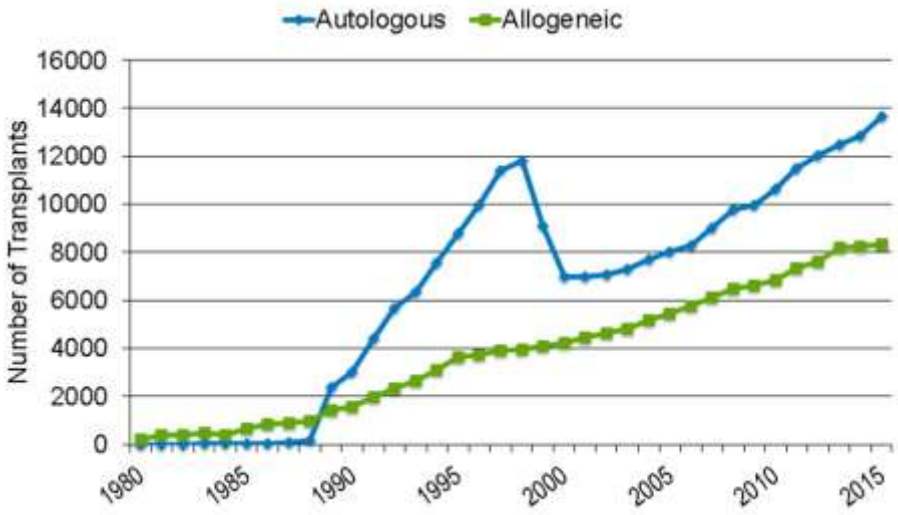


Figure 6.1 - Source: CIBMTR 2016 Summary Slides (*www.cibmtr.org*)

6.2 Indications for HSCT

Of the allogeneic HSCT treatments in Europe, approximately 85% involve patients with blood cancers, such as leukaemia, and myelodysplastic syndromes (MDS), a precursor stage of acute myeloid leukaemia, as shown in Figure 6.2 below. The remainder of the allogenic HSCT treatments target other cancers, or inherited blood disorders, such as thalassaemia,

and immune disorders. The two indications most relevant for Kiadis' product candidates are blood cancers and thalassaemia.

Blood cancers

Blood cancers are malignancies of the bone marrow and blood. The most common are acute myeloid leukaemia (AML), acute lymphoblastic leukaemia (ALL), chronic myeloid leukaemia (CML), chronic lymphocytic leukaemia (CLL) and NHL. First and second line treatments include chemotherapy and immunotherapies, such as monoclonal antibodies. An HSCT is initiated for patients who are at high risk of cancer relapse, who do not respond fully to initial treatment, or who relapse after prior successful treatment. To reduce the risk of cancer relapse, current clinical practice recommends performing HSCT as soon as remission has been reached. An HSCT is generally considered a potentially curative approach in post-remission therapy (*Gratwohl et al., Leukemia (2003); 17: 941-959; Park et al., Blood Res (2015); 50(4):194-203*).

Thalassaemia

Thalassaemia is an inherited blood disorder arising from defects in haemoglobin, which results in improper oxygen transport and the destruction of red blood cells. Patients with β-thalassaemia major typically present with life-threatening anaemia within the first year of life. Other symptoms include jaundice, enlarged organs, misshapen bones and stunted growth. If left untreated, patients will have a life expectancy of no more than three years (*Galanello R., Origa R., Orphanet Journal of Rare Diseases (2010); 5:11*). There is no curative treatment for β-thalassaemia major. Its main symptom, anaemia, is treated through frequent red blood cell transfusions, which can lead to iron overload, the principal cause of mortality in patients. To control iron overload, iron chelation therapy is required and typically begins after patients have received approximately twenty transfusions. HSCT presents a treatment opportunity for β-thalassaemia as it can replace the diseased bone marrow and restore the proper production of haemoglobin. Whilst the adoption of HSCT in β-thalassaemia major has been slower in comparison to blood cancers, transplantation with a sibling donor (SIB) is now more commonly accepted as a standard practice. Recent clinical trials have shown consistent overall survival data of >90% and transplant related mortality (TRM) of ~5% or less (*Angelucci et al., Haematologica (2014); 99(5)*) showing the effectiveness of treatment.

Indications for allogeneic HSCT treatments in Europe

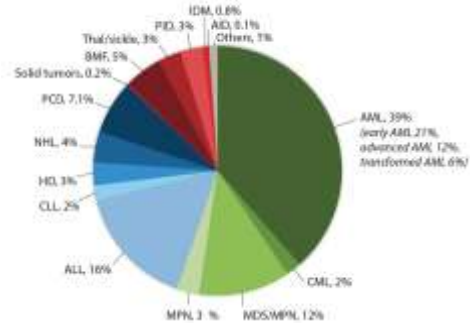


Figure 6.2 - Source: *Passweg et al., Bone Marrow Transplantation (2017), 1-7*

6.3 The HSCT procedure

Prior to beginning HSCT, patients receive high doses of chemotherapy and sometimes radiation therapy as part of their initial treatment regime. This "conditioning regime" destroys cancer cells to make their recurrence less likely. This process also damages and destroys the blood forming system in the bone marrow, including the patient's immune system, in order to minimise the possibility of rejection of the donor graft. A number of different high-dose conditioning regimes can be used, and may consist of chemotherapy drugs alone, such as busulfan and cyclophosphamide, or combined with total body radiation. Conditioning drugs and radiation therapy are given during the two weeks leading up to the transplant. The number of treatment days and the sequence of administration depend on the patient and specific conditioning regime.

After conditioning, the patient is given a 'graft' of the donor cells. The graft contains stem cells as well as, preferably, mature immune cells such as T-cells, B-cells and NK cells from the donor. The mature immune cells help the donor stem cells take hold (engraft) and multiply in the recipient's marrow and can also immediately fight remaining tumour cells and infections. However, as further set out in paragraph 6.4 below, mature immune cells may have an adverse effect on patients as they are the main cause of Graft Versus Host Disease (GVHD).

6.4 HSCT risks

The main risks of HSCT are GVHD, opportunistic infections and cancer relapse. As shown in Figure 6.4 below, GVHD, opportunistic infections and cancer relapse represent 51% of all causes of death following HSCT with a matched unrelated donor within 100 days post-transplant and 65% beyond 100 days post-transplant.

Causes of death after unrelated donor HSCT done in 2013-2014

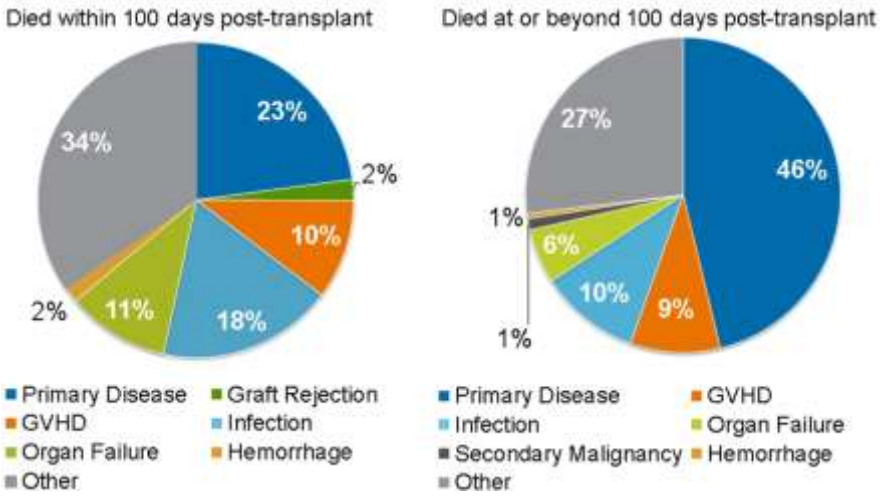


Figure 6.4 – Source: CIBMTR 2016 Summary Slides (*www.cibmtr.org*)

The risk of GVHD is caused by the *presence* of mature T-cells in the graft administered to patients whereas the risks of relapse and infections are caused by the *absence* of such mature T-cells in the graft. T-cells, a major component of the immune system, allow the immune system to distinguish 'non-self' from 'self'. Part of the non-self-recognition leads to T-cells recognising cells and tissues infected by bacteria, viruses or fungi. Upon 'non-self' recognition, the T-cells will try to eliminate all cells or tissues that express the 'non-self' structures. During HSCT treatment, the patient's bone marrow and mature T-cells are completely destroyed, and it usually takes at least six to twelve months for new mature T-cells to be reconstituted out of the stem cells in the donor graft (*Tomblyn et al., Biol Blood Marrow Transplant (2009); 15: 1143-1238*). During this period, the patient is highly vulnerable to relapse of the cancer and to infections. Thus, potent mature T-cells are required in the HSCT graft to provide for immediate protection. However, potent mature T-cells are also the main cause of GVHD.

Graft Versus Host Disease

GVHD is a potentially lethal side effect that occurs in many allogeneic transplant patients. With GVHD, mature transplanted donor T-cells recognise the patient's tissue as 'non-self' and start attacking the patient's body, and may cause, amongst others, skin disease, gastrointestinal malfunction, liver disease, infections, muscle constriction, bone loss, pulmonary disease, thyroid dysfunction, ophthalmology, solid tumours, sleep deprivation and/or depression. The severity of GVHD depends on the extent of genetic differences between patient and donor. Acute GVHD can occur soon after transplantation, typically in the first 100 days. It is graded from I (mildest) to IV (most severe). Grade III/IV acute GVHD is regarded as life-threatening. In 2011, the long-term mortality rate for severe chronic GVHD was as high as 50% (*Wolff, D., et al., The treatment of chronic graft-versus-host disease: consensus recommendations of experts from Germany, Austria, and Switzerland. Dtsch Arztebl Int., 2011. 108(43): p. 732-40*). Chronic GVHD tends to manifest itself only as of the fourth month after a transplant. Chronic GVHD is more likely to occur in older patients, or in patients who previously had acute GVHD. Chronic GVHD is graded as mild, moderate or severe, can persistent for years, leads to increased risk of infections and can be severely incapacitating and can severely impact quality of life. In 2016, there were approximately

45,000 chronic GVHD patients in the US, of which 75% lost three years of earnings and 25% were unable to return to paid employment (*Jones (2016)*).

In current bone marrow transplant regimes, the key focus is on minimising the risk of GVHD, albeit at the expense of the body's ability to fight infections and residual cancer cells. Currently multiple immunosuppressive agents are used to prevent GVHD, such as cyclosporine, tacrolimus, mycophenolate mofetil and sirolimus. Even with the use of these medications, the incidence of severe (grade III/IV) GVHD as a result of HSCT is approximately 30% (*Jagasia et al., Blood (2012); 119(1): 296-307)*. If GVHD develops, treatment relies on administrating glucocorticoids such as methylprednisolone or prednisone, antithymocyte globulin, monoclonal antibodies, mycophenolate mofetil, sirolimus and oral non-absorbable corticosteroids, to suppress the disease. Patients may need to continue taking such medications for many months or years after transplantation. GVHD does not always respond to these treatments, and patients may require intervention treatments to stem side effects such as tube feeding or lung transplantations. Inability to respond to GVHD can result in death, and many deaths related to GVHD occur as a consequence of opportunistic infections that develop in patients with suppressed immune systems.

Opportunistic infections

The term "opportunistic infection" applies to infections caused by bacterial, fungal and viral agents that rarely cause disease or infection in healthy individuals. In a healthy individual, the body easily fends off such microbes. As set out above in this paragraph 6.4, after HSCT treatment it often takes at least six to twelve months to recover to near-normal blood cell levels and immune cell function. In addition, the use of immunosuppression to prevent or treat GVHD further limits the immune system's ability to fight off infections. During this period, the patient is highly susceptible and vulnerable to infections. Many precautions must therefore be taken to minimise the risk of infection, such as the use of prophylactic antibiotics and anti-viral agents. Patients may also be put in quarantine for a month or longer.

Cancer relapse

Cancer cells that have survived even after high doses of chemotherapy in the conditioning regime may lead to a relapse of the disease after HSCT. The effectiveness of HSCT in preventing cancer relapse therefore depends on what is called the Graft-versus-Leukaemia (GVL) effect, whereby the recipient's new immune system may destroy any remaining cancer cells.

To assess the effectiveness of HSCT, typical endpoints are Overall Survival (OS), relapse, acute GVHD (grade I-IV), chronic GVHD and Non Relapse Mortality (NRM). These endpoints, however, do not capture the interrelated risks as described above, where patients having undergone an HSCT typically receive immunosuppression to prevent or treat GVHD, which in turn compromises the immune system and thus leads to an increased risk of relapse and infections. An end-point that does capture the relationship between these various effects is called GVHD-Free Relapse-Free-Survival (GRFS). GRFS is defined as survival without acute grade III/IV GVHD, chronic GVHD requiring systemic immunosuppression, and relapse, and is thus a composite endpoint that captures survival, quality of life and future prognosis. Long term GRFS is less than 35% for matched related, matched unrelated and half matched haploidentical transplantations (*Solh et al., Biol Blood Marrow Transplant (2016); 22: 1403-1409*). New therapies that improve GRFS by mitigating the risks of relapse, infections and GVHD would allow for much broader use of the HSCT therapy for patients

with blood cancers and inherited blood and immune disorders.

6.5 Donors

To curtail the HSCT risks of GVHD, while retaining protection against relapse and infections, clinical practice has historically focused on finding genetically matched donors, which contain the lowest number of potentially alloreactive mature T-cells. Genetic matching is done on the types of human leukocyte antigen (HLA) molecules, which are expressed on the cell surface. The immune system uses these molecules to verify that a given cell is part of the body ("self") and not a foreign invader ("non-self"). The risk of GVHD increases with the extent of HLA mismatch between patient and donor. The HLA type of a potential donor can be determined by looking directly at the person's DNA, obtained from the blood or from cells extracted from the inside of the cheek.

Depending on family size and genetics 20-80% of eligible patients who are in urgent need of HSCT will not find a matched related donor, matched unrelated donor or cord blood donor in time (*Gragert et al., New England Journal of Medicine (2014); 371:339-348 and Kasamon et al., Blood Advances (2017); 1:288-292*). In 2012, an estimated 13,000 patients were waiting for a matched donor in the U.S. (*Besse et al., Journal of Oncology Practice (2015); 11(2): 120-130*). To address the lack of matched donors, new approaches have been developed to enable the use of genetically half matched haploidentical donors, by depleting or treating alloreactive donor mature T-cells in the grafts from those donors to decrease the risk of GVHD. A haploidentical family donor, a child or parent or many other family members, would greatly increase the available donor pool.

Matched related and unrelated donors and cord blood donors

Matched related donors/sibling donors (MRD or SIB) match the patient's tissue type most closely, because the patient and the sibling donor (brother or sister) have received their genes from the same parents. However, siblings do not always have closely matched HLA types. The likelihood of a sibling being an HLA match is 25% for each sibling. In Europe and North America, where the average number of children per woman is less than two (*Eurostat; total fertility rate*), the chances of finding a SIB is below 25% and is expected to decrease in parallel with decreasing birth rates.

A matched unrelated donor (MUD) is a donor who is not a blood relative. An unrelated donor is found by searching registries of volunteer donors for an individual that is identical or very similar in HLA type to the patient. Despite the establishment of worldwide donor registries, the probability of finding a MUD is low, ranging from around 20% in poorly represented ethnic groups up to 80% in Caucasians (*Fuchs Blood Advances (2017) and Gragert (2014)*). Even when a donor has been identified, it is not always guaranteed that the donor is able or willing to donate stem cells. Obtaining search results can take up to four months (*Hirv et al., Bone Marrow Transplantation (2009); 44: 433-440; Heemskerk et al., Bone Marrow Transplantation (2005); 35: 645-652*). This timeframe makes it less of an option for patients who are in urgent need of an HSCT, particularly for those patients with acute forms of blood cancer.

The blood in the umbilical cord and placenta contains stem cells. After a baby is born, the blood in the umbilical cord and placenta can be collected and stored, which is called a cord blood unit. On average, more than one cord blood unit is required for HSCT treatment in adult patients. Due to the smaller number of stem cells in a cord blood unit, cord blood stem cell transplants engraft more slowly than stem cells from marrow or peripheral blood.

Additionally, the immune cells in the cord blood unit are "baby" cells that have not yet encountered any pathogens. Therefore, neither memory T-cells nor any other educated T-cells are transplanted resulting in a lack of immunological memory. Consequently, patients require substantially longer time in hospital after the transplantation.

Haploidentical donor

Each parent's contribution to the HLA type is referred to as a "haplotype". The term "haploidentical" indicates that the potential donor shares at least half the HLA type of the potential recipient. A haploidentical donor is therefore a genetically half matched donor: parents, children and many other family members are haploidentical. An ability to use half matched donors could make transplantation available to more than 95% of patients (*Fuchs Blood Advances (2017) and Fuchs et al., Hematology Am Soc Hematol Educ Program (2012*) 230-236).

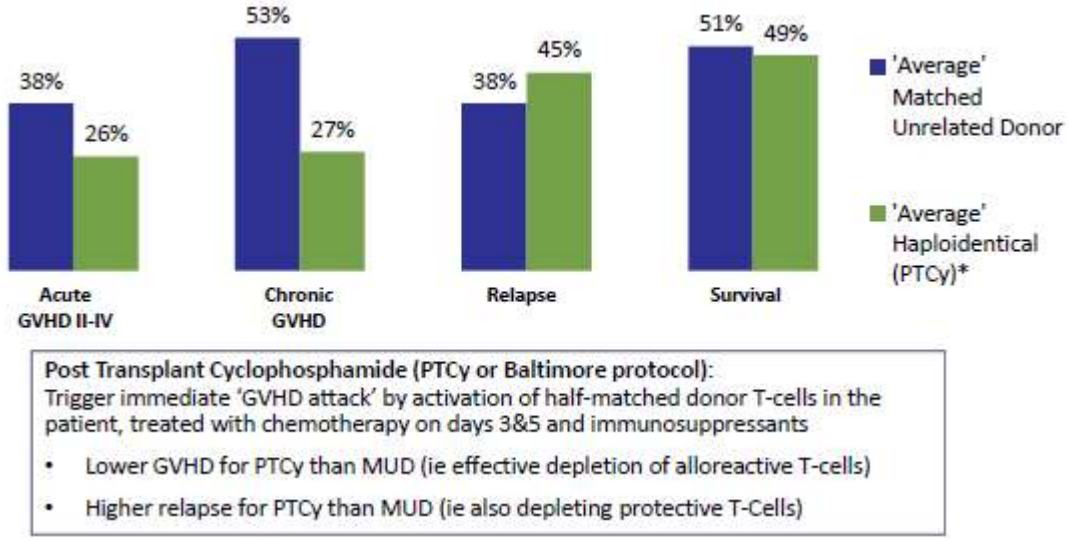
With haploidentical donors, the inherent risk that mature T-cells in the graft could cause an alloreactive immune response leading to GVHD is significantly higher than with matched donors, due to the larger genetic difference in HLA types. To enable haploidentical transplantations, different strategies have been developed to deplete or treat alloreactive T-cells *ex vivo* or in the patient as illustrated in Figure 6.5(a) below.

	Haplo HSCT	Haplo donor T-cell Product (after HSCT)	GVHD Treatment/ Prophylaxis (in patient)	Approach to GVHD
ATIR (Kiadis)	T-cell depleted	*'Safe' subset* of T-cells, depleted of alloreactive T-cells	No prophylactic immunosuppressant	*Prevent*
Zalmoxis (MolMed) BPX-501 (Bellicum)	T-cell depleted	*All* T-cells, but engineered with 'suicide gene'	Eliminate activated T-cells by infusing suicide agent, if GVHD occurs	***Treat***
PTCy or Baltimore protocol	T-cell replete (*All* T-cells)		Post Transplant Cyclo-phosphamide & immunosuppressants	***Treat***

Figure 6.5(a) – Note: Table provide for illustrative purposes, not for direct comparison

With a T-cell repleted graft, an unmanipulated (i.e. T-cell containing) haploidentical graft is infused. Due to the HLA mismatch, this causes an immediate alloreactive immune response, which, if not treated, could lead to severe, acute GVHD. Therefore, patients are treated with high doses of Post-Transplant Cyclophosphamide (PTCy) in the first days after the transplant to deplete the alloreactive T-cells. The depletion thus occurs within the patient. First developed at Johns Hopkins University in Baltimore, this approach is often called the Baltimore protocol. After the HSCT, patients remain under immune suppression to further address the risk of GVHD. An analysis of various publications comparing the PTCy protocol with MUD transplants shows that the PTCy protocol has a lower rate of GVHD than MUD donors, but unfortunately also a higher relapse rate and lower survival (*Fuchs E 2017*).

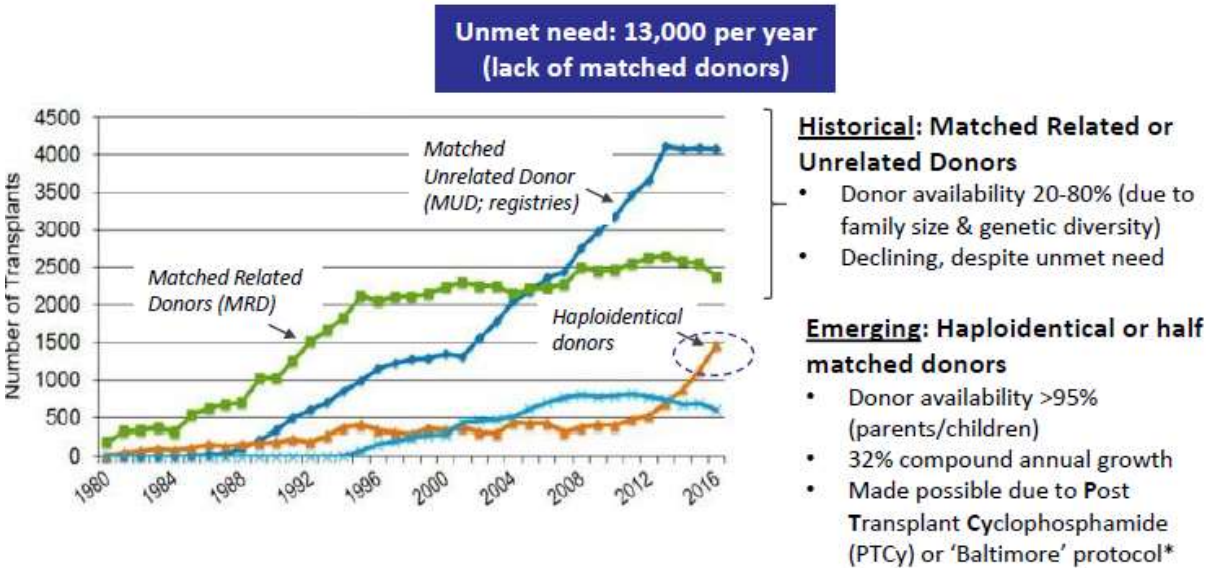
Haplo PTCy/Baltimore Protocol versus Match Unrelated Donors



* Not a 'true' average: Mix of indications (AML, NHL, HL), follow up (1.5, 2 and 3 yr) and patient populations; analysis based on ratio within each of the publications in the review paper shows similar results

Figure 6.5(b) – Source: *Fuchs E 2017*

In recent years, the adoption of the PTCy protocol has led to a growth in the number of haploidentical transplantations, in the U.S. at the expense of matched unrelated donor and cord blood transplants – see Figure 6.5(c) below.



* Cyclophosphamide (chemotherapy, days 3 and 5) & immunosuppressants to treat immediate attack from alloreactive haploidentical donor T-cells

Figure 6.5(c) – Source: CIBMTR 2017 Summary Slides; Fuchs 2017; Gragert 2014; Besse 2015

For T-cell depleted grafts, T-cells are *ex-vivo* depleted from the graft prior to HSCT, to

reduce the presence of alloreactive immune cells. Approaches include α/β T-cell depletion, CD3/CD19 depletion or CD34+ selection. Miltenyi Biotech GmbH ("**Miltenyi**") (Germany) has developed its CliniMacs cell sorter equipment to perform such depletion and selection, and is involved in various clinical trials. T-cell depletion has demonstrated to be effective in minimising GVHD, but is hampered by slow reconstitution of the immune system from the transplanted stem cells, leading to a long period without adequate protection against relapse and infection. Infusion of the T-cell depleted graft can be followed with a subsequent infusion of mature immune cells to provide such immediate protection. These mature immune cells need to be manipulated to address the risk of GVHD. Two strategies exist: MolMed SpA ("**MolMed**") (Zalmoxis) and Bellicum Pharmaceuticals, Inc. ("**Bellicum**") (BPX501) engineer T-cells with a gene that can trigger "cell suicide" (apoptosis) in the patient upon dosing of ganciclovir (Zalmoxis); also commonly used as an antiviral agent to treat CMV) or rimiducid (BPX501). This allows treatment of GVHD when it occurs. Kiadis (ATIR) has developed a preventative strategy that depletes alloreactive T-cells *ex-vivo* prior to infusion into the patient.

7 Business

7.1 Overview

Kiadis is a clinical stage, biopharmaceutical company focused on research, development and future commercialisation of cell-based immunotherapy products as adjunctive treatment for HSCT in blood cancers and inherited blood disorders.

To date, the side effects and risks associated with HSCT have not been fully addressed by the pharmaceutical industry, which has focused on the treatment itself rather than alleviating and mitigating the risks and side effects associated with HSCT treatment. Kiadis believes that its product candidates can address an important and significant unmet need by making HSCT safer and more effective for a substantially larger patient population, while improving overall patient survival rates and quality of life. Kiadis' product candidates for HSCT provide for "Allodepleted T-cell ImmunotheRapeutics" (ATIR). ATIR is a cell-based, personalised medicinal product manufactured on an individual patient basis. ATIR is a donor-derived T-lymphocyte enriched leukocyte preparation depleted *ex-vivo* of host-alloreactive T-cells.

ATIR is produced from immune cells from the same haploidentical donor used for the HSCT. To produce ATIR, those T-cells that are reactive against the patient, and that can thus cause GVHD, are depleted from the donor immune cells using Kiadis' Theralux technology platform. This depletion of alloreactive immune cells in ATIR reduces the risk of severe GVHD and its related morbidity and mortality. Due to the depletion process, a single dose of ATIR can be dosed at 2 million cells/kg, whereas an unmanipulated donor lymphocyte infusion (DLI) from a haploidentical donor would already cause GVHD at significantly lower doses (*Lewalle et al., Bone Marrow Transplantation (2003); 31(1): 39-44*). The remaining immune cells in ATIR are given to patients, with the intent to help fight residual cancer cells and opportunistic infections ATIR is dosed approximately one month after the haploidentical HSCT graft has been given to the patient.

To date, all clinical studies with ATIR have been performed with CD34+ selected haploidentical HSCT grafts, which contain in general more than $5x10^6$ CD34+ stem cells and less than $3x10^4$ CD3+ T-cells (Perugia protocol). For preparation of these grafts, standard selection columns are used (Miltenyi), which are widely established and used in transplantation centres.

Kiadis is focused on two therapeutic indications:

- ATIR101: Kiadis' lead product candidate for haploidentical HSCT treatments in blood cancers.

- ATIR201: Kiadis' second product candidate for haploidentical HSCT for inherited blood disorders, with an initial focus on thalassaemia.

ATIR is expected by Kiadis to be able to decrease healthcare costs and to increase the quality of life in patients. ATIR is aimed at reducing the appearance of severe forms of GVHD and aimed at reducing the patient relapse rate.

ATIR101 for blood cancers

Kiadis has completed a Phase I/II dose escalation clinical trial in patients with advanced blood cancers (CR-GVH-001). In this trial, ATIR101 was given up to high doses without

causing severe (grade III/IV) GVHD and an effective dose range of 2 million cells/kg was identified. Long-term follow-up (five years) has provided strong indications of the efficacy of ATIR101.

Subsequently, ATIR101 was tested in an open-label Phase II trial in patients with AML and ALL for whom no matching donor was available (CR-AIR-007). In this trial, no acute grade III/IV GVHD was elicited by ATIR101, confirming the effectiveness of depletion of patient reactive T-cells. This Phase II trial showed that ATIR101, as an adjunctive treatment in patients receiving a haploidentical T-cell depleted (CD34+ cell selected) HSCT, led to a clinically meaningful and statistically significant reduction in transplant related mortality (TRM) and a statistically significant increase in overall patient survival (OS) when compared to matched historical controls for patients receiving a haploidentical T-cell depleted (CD34+ cell selected) HSCT only. Based on the available literature for other haploidentical HSCT approaches such as use of high doses of post-transplant cyclophosphamide (PTCy) and genetically-engineered donor lymphocytes (Zalmoxis), HSCT treatment with ATIR101 as an adjunctive resulted in improved OS, less relapse, less chronic GVHD, less acute grade III/IV GVHD and improved GVHD-Free, Relapse-Free Survival (GRFS).

Based on the clinical results from this trial and following positive interactions with the EMA Rapporteur and Co-Rapporteur, Kiadis announced on 26 April 2017 that it had submitted its request for marketing authorisation with the EMA for ATIR101 in the EU. As part of the marketing authorisation approval process and in accordance with applicable timelines, day-120 questions from the EMA's Committee for Advanced Therapies were received by the Company in September 2017. Kiadis has six months to provide the EMA with a response to the day-120 questions. In addition, based on the clinical results from this trial Kiadis obtained a Regenerative Medicine Advanced Therapy designation from the FDA.

Following the results of the Phase II trial, the clinical protocol for a Phase III trial with ATIR101 (CR-AIR-009) has been submitted to national authorities in the United States, Canada and the EU and Kiadis has received regulatory approval in multiple countries to perform the trial. Kiadis enrolled the first patient in December 2017.

ATIR201 for β-thalassaemia major (postponed)

The protocol for a Phase I/II trial to test ATIR201 for use in patients suffering from β-thalassaemia major (CR-BD-001) has been approved by the national authorities in the United Kingdom and Germany. As Kiadis has focussed its available resources on ATIR101, this trial has been postponed and Kiadis has not yet decided when to start the trial and will first establish a safe dose in a paediatric population with a dose finding study in paediatric acute leukemia for ATIR101 within the agreed EMA Paediatric Investigation Program.

7.2 History

Scientists from the University of Leiden, the Netherlands founded Kiadis' business in 1997. Since its inception, Kiadis has expanded into a product development company through, among other things, acquisitions.

Key highlights of Kiadis' history:

Year	Description
1997	Kiadis was founded by scientists from the University of Leiden, the Netherlands.

2003	In the period prior to 2003, Kiadis raised approximately €10 million from private equity investors and, in 2003, it acquired Selact B.V. and its chemical synthesis technology.
2004	Kiadis raised approximately €2.1 million in an equity financing round.
2006	Kiadis raised approximately €2.5 million in an equity financing round. Kiadis acquired Celmed, a Canadian company active in the clinical development of cancer therapies that focused on the treatment of blood cancers through its Theralux platform.
2007	Kiadis raised approximately €15.4 million in an equity financing round (Series A).
2008	Kiadis decided to focus on ATIR.
2009	Kiadis obtained funding through an €8.2 million convertible bridge loan, which was subsequently converted into equity (Series B). In the period 2009 through 2011 Kiadis obtained a €2.8 million investment loan for the development of ATIR granted by RVO Nederland.
2010	Kiadis obtained funding through a €2.2 million convertible bridge loan, which subsequently converted into equity (Series C). Kiadis signed a licence agreement with Hospira to develop and commercialise ATIR in certain territories.
2012	Kiadis signed a termination and royalty agreement with Hospira, terminating the 2010 licence agreement, thereby retrieving all its licensed and marketing rights related to ATIR that had been licensed to Hospira. Kiadis terminated its open-label Phase II clinical trial CR-AIR-004 due to manufacturing issues. Kiadis raised approximately €10.1 million in an equity financing round (Series AA).
2013	Kiadis initiated its international open-label Phase II clinical trial for ATIR101, CR-AIR-007. Kiadis completed the five-year follow-up of its Phase I/II dose escalation trial with ATIR101, CR-GVH-001. Kiadis obtained an additional €2.2 million investment loan for the development of ATIR granted by RVO Nederland.
2014	Kiadis obtained interim data from its ongoing international open-label Phase II clinical trial for ATIR101, CR-AIR-007, supporting the safety profile and showing efficacy of ATIR101 administration. Kiadis raised approximately €5.1 million in an equity financing round (Series BB).
2015	The EMA granted Kiadis an advanced therapy medicinal products (ATMP) certificate for quality and non-clinical data for ATIR. Kiadis listed on Euronext Amsterdam and Euronext Brussels with gross proceeds from the IPO of €34.7 million and net proceeds of €31.2 million.

2016	Kiadis entered into collaboration with the Leukemia & Lymphoma Society (LLS) on the development of ATIR101 and issued Shares for €1.6 million in cash to LLS. Kiadis obtained one year follow-up data from its international open-label Phase II clinical trial with ATIR101, CR-AIR-007, confirming the safety profile and efficacy of ATIR101 administration. Kiadis announced that a protocol for a Phase I/II trial with ATIR201 was approved in various countries.
2017	Kiadis filed a Marketing Authorisation Application (MAA) with the EMA in April, and received Day 120 questions in September. Kiadis obtained FDA Regenerative Medicine Advanced Therapy designation. The clinical protocol for a Phase III trial with ATIR101 received regulatory approval in various countries and began enrolling patients. Kiadis raised €5 million in a private placement of Shares with institutional investors, with subsequent warrant exercises bringing in an additional €4 million. Kiadis obtained €15 million debt financing from Kreos Capital. Out of the loan received thereunder, Kiadis fully repaid the RVO Nederland investment loans. Kiadis raised €18 million in a private placement of Shares with institutional investors.

7.3 Company strengths

Compelling clinical data and clear route to market

The pivotal Phase II trial for ATIR101 (CR-AIR-007, 23 patients, ongoing with recruitment completed) showed that ATIR101 as adjunctive treatment in patients receiving haploidentical, T-cell depleted (CD34+ cell selected) HSCT led to a clinically meaningful and statistically significant reduction in TRM and a statistically significant increase in OS when compared to matched historical controls. Based on this data Kiadis filed a Marketing Authorisation Application (MAA) with the EMA on 25 April 2017.

For a future filling with the FDA and other regulatory authorities, Kiadis has also initiated a randomised Phase III clinical trial with ATIR101 comparing the clinical benefit of a T-cell depleted HSCT with ATIR101 as adjunctive treatment against the use of PTCy/Baltimore protocol.

Experience in manufacturing processes for cell-based therapies

ATIR101 is manufactured in centralised facilities. The manufacturing process allows for an attractive cost of goods and capex versus genetically engineered cell therapy (which requires the use of additional Biosafety Level 2 facilities), providing a basis for potentially attractive margins in the future. In addition, the supply chain fits effectively into routine transplant procedures.

Kiadis works with specialised contract manufacturing organisations (CMOs) but maintains critical know-how and expertise in-house. Kiadis received an Advanced Therapy Medicinal Products (ATMP) certificate for quality and non-clinical data for ATIR from the EMA in April

2015.

Seasoned senior leadership team

Kiadis' senior leadership team has extensive industry experience and complementary skill sets. The team has an established track-record in pursuing development, operations and deal-making, both in smaller biotechnology companies and in large pharmaceutical companies. The Company plans to expand the organisation to add further expertise and experience in operations and commercialisation as the company matures.

Significant unmet medical need

With the adoption of the PTCy/Baltimore protocol, the use of haploidentical HSCT has become more widespread. Kiadis' product candidates address the haploidentical HSCT market which Kiadis estimates includes up to approximately 27,900 patients each year in Europe, the U.S. and Canada combined. The PTCy/Baltimore protocol still has significant shortcomings regarding GVHD and relapse rates and Kiadis believes that ATIR is well positioned to effectively address these deficiencies. Although different haploidentical transplantation approaches may become available to patients, Kiadis believes that ATIR products could be the product of choice for a significant portion of the patient population.

7.4 Strategy

To advance ATIR to commercialisation

Subject to successful regulatory approvals, Kiadis aims to pursue its ATIR products to commercialisation in the EU, U.S. and Canada.

To use ATIR in combination with other approaches and in additional indications

Kiadis aims to design and initiate additional studies to investigate the use of ATIR101 in paediatric patients, and to combine ATIR101 as an adjunctive therapy with other (haploidentical) transplant protocols such as α/β T-cell depleted HSCT or PTCy.

To expand its suite of cell-based immunotherapy products

Kiadis has substantial expertise in the development of HSCT focused products and in the manufacturing of cell-based therapeutics. The Company has developed a network of medical specialists and advisors covering all relevant aspects of its business. Based on this, Kiadis believes that it will be able to capitalise on additional opportunities in HSCT and cell-based immunotherapy.

To enter into transactions with other pharmaceutical and biotechnology companies

Kiadis continues to explore ways in which it can collaborate with other companies. Future collaborations or partnerships may include working with partners to share the risk of additional clinical studies, granting licenses for commercialising Kiadis' product candidates in different geographic markets, or developing Kiadis' technology in combination with other treatments in order to offer complementary solutions to different diseases to maximise the value of ATIR. In addition, Kiadis will continue to explore possibilities for in-licensing or acquiring additional or complementary technology platforms or products.

To expand and defend its patent portfolio protecting its technology platforms

Kiadis seeks to expand and protect its product candidates and technologies by filing and prosecuting patent applications in major commercially relevant territories and countries. Kiadis has historically focused on the United States and the European Union and may in the future seek patent protection in other markets.

7.5 Stategic objectives

Without prejudice to the risks described in Chapter 1 (*Risk Factors*), Kiadis' business plan for the next two years is based upon the following key assumptions:

1 the Company will be able to attract or generate sufficient cash to fund its activities;

2 the EMA will approve the MAA submitted for ATIR101, and Kiadis successfully launches and commercialises ATIR in the EU;

3 the Phase III clinical trial with ATIR101 will continue to successfully enrol patients; and

4. Kiadis will be able to retain and attract key employees or replacements (if necessary).

A significant portion of the efforts of the Management Board and Senior Management are directed towards these priorities. The Company takes the following view on the risks associated with these assumptions and the sensitivity of these assumptions with respect to the business in the next two years.

The first assumption is a *conditio sine qua non* and, by far, the most important assumption. At the Registration Document Date Kiadis had cash and cash equivalents of approximately €27 million. Based on its operating plans, Kiadis believes that it will be able to meet its financing needs until February 2019. Based on its present requirements, Kiadis believes its operations will require cash resources of approximately €29 million to provide it with sufficient working capital for the next twelve months following the Registration Document Date and that the current working capital shortfall amounts to approximately €2 million.

Kiadis may raise additional capital through public or private equity offerings, debt financings, convertible loans, warrants, collaborations or other means. It may consider raising additional capital to take advantage of favourable market conditions or other strategic considerations even if Kiadis has sufficient funds for planned operations. At the date of this Registration Document, Kiadis is working on options to enable it to secure additional funds to continue operations beyond the existing cash runway. However, in case Kiadis is not able to attract sufficient additional cash from these resources, it may ultimately enter into bankruptcy.

After having secured EMA approval (the second assumption above) the Company anticipates it will be able to launch ATIR101 commercially in the EU. Non-approval by the EMA would, however, cause a delay and may, ultimately, jeopardise the product development program as well as the commercialisation thereof in the EU and would adversely affect the Company's business, financial condition and prospects. Gaining market access across the EU is generally slow, reflecting the process of obtaining national, regional and local listings and reimbursements. This is a challenge faced by the entire industry and is

not unique to Kiadis. Therefore, the Company does not anticipate that ATIR101 will be available in all of the major European markets within the next two years. Kiadis' business model does not currently depend on commercial partners to market its product in the various territories. However, it may seek such partners in the future in order to commercialise ATIR101 in the EU. The Company continues to believe that ATIR101 is a valuable addition to the therapeutic options available to HSCT patients but the standard of care may evolve and physicians may deem the product not to be attractive enough.

Continued enrolment in the Phase III clinical trial with ATIR101 (the third assumption above) will require contracts and approvals from clinical sites, manufacturing capacity, capabilities and approvals at CMOs and enough patients to participate. Delay in enrolment would jeopardise the product development program and the commercialisation of ATIR101 in the EU, the U.S. and elsewhere, and would adversely affect the Company's business, financial condition and prospects. To execute this Phase III trial, the Company depends on contracts with and the support and performance of its CMOs, on CROs, on hospital clinics to participate in the trial in the US, Canada and Europe and on regulatory agencies such as the FDA (U.S.), MHRA (UK) and PEI (Germany). The Company continues to believe that the existing data for ATIR101 makes the Phase III trial an attractive trial for clinics, physicians and patients.

The ability to retain and attract key employees or replacements if necessary (the fourth assumption above) is also important for the future growth of the Company. Kiadis' business is highly specialised and requires specific expertise from highly educated and trained professionals. Since there is severe competition on an international level between companies in the relevant industry for talented and experienced individuals, there is a risk that one or more of these employees may leave causing delays in the execution of the business plan. Kiadis aims to attract and retain talent with a combination of incentives including competitive compensation structures, participation in option and share plans and providing an attractive employment culture.

7.6 Clinical development

Every new drug or treatment regimen goes through a series of studies called "clinical trials" before it can be approved by relevant regulatory bodies to become part of standard therapy. Before a clinical trial begins, a new therapy is developed and tested in a laboratory. If this early research (so-called "pre-clinical trials") shows the therapy is safe and effective, a carefully planned and monitored clinical trial of the drug or treatment will be conducted in humans.

Clinical trials are conducted in "phases" Each phase has a different purpose and assists researchers in answering different questions.

- Phase I trials – an experimental drug or treatment in a small group of people for the first time. The purpose is to evaluate its safety and identify potential side effects.

- Phase II trials – an exploratory stage of clinical testing, in which the experimental drug or treatment is administered to a larger group of people to determine whether and how well it works (efficacy) and to further evaluate its safety.

- Phase III trials – the experimental drug or treatment is administered to large groups of people to confirm its efficacy, monitor side effects and compare it with

standard or equivalent treatments.

- Phase IV trials – upon approval, ongoing "real-world" studies are conducted to monitor and report on the use of its drug or treatment.

7.7 Product pipeline

Kiadis' product pipeline contains two product candidates: ATIR101 for use with HSCT in blood cancers and ATIR201 for use with HSCT in inherited blood disorders, with an initial focus on thalassaemia.

7.7.1 ATIR101

ATIR101 was evaluated in a Phase I/II dose escalation trial completed in 2013 (CR-GVH-001). A subsequent Phase II trial (CR-AIR-004) was stopped due to manufacturing issues. Kiadis resolved the manufacturing issues and thereafter initiated a new Phase II clinical trial which was completed in September 2017 (CR-AIR-007).

An additional Phase II clinical trial (CR-AIR-008) was initiated in September 2015 to test the safety of a second dose of ATIR101 to determine whether there was a potential upside. Following certain issues further set out in paragraph 7.7.1.5 below, the administration of the second dose has been halted and this trial is currently only enrolling patients with a single dose. The Company does not believe that the issues with the second dose in the CR-AIR-008 trial will have a material impact on the potential for ATIR101: the EMA filing and the Phase III clinical trial have been based on the application of a single dose. Clinical trial data to date with patients with at least one year of follow up has shown that infusing a single dose of ATIR101 continues to be safe: five patients in the CR-AIR-008 trial have been treated with a single dose of ATIR101 only, more than one year ago. None of these patients have shown severe GVHD and their OS is currently in line with the one year results of the single dose Phase II trial (CR-AIR-007).

Kiadis also initiated and completed an observational cohort trial to collect matched historical data to serve as a control arm for the single dose Phase II trial (CR-AIR-006).

Following the successful data obtained in the ongoing Phase II trial (CR-AIR-007) and a Paediatric Investigation Plan having been agreed upon with EMA, Kiadis filed an MAA on 25 April 2017 seeking approval in the EU for the use of ATIR101 as adjunctive treatment in HSCT for any malignant disease. The filing passed EMA validation in May 2017. In accordance with applicable timelines, the day-120 questions from the EMA were received by the Company in September 2017 and Kiadis will have to submit a response to those day-120 questions by the end of Q1 2018. Conditional approval, if granted (potentially in Q4 2018), will pave the way for a potential launch in the second half of 2019. Kiadis expects that if granted, approval will be conditional on successful completion of a Phase III trial.

In addition to the above trials, the clinical protocol for a randomised, open label, parallel arm Phase III international multicentre trial (CR-AIR-009) has received regulatory approval from the national authorities in the United States, Canada and Europe and began enrolling patients in December 2017 (see Figure 7.7.1 below). As at the Registration Document Date, 4 patients have been enrolled of which none has been treated with ATIR101 yet.

To further expand the use of ATIR101, Kiadis seeks to set up additional studies to investigate its use in paediatric patients and in combination with other (haploidentical)

transplant protocols such as α/β T-cell depletion or PTCy.

Overview of clinical studies in the ATIR101 clinical development program

Trial No. Phase (Countries)[1]	**Objective**	**Trial design**	**Patients**[2]	**Trial status**
ATIR101 studies				
CR-GVH-001 Phase I/II (CA)	Dose escalation	Open-label, uncontrolled, dose-escalation trial	N=19	Completed
CR-AIR-007 Phase II (BE, CA, GE, UK)	Efficacy, safety	Open-label, uncontrolled, multi-centre trial, using a single dose of 2 x 10^6 viable T-cells/kg	N=23	Completed
CR-AIR-008 Phase II (CA, EU)	Efficacy, safety	Open-label, uncontrolled, multi-centre trial, evaluating a 2-dose regimen of ATIR101	N=15	Ongoing/ enrolment complete
CR-AIR-009 Phase III (planned: CA, EU, US)	Efficacy, safety	Open-label, randomised, controlled trial of a single dose of ATIR101 (2 x 10^6 viable T-cells/kg) vs. post-HSCT PTCy (Baltimore protocol)	N=195	Ongoing/ recruiting
Non-ATIR101 studies				
CR-AIR-004 Phase II (BE, CA, GE, NL, UK, US)	Efficacy, safety	Open-label, uncontrolled, multi-centre trial	N=40	Terminated early
Non-interventional studies				
CR-AIR-006 (BE, CA, GE, NL, UK, US)	Control	Observational cohort trial	N=158	Completed

(1) Abbreviations: BE= Belgium, CA= Canada, EU= European Union, GE= Germany, NL= the Netherlands, UK = United Kingdom, US = United States of America

(2) Number of treated patients for completed or terminated studies; planned patient number for ongoing studies.

Figure 7.7.1 – Overview of clinical studies in the ATIR101 clinical development program

7.7.1.1 CR-GVH-001 - Phase I/II Dose Escalation (completed)

Kiadis started a Phase I/II open-label, dose escalation trial in 2005 and completed the five-year follow up in 2013. The trial was conducted at the Maisonneuve-Rosemont Hospital in Montreal, Canada.

The primary objective of trial CR-GVH-001 was to determine the safe and potentially efficacious dose range of ATIR101, following a T-cell depleted haploidentical HSCT. The maximum tolerated dose (MTD) was defined as the highest dose of ATIR101 in which severe GVHD (grade III/IV) does not occur in more than one-third of patients.

A total of 19 patients with advanced haematological malignancies were treated in this trial, with ages (as of 2005) ranging from 20 to 62 (median age was 54). The majority of patients (14) were not in remission at the time of transplant, indicating patients had a poor survival

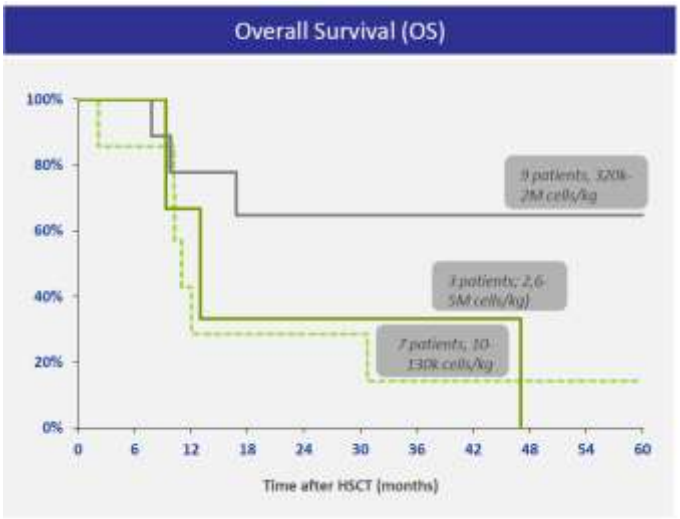
prognosis.

ATIR101 was infused at different cell dose levels (L1 – L7) between 28 to 40 days (median of 30 days) after the initial stem cell transplantation. No patient, at any of the dose levels tested, experienced grade III/IV (life-threatening) acute GVHD, the primary (safety) endpoint of this trial, so dose-limiting toxicity was not observed and the MTD was not formally determined. Additionally, no ATIR101-related side effects (serious adverse events (SAEs)) were reported for any of the dose cohorts. In the dose range between 3.2×10^5 cells/kg and 2.0×10^6 cells/kg (nine patients) no patient died as a result of TRM over the full five-year period.

The secondary endpoints of the trail regarded among others immune reconstitution, rate of disease relapse, TRM, relapse-related mortality (RRM) and OS. TRM entails all transplant related causes of death, primarily death from GVHD or infections. Death from cancer relapse is not considered transplant related. Only at the highest dose cohort (L7 - 5.0×10^6 cells/kg) TRM reappeared, mostly related to infections resulting from the immunosuppressive treatment for mild GVHD.

This trial shows that ATIR101 is both safe and well tolerated at an effective dose cohort (L4-L6) as adjunctive treatment to a haploidentical T-cell depleted transplant.

Based on the results of trial CR-GVH-001, the optimal dose of ATIR101 for further development was considered to be 2×10^6 cells/kg. This is the dose that was used in the Phase II trial (CR-AIR-007) (further described below). The five-year follow-up of patients in the CR-GVH-001 trial was completed in 2013 and showed a 67% overall survival of patients treated at the effective dose range (L4 – L6).



Note: Unmanipulated haplo-identical Donor Lymphocyte Infusion escalated above 10k T cells cells/kg induce GVHD

Figure 7.7.1.1 – CR-GVH-001: overall survival (5 year)

7.7.1.2 CR-AIR-004 - Phase II Safety & Efficacy (terminated early due to manufacturing issues)

Kiadis initiated an open-label Phase II clinical trial in blood cancer patients (AML, ALL, CLL, CML, MM, MDS, MPS and non-Hodgkin lymphoma) in ten hospitals in North America and

Europe (EudraCT no. 2008-008198-73) in 2009.

After 40 patients were transplanted and treated, Kiadis decided to temporarily halt patient enrolment due to a high number of manufactured batches of ATIR101 that could not be released for use (out of specification). During the investigation of these manufacturing batches, it became clear that Kiadis also had to investigate the quality of retained samples of the investigational medicinal product (IMP) that was released for use and had to conduct an interim analysis on the clinical outcome.

Characterisation of the IMP (and intermediates) manufactured for this trial showed that the IMP mostly consisted of dead or dying cells. Further investigations revealed that the storage of the donor cells (mostly 48 - 72 hours at 2 - 8 °C) before the start of manufacturing of the IMP was likely to have contributed to the low number and poor quality of cells that survived. Kiadis also re-analysed retained samples from the Phase I/II CR-GVH-001 trial where the IMP was manufactured from freshly collected donor cells. Those analyses confirmed that the quality of IMP in CR-GVH-001 was within specifications.

Interim data of all patients treated with the trial medication (N=40) did not show an improvement of TRM or OS over patients who received a haploidentical HSCT without the addition of donor T-cells (*Literature data and initially collected historic data; Ciceri et al., Blood (2008); 112(9): 3574-3581*). Thus, the IMP manufactured for the CR-AIR-004 trial was not clinically beneficial.

Given that the IMP consisted mostly of dead and dying cells and was not produced to specification, Kiadis determined that the IMP manufactured during this trial was not ATIR101, which was confirmed by the EMA during subsequent interactions and correspondence. As a result, Kiadis decided to prematurely terminate the CR-AIR-004 trial on 8 February 2012 (see also paragraph 7.11.1 below).

7.7.1.3 CR-AIR-006 - Observational Cohort Trial (completed)

CR-AIR-006 is an observational cohort trial which began in 2010, in which data was collected on transplant outcomes for different donor sources. The design of the non-interventional, observational cohort trial CR-AIR-006 was aligned as much as possible with that of the pivotal trial CR-AIR-007. The trial was specifically designed to provide a control group of patients receiving haploidentical, T-cell depleted (CD34+ cell selected) HSCT, matching patients receiving haploidentical, T-cell depleted (CD34+ cell selected) HSCT with ATIR101 in the pivotal trial.

In this observational trial, data was collected from four different patient groups in a number of centres:

1 HAPLO group: patients who received an HSCT from a haploidentical family donor without ATIR101 administration between 1 January 2006 and 30 June 2013 (N=35). This is the most suitable control group to compare the outcome of haploidentical donor transplantations with ATIR101 and thus to determine the superiority of ATIR101 in this transplant setting.

2 Unrelated donors: patients who received HSCT from a fully matched donor (MUD with HLA match of 10/10) or partially matched donor (MMUD with HLA match of 9/10) between 1 January 2010 and 31 December 2012 (N=64 and N=37

respectively).

3 UCB group: patients who received a double umbilical cord blood transplantation between 1 January 2010 and 31 December 2012 (N=22).

For all patients, information was collected up to twelve months after the HSCT. To determine the efficacy of the HSCT, Kiadis looked at TRM, RRM, OS and PFS. The primary endpoint was established at TRM, RRM, OS and PFS at up to twelve months after HSCT. The secondary endpoint consisted of the incidence and severity of acute and chronic GVHD at up to twelve months after HSCT.

Data collected on TRM and OS confirms that haploidentical donor transplantations without adjuvant immunotherapy have inferior outcomes compared to haploidentical donor transplantations with ATIR101.

	Overall Survival[(1)]		Transplant Related Mortality[(1)]	
	6 mo post HSCT	12 mo post HSCT	6 mo post HSCT	12 mo post HSCT
HAPLO 006 (n=35)	63%	20%	37%	70%
MMUD 006 (n=37)	73%	64%	22%	25%
MUD 006 (n=64)	91%	86%	6%	9%
UCB 006 (n=22)	64%	55%	32%	37%

[(1)] Kaplan-Meier estimate

Figure 7.7.1.3 – Source: *Clinical Study Report CR-AIR-006*

The HAPLO group from this study is the primary control group for comparing with the transplant outcome of the pivotal Phase II study (CR-AIR-007), as it provides data from similar patients undergoing a similar transplant, but without adjunctive treatment with donor lymphocytes. As one patient in the HAPLO group died before day 30 post HSCT, a sensitivity analysis was conducted and the six-month and 12-month OS for the control group without this subject (N=34) was 65% and 21% respectively.

7.7.1.4 CR-AIR-007 - Phase II Safety & Efficacy (completed)

Kiadis started an open-label, single arm, Phase II clinical trial in 2013 in patients with haematological malignancies (AML, ALL, MDS). The trial was performed in eight hospitals: three in Canada (Montreal, Hamilton and Toronto), three in Belgium (Leuven, Brussels and Bruges), one in Germany (Würzburg) and one in the United Kingdom (London), under trial number NCT01794299/EudraCT number 2012-004461-41. The trial was conducted under a U.S. Investigational New Drug application (IND) and the two-year follow up for the trial was completed in 2017.

Eligible patients had no suitable matching donor available and had (a) AML in first remission with high-risk features or in second or higher remission, (b) ALL in first remission with high-risk features or in second or higher remission, or (c) MDS: transfusion-dependent or

intermediate or higher revised international prognostic scoring system (IPSS-R) risk group. All patients were given a single infusion of ATIR101 at a dose of $2x10^6$ cells/kg between 28 and 32 days after a T-cell depleted HSCT (CD34+ selected stem cells) from a haploidentical donor was infused. After HSCT, no additional medication was given to prevent GVHD. The primary endpoint of this trial was defined as TRM at six months after HSCT with secondary endpoints including acute/chronic GVHD, infections, recovery of immune cells, and TRM, RRM and OS at two years. The condition of patients was closely observed, initially once every week during the eight weeks following ATIR101 infusion, and then monthly until one year after the HSCT and every half year until two years after the HSCT.

The trial began in March 2013 and completed enrolment in July 2015. A total of 23 patients were recruited, transplanted and given ATIR101. Patient age ranged from 21 to 64 years (median: 41 years). The majority of patients had AML (16 patients, 70%) and 7 patients (30%) had ALL. At the time of transplant, 15 patients were in first remission (CR1) and 8 patients were in second or subsequent remission (CR2). The Disease Risk Index (DRI) (*Armand et al., Blood (2014); 3664-3671*), which according to the author is the strongest prognostic factor for survival in HSCT, was high in 57% of patients and intermediate in 43% of patients; the cytogenetic risk profile was intermediate for 39% and adverse for 61% of the patients.

Patients underwent myeloablative conditioning, consisting of a) TBI (1200 cGy: n=11) or b) melphalan (120 mg/m2: n=12), along with thiotepa (10 mg/kg), fludarabine (30 mg/m2 x 5d) and ATG (2.5mg/kg x 4d). A CD34+ selected stem cell graft from a haploidentical donor was given, containing a mean of $11x10^6$ CD34+ cells/kg (range: 4.7 – $24.4x10^6$) and $0.29x10^4$ CD3+ cells/kg (range: 0.01 – $1.8x10^4$). In addition, donor lymphocytes from the same donor were processed using a selective photodepletion technology, creating a donor lymphocyte infusion depleted of alloreactive T-cells (ATIR101). ATIR101 was then infused at a median of 28 days (range: 28-73) post-HSCT at a fixed dose of $2x10^6$ CD3+ cells/kg, without use of any post-transplant GVHD prophylaxis.

Results for trial CR-AIR-007 are available from three analyses (i.e. from a protocol-specified interim analysis performed when the first ten patients had six months' follow-up data available (cut-off date: 25 September 2014), from the primary trial analysis which was performed when the last patient achieved six months' follow-up (cut-off date: 24 March 2016) and from an interim analysis when the last patient achieved 12 months' follow-up (cut-off date: 22 September 2016).

At present, all patients have completed the study. Final clinical study results (CSR) with an analysis up to and including the last patient achieving 24 months' follow-up are expected to be available at the end of Q1 2018.

Analysis of the primary efficacy endpoint and secondary endpoints

The primary endpoint of the trial (TRM at six months after HSCT) was reached in March 2016. The regulatory agencies also requested 12-month TRM data and the data presented for trial CR-AIR-007 in this section uses the later data, with the cut-off date of 22 September 2016, the last date for which data has been analysed. Initial data on the 24 month follow-up, with the cut-off date of 22 September 2017, are provided below, but no Clinical Study Report with (statistical) analysis is available yet and thus these numbers may still change.

All patients engrafted rapidly after transplantation, with neutrophil and platelet engraftment

achieved at a median of 12 days (range 8-34 and 9-35 respectively).

The TRM probability at six months was estimated as 13% (95% CI 5%, 36%). The TRM probability at twelve months was estimated as 32% (95% CI 17%, 56%). The TRM probability at 24 months was 48%.

The RRM probability at twelve months was estimated as 10% (95% CI 3%, 35%). RRM probability at 24 months was estimated as 25%. A PFS event (i.e. disease progression or death, whichever occurred first) occurred in 14 patients (60.9%). The PFS probability at 12 months was 61% (95% CI 38%, 77%). PFS probability at 24 months was 39%. The OS probability at twelve months was estimated as 61% (95% CI 38%, 77%). OS probability at twenty-four months was estimated as 39%. At 1 year follow-up, OS was calculated at 61% and death was reported for 9 patients (39%): 2 patients (9%) experienced RRM and 7 patients (30%) experienced TRM. At the Registration Document Date, OS was calculated at 41% and death was reported for 14 patients (60.9%): four patients (17.4%) experienced RRM and 10 patients (43.5%) experienced TRM. All three patients that died in the second year of TRM were immunosuppressed and subsequently contracted infections, leading to death: two of those patients received unmanipulated DLI's and subsequently developed severe GVHD; one of those patients had chronic GVHD. All MITT patients have completed the study (see Figure 7.7.1.4(a) below).

Period post HSCT	Classification	No. of pts	Classification of cause of death
< 6 months	Relapse	1	
	TRM – Infections	2	Adenovirus and JC virus infections
	TRM – Other	1	Pulmonary embolism
6-12 months	Relapse	1	
	TRM – Infections	3	Respiratory/pulmonary infections/distress
	TRM – Other	1	Multi-organ failure
12-24 months	Relapse	2	
	TRM-Infections	3*	Pneumonia/sepsis/septic shock
Total		14 (61%)	

* All 3 patients immunosuppressed, subsequently contracted infections, leading to death: 2 patients who received unmanipulated DLI's and subsequently developed severe acute GVHD; 1 patient with chronic GVHD

Figure 7.7.1.4(a) – Source: Clinical Study Report CR-AIR-007 (expect for data from 12-24 months)

Kaplan-Meier estimates for primary and secondary efficacy endpoints - trial CR-AIR-007, MITT

	6 months	12 months
TRM probability [%] (95% CI)	13 (5, 36)	32 (17, 56)
RRM probability [%] (95% CI)	5 (1, 28)	10 (3, 35)
PFS probability [%] (95% CI)	78 (55, 90)	61 (38, 77)
OS probability [%] (95% CI)	83 (60, 93)	61 (38, 77)

The six-month probability of TRM was defined as the primary endpoint in trial CR-AIR-007.

Figure 7.7.1.4(b) - Source: *Clinical Study Report CR-AIR-007*

Only one patient developed chronic (severe) GVHD during the study. All cases of acute GVHD with an onset in the first year after HSCT administration, a time period in which acute GVHD may be expected after any HSCT, were of grade I (13%) or II (13%). Three patients experienced acute GVHD of grade III or IV and of very late onset, i.e. about 380 to 530 days after HSCT. However, all three patients developed this acute GVHD shortly after the administration of unmanipulated DLIs which they had received at doses between 3×10^4 and 3×10^5 T-cells/kg shortly before onset of this GVHD. While DLIs may be used to manage severe infections or to induce a graft-vs-leukaemia response in patients whose disease is relapsing, it is also a known risk factor for GVHD (*Deol and Lum; Cancer Treat Rev (2010); 36(7): 528-538*). From literature it is known that the administration of unmanipulated T-cells early after HSCT, especially at doses of $>5 \times 10^4$ cells/kg, may lead to life-threatening, acute GVHD (*Lewalle (2003)*).

The above primary analyses are all based on patients that received an HSCT and ATIR101 (Modified Intent to Treat; MITT; n=23). An alternative post-hoc analysis has been performed based on all patients that were enrolled and underwent an HSCT, whether they received ATIR101 or not (Intent To Treat population; ITT; n=26). There are 3 patients in the ITT population that are not in the MITT population: 1 patient died within a couple of days after HSCT, 1 patient had an HSCT engraftment failure (physician subsequently performed rescue HSCT, without ATIR101); and 1 patient was faced with an ATIR101 batch failure (physician had started conditioning prior to batch release, continued the HSCT without ATIR101). Of the ITT population, at 1 year follow-up, OS was calculated at 58% with death reported for 11 patients (42%): 2 patients (8%) experienced RRM and 9 patients experienced TRM (34%). Rates of GVHD are the same as in the MITT analysis.

Comparison of trial CR-AIR-007 results with trial CR-AIR-006 observational cohort data

The principal proof of the efficacy of ATIR101 is based on the single-arm, open-label, uncontrolled, pivotal trial CR-AIR-007. The non-interventional, observational cohort trial CR-AIR-006 was set up as an external, historical control for this pivotal trial and the HAPLO group of patients receiving a haploidentical, T-cell depleted (CD34+ cell selected) HSCT was used as control group for ATIR101-treated patients in trial CR-AIR-007. This strategy was discussed and agreed upon with the EMA and with several European National Competent Authorities during scientific advice meetings.

Pooling of the two studies was possible because trial CR-AIR-006 recruited an almost identical patient population as CR-AIR-007 (i.e. the eligibility criteria were chosen to match as closely as possible). Centres participating in trial CR-AIR-006 were chosen among centres participating in trial CR-AIR-007, if possible. Furthermore, the recruitment times of studies CR-AIR-007 and CR-AIR-006 were sufficiently close to assume that the medical practice at the sites would be highly similar if not necessarily identical (CR-AIR-007: March 2013 to September 2016; CR-AIR-006, HAPLO group: January 2006 to June 2013). Comparison of the demographics and baseline disease characteristics confirms that the patient populations of the two studies were similar, as discussed below.

Transplant Related Mortality

TRM at six months was defined as the primary endpoint in the pivotal trial. The number of patients with a TRM event at six months was three (13.0%) in the pivotal trial. The incidence in the HAPLO group in trial CR-AIR-006 was almost three times as high: 13 patients (37.1%) experienced TRM in the first six months after HSCT. The odds ratio (OR) for TRM at six months for patients in the pivotal trial versus the HAPLO group in trial CR-AIR-006 was

0.21 (95% CI 0.05, 0.92). This represents a statistically significant comparison (p=0.0309), indicating that patients administered ATIR101 after a T-cell depleted HSCT had a significantly lower TRM than patients who did not receive adjunctive treatment with ATIR101. The treatment difference was maintained at twelve months, when seven patients (30.4%) and 23 (65.7%) patients, respectively, had experienced TRM, with an OR of 0.23 (95% CI 0.07, 0.75; p=0.0147).

The hazard ratio (HR) for TRM was 0.30 (95% CI 0.12, 0.75) with a p-value of 0.0066, indicating a statistically significantly lower TRM in trial CR-AIR-007 compared to the HAPLO group in trial CR-AIR-006 (Figure 7.7.1.4(c) below). The 12-month TRM probability was 32.2% in the pivotal trial, versus a more than two-fold higher TRM probability of 70.3% in the control group.

Transplant-related mortality - trial CR-AIR-007 vs. trial CR-AIR-006

	CR-AIR-007 HSCT plus ATIR101	**CR-AIR-006 HSCT**
Patients, n (MITT)	23 (100.0)	35 (100.0)
Patients with TRM event, n (%)[1]		
At 6 months	3 (13.0)	13 (37.1)
At 12 months	7 (30.4)	23 (65.7)
Time to TRM [months], median (95% CI)	Ne[2] (8.5; ne)	7.6 (5.8; 8.4)
Hazard ratio (95% CI)[3]	0.30 (0.12; 0.75)	
p-value[3]	0.0066	
TRM probability (%) at landmark time points[3]		
6 months	13.5	37.1
9 months	32.2	66.6
12 months	32.2	70.3

(1) Descriptive statistic, may slightly deviate from model- based Kaplan-Meier estimates
(2) Abbreviation: ne = not estimable
(3) Analysis based on the MITT for trial CR-AIR-007 and all patients in trial CR-AIR-006; hazard ratio of HSCT plus ATIR101 (CR-AIR-007) vs. HSCT (CR-AIR-006); log-rank test

Figure 7.7.1.4(c) - Source: *Clinical Study Report CR-AIR-007*

Overall Survival

Nine patients (39.1%) died in the pivotal trial within the first 12 months versus 28 patients (80.0%) in the HAPLO group in trial CR-AIR-006. The HR for OS was 0.32 (95% CI 0.15, 0.71; p=0.0035), indicating a statistically significant improvement of OS in ATIR101-treated patients, as compared to the control group (Figure 7.7.1.4(d) below).

At all landmark time points, the OS probability was higher in the pivotal trial than in the control group. This is also reflected in the 12-month survival probability which was 60.9% in the pivotal trial and 20.0% in the HAPLO group in trial CR-AIR-006.

Overall survival - trial CR-AIR-007 vs. CR-AIR-006

	CR-AIR-007 HSCT plus ATIR101	**CR-AIR-006 HSCT[4]**
Patients, n (MITT)	23 (100.0)	35 (100.0)
Patients with event[1]	9 (39.1)	28 (80.0)
OS [months], median (95% CI)	ne (6.9; ne)	6.8 (5.8; 8.2)

Hazard ratio (95% CI)[2]	0.32 (0.15, 0.71)	
p-value[1]	0.0035	
OS probability at landmark time points[3]		
6 months	82.6	62.9
9 months	60.9	25.7
12 months	60.9	20.0

(1) Descriptive statistic, may slightly deviate from model-based Kaplan-Meier estimates
(2) Hazard ratio of HSCT plus ATIR101 (CR-AIR-007) vs. HSCT (CR-AIR-006); log-rank test
(3) Kaplan-Meier estimates
(4) As one patient in the HAPLO group died before day 30 post HSCT, a sensitivity analysis was done and the six- and 12-month OS for the control group without this subject (N=34) was 65% and 21% respectively

Figure 7.7.1.4(d) - Analysis based on the MITT for trial CR-AIR-007 and all patients in trial CR-AIR-006

Graft Versus Host Disease

The 12-month cumulative incidences for acute GVHD grade II-IV, acute GVHD grade III/IV, and chronic GVHD were all lower in the pivotal trial than in the control group. However, numerical differences between the groups did not reach statistical significance (Figure 7.7.1.4(e) below).

12-month cumulative incidence of GVHD - trial CR-AIR-007 vs. CR-AIR-006

	CR-AIR-007 HSCT plus ATIR101	**CR-AIR-006 HSCT**	**p-value[1]**
Patients, n (MITT)	26 (100.0)	35 (100.0)	
Acute GVHD grade II-IV (95% CI)[1]	15.4 (4.7, 31.8)	20.0 (8.7, 34.7)	0.5689
Acute GVHD grade III/IV[1]	0.0 (ne, ne)	5.7 (1.0, 16.9)	0.2191
Chronic GVHD[1]	3.8 (0.3, 16.8)	8.6 (2.1, 20.8)	0.4492

(1) Gray's test for equality of cumulative incidence functions

Figure 7.7.1.4(e) - Analysis based on the ITT for trial CR-AIR-007 and all patients in trial CR-AIR-006

GVHD-free, relapse-free survival

A post-hoc analysis was conducted using the recently introduced composite endpoint of GRFS, GVHD-free, relapse-free survival (*Holtan et al., Blood (2015); 125(8): 1333-1338*). GRFS is defined as survival without relapse, acute GVHD grade III/IV or chronic GVHD requiring systemic treatment. The one-year GRFS for patients treated with ATIR101 was 57%.

7.7.1.5 CR-AIR-008 - Phase II Trial (ongoing/enrolment complete)

To broaden the applicability of ATIR101, Kiadis started another Phase II trial assessing the safety of administration of a second dose of ATIR101 (CR-AIR-008). The aim of the trial was to further reduce the time to T-cell reconstitution and extend the length of protection and thereby decrease the occurrence of severe infections and TRM, and to investigate the

flexibility for physicians (instead of using an unmanipulated DLI).

This is an exploratory, open-label, multicentre trial. Patients with hematological malignancies (AML, ALL, MDS) who are eligible for HSCT but do not have a fully matched related or unrelated donor following a donor search can participate in the trial. This trial was initiated in September 2015 and is currently conducted under a U.S. IND, in Canada and in Europe. The objective of trial CR-AIR-008 is to evaluate the safety and efficacy of a repeat dose administration of ATIR101 in adult patients with a hematologic malignancy who received a T-cell depleted haploidentical HSCT. ATIR101 is administered at a dose of 2×10^6 viable T-cells/kg at approximately 30 days post-HSCT as was done within the single dose trial CR-AIR-007. The infusion of the second dose of ATIR101 (1×10^6 or 2×10^6 viable T-cells/kg) is done at 72 days after the HSCT.

At the Registration Document Date, 21 patients have been enrolled with 16 given an HSCT, of which nine have been infused with a single dose of ATIR101 and six have been infused with two doses of ATIR101. One patient died between HSCT and ATIR infusion. Follow-up of 11 patients is more than one-year post-HSCT (all of the patients infused with two doses, five of the patients infused with a single dose). The study is ongoing, not all data has yet been monitored, and data is thus subject to change.

Of all 11 patients infused with ATIR101 with more than one year follow-up post-HSCT, two patients developed grade III/IV acute GVHD after ATIR101 infusion, in both cases within 30 days after infusion of the second dose (on day 18 and 25 post second ATIR101 infusion). Two patients developed chronic GVHD after infusion of the second dose of ATIR101.

Summary of cumulative GVHD incidences for patients with more than one year follow-up in trial CR-AIR-008 as at the Registration Document Date

	Dose schedule	
	Single dose (N=5)	**Two doses (N=6)**
GVHD overall	3	5
Acute GVHD grade III/IV	0	2
Acute GVHD grade II	1	1
Acute GVHD grade I	2[(1)]	1
Chronic GVHD	0	2[(2)]

(1) Before ATIR101 infusion
(2) Chronic GVHD occurred in 1 patient after earlier reported acute GVHD

Figure 7.7.1.5 – Source: *Kiadis clinical trial information*

Five patients have died on trial, four due to TRM and one due to disease relapse. All of the deaths reported due to TRM occurred in patients receiving two doses of ATIR101 and three of these four patients suffered from GVHD at the time of death. One patient given a single dose of ATIR101 died, due to disease relapse.

Based on the higher than expected incidence of GVHD and specifically the occurrence of severe (grade III/IV) acute GVHD in patients administered a second dose of ATIR101, it was decided to abandon the administration of the second dose within the trial and continue to

enrol and treat patients with a single dose of ATIR101. The trial has continued to enrol patients with a single dose of ATIR101 and will be followed up for long-term efficacy results (OS). At the Registration Document Date, the trial has been fully enrolled.

The issues with the second dose in the CR-AIR-008 trial will not have a material impact on the potential for ATIR101: the EMA filing and the Phase III clinical trial have been based on the application of a single dose. The flexibility for physicians with a single dose is not impacted. The second dose was explored as a potential upside and to provide additional tools for the physicians.

Five patients in this trial have been treated with a single dose of ATIR101 only, more than one year ago. None of these patients have shown severe GVHD. At 1 year follow-up, for these 5 patients, OS is calculated at 80% and thus in line with the results of the single dose Phase II trial (CR-AIR-007). Of these 5 patients, one patient (20%) experienced RRM and no patient (0%) experienced TRM. Of the 4 patients treated with a single dose of ATIR less than a year ago, one patient has a suspected grade III acute GVHD. The interim conclusion shows the safety and efficacy of ATIR101 as demonstrated in the findings of studies CR-AIR-001 and CR-AIR-007 for patients treated more than a year ago with a single dose of ATIR101 but not with two doses or with the remainder of the single dose patients.

A post hoc analysis has been performed based on all 28 AML/ALL MITT patients that underwent an HSCT and received a single dose of ATIR101 in the CR-AIR-007 (n=23) and CR-AIR-008 (n=5, the patients with more than 1 year of follow-up). Of this MITT population, at 1 year follow-up, OS was calculated at 64% with death reported for 10 patients (36%): 3 patients (11%) experienced RRM and 7 patients experienced TRM (25%). Rates of GVHD are the same as in the MITT analysis for CR-AIR-007. A post-hoc analysis for all 28 AML/ALL MITT patients who received a single dose of ATIR101 was also conducted for GRFS for patients treated with ATIR101, indicating 1 year GRFS to be 61%.

7.7.1.6 CR-AIR-009 - Phase III (ongoing/recruiting)

Kiadis has initiated a pivotal Phase III trial with a head-to-head comparison of HAPLO-HSCT in combination with ATIR101 against HAPLO-HSCT with post transplantation cyclophosphamide (PTCy; a so-called T-cell replete transplantation or the "Baltimore protocol"). This transplantation method originated in academic centres in the United States and is an alternative to T-cell depleted transplantation strategies.

Kiadis is establishing this trial as a multi-centre, randomised, controlled, open-label worldwide trial involving 40-50 sites in Canada, the United States and Europe. Kiadis plans to recruit 195 patients in this trial with the trial designed and powered for 20% difference in GRFS (40% in the PTCy arm and 60% in ATIR101 arm). The trial would have to be increased to 245 patients for an 18% difference in GRFS. Kiadis has submitted the clinical protocol to national authorities in the United States, Canada and Europe and has received regulatory approval in multiple countries to perform the trial. The first patient was enrolled in December 2017.

Based on an End-of-Phase II meeting with the FDA and discussions with Key Opinion Leaders (KOLs) and the Company's advisors, the following framework for this pivotal trial has been established (clinical trial protocol CR-AIR-009 dated 23 November 2016):

- A Phase III, multicentre, randomised controlled study to compare safety and efficacy of a haploidentical HSCT and adjunctive treatment with ATIR101, a T-

lymphocyte enriched leukocyte preparation depleted *ex vivo* of host alloreactive T-cells, versus a haploidentical HSCT with post-transplant cyclophosphamide in patients with a hematologic malignancy (HATCY study).

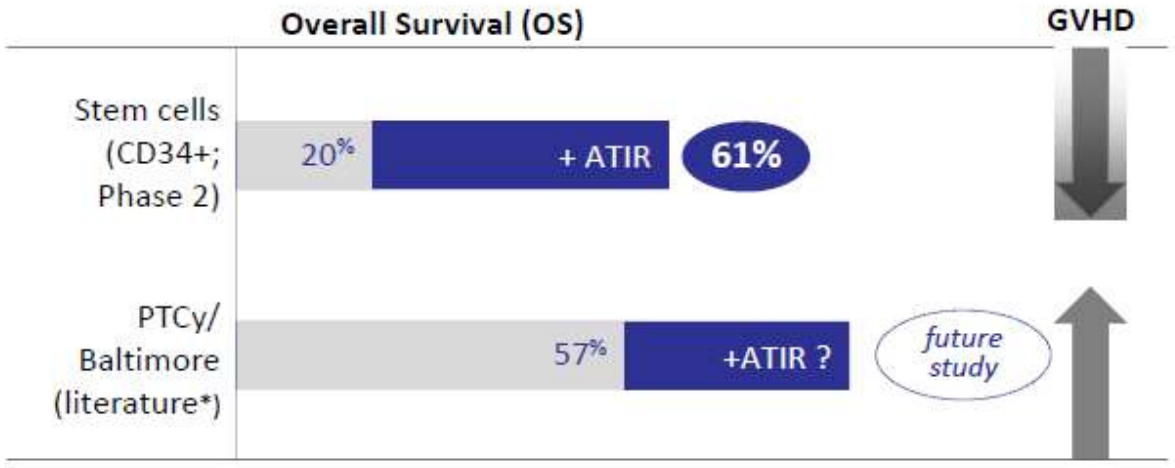
- Adult (18 to 70 years) patients with a hematological malignancy (AML, ALL, or MDS) who are in complete remission and eligible for a haploidentical, T-cell depleted HSCT will be able to participate in the trial.

- 195 patients are planned to be randomised (1:1) to either ATIR101 or a high dose of PTCy. Patients randomised to ATIR101 will receive a single ATIR101 dose of 2.0×10^6 viable T-cells/kg, administered 28 to 32 days after HSCT. Patients randomised in the PTCy group will receive cyclophosphamide 50 mg/kg/day at three days and four to five days after HSCT. All patients will be followed for 24 months after HSCT.

- The primary endpoint of the trial is GVHD-free, relapse-free survival (GRFS), defined as time from randomisation until grade III/IV acute GVHD, chronic GVHD requiring systemic immunosuppressive treatment, disease relapse, or death, whichever occurs first. The study is event driven, and primary analysis will be done at 93 GRFS events and an interim analysis will be done at half the GRFS events. Secondary endpoints will include OS, progression-free survival, RRM and TRM. Safety will be assessed in terms of AEs, clinical laboratory safety parameters, vital signs, and viral monitoring (CMV, EBV).

7.7.1.7 Potential future studies for ATIR101

To further expand use of ATIR101, Kiadis aims to design and initiate additional studies to combine ATIR101 with other haploidentical protocols such as PTCy or α/β T-cell depleted HSCT, and to demonstrate the safety and efficacy of ATIR101 in paediatric patients.



* Ciurea 2015; McCurdy 2017, Devillier 2016, Sugita 2015 (normalization based on Armand 2014); DRI CR-AIR-AIR-007: 53% high/47% intermediate

Figure 7.7.1.7– Note: Comparison provided for illustrative purposes, based on literature comparison, NOT based on randomized controlled trials

The first such additional study which Kiadis intends to initiate is a trial to add ATIR101 to the PTCy approach for haploidentical donor transplantations. Although regarded as an improvement over matched unrelated donor transplantations for GVHD, the PTCy protocol suffers from high relapse rates and still high rates of GVHD (*Fuchs Blood Advances (2017)*). Therefore, and considering the low relapse rate observed in CR-AIR-007, the rationale would be to add ATIR101 to support the patients' immune defense against residual tumour cells. This exploratory trial would provide insight into the potential of ATIR101 in the context of those patients where doctors might prefer to use a PTCy-based haploidentical transplantation. Adding ATIR101 to this approach holds the promise of better relapse prophylaxis and may expand the use of ATIR101. Kiadis currently assumes that the exploratory trial would be conducted in a small number of patients and is aligning with U.S. and EU experts on the best design for such a trial.

7.7.2 ATIR201 for thalassaemia (postponed)

Kiadis started preparing a Phase I/II trial in β-thalassaemia major patients (CR-BD-001). The objective of the trial is to evaluate the safety and feasibility of ATIR201 in paediatric patients with β-thalassaemia major who received a T-cell depleted haploidentical HSCT.

In total, ten paediatric patients with β-thalassaemia major who are eligible for a haploidentical HSCT are to be treated with ATIR201.

A clinical protocol to start the trial has been approved by the national regulatory authorities of the United Kingdom and Germany. Patients have not yet been enrolled and Kiadis has not yet decided when to start this ATIR201 trial and will first establish a safe dose in a paediatric population with a dose finding study in paediatric acute leukemia for ATIR101 within the agreed EMA Paediatric Investigation Program.

Based on discussions with KOLs and the Company's advisors, the following framework for this trial has been established:

- An exploratory, open-label multicentre Phase I/II study to evaluate the safety and feasibility of ATIR201, a T-lymphocyte enriched leukocyte preparation depleted *ex vivo* of host alloreactive T-cells (using photodynamic treatment), as adjunctive treatment to an α/β T-cell depleted haploidentical hematopoietic stem cell transplantation in paediatric patients with β-thalassaemia major.

- Patients will receive an HSCT from a haploidentical donor, followed by ATIR201 infusion of T-cells from the same donor between 28 and 32 days after the HSCT.

- Inclusion criteria: Hypertransfusion program, iron chelation therapy initiated or at risk of transfusional iron overload and Lansky performance score > 70%.

- Eligible for haploidentical stem cell transplantation according to the investigator taking into account the feasibility of transplanting patients with pre-existing antibodies.

- Male or female, age ≥ 2 years and ≤ 16 years.

- Safety and tolerability will be primarily evaluated by the occurrence of acute graft-versus-host disease (GVHD) grade III/IV within 180 days post HSCT. Efficacy will be primarily evaluated by transfusion-free survival (TFS), occurrence of severe

infections, and time to T-cell reconstitution, taking into account hematologic and sustained engraftment.

7.8 Competition

The biotechnology industry, including in the immunotherapy field, is characterised by rapidly advancing technologies, intense competition and a strong emphasis on intellectual property. Kiadis faces competition from different sources, including from a protocol used in academic centres, as well as from a number of large and specialty biotechnology companies.

Post Transplantation Cyclophosphamide (PTCy, the 'Baltimore protocol')

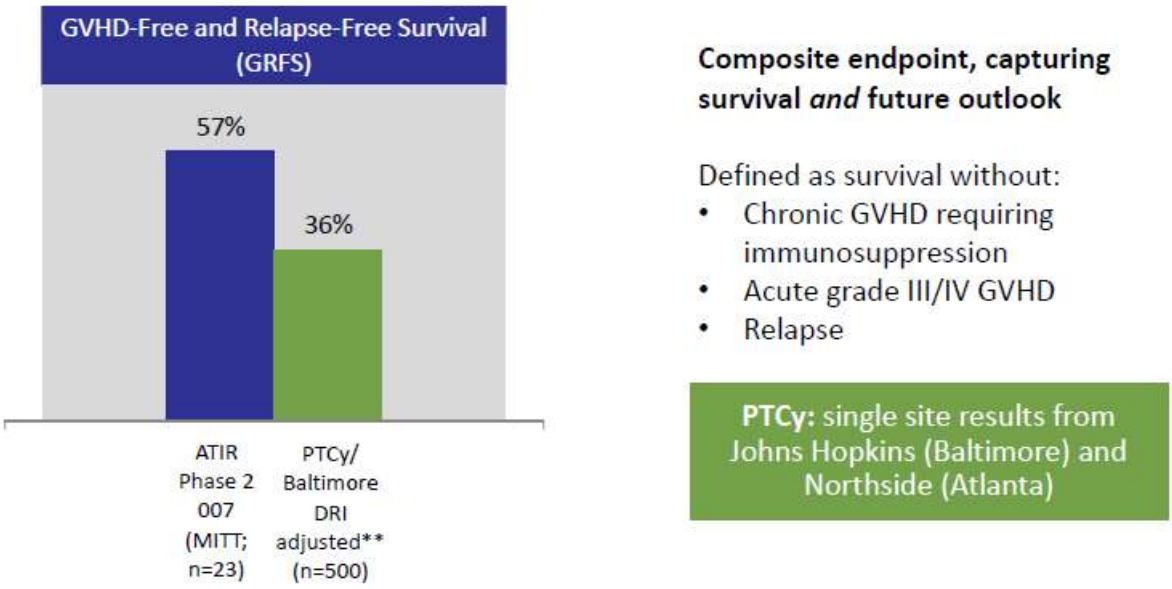
In recent decades, clinicians have initiated several investigator-led trials assessing approaches that allow the use of partially matched (haploidentical) family donors without the need for elimination of T-cells from the graft (T-cell replete transplantation).

The most widely adopted approach involves the post transplantation treatment with cyclophosphamide. In this approach, patients are given a high dose of the cytotoxic agent cyclophosphamide shortly after transplantation in order to suppress the immediate immune response of alloreactive T-cells from the donor in the graft, with additional use of immune suppressants for a prolonged period post HSCT.

The academic group around Ephraim Fuchs at Johns Hopkins University in Baltimore spearheaded the PTCy approach. His approach is referred to in academic literature as the "Baltimore protocol" (*Luznik et al., Biol Blood Marrow Transplant (2008); 14(6): 641-650*). Advantages of this approach are its low cost and simplicity. The protocol allows use of family donors without further manipulation. Cyclophosphamide is off patent, and is used off label for this purpose. Drawbacks of this approach are the need for prolonged immunosuppression, the still high rate of severe GVHD and relapses, and the toxicity of cyclophosphamide. Kiadis believes the considerable focus from the clinical community underscores the demand and unmet medical need for a viable solution to the use of haploidentical donors for HSCT.

For the design of Kiadis' Phase III CR-AIR-009 trial, the available literature for PTCy on GVHD and GRFS was screened. GRFS is a composite endpoint that is increasingly adopted in the medical community that captures immediate and future survival and quality of life. For GRFS for the PTCy/Baltimore protocol, two relevant publications were identified and, based on the results presented in these publications, one year GRFS is 37% for PTCy after a normalisation on the basis of the Disease Risk Index (*Armand (2014)*). In comparison, one year GRFS with ATIR101 was 57% based on Phase II data from CR-AIR-007. See Figure 7.8(a) below.

Phase 2 (007): GRFS versus literature for PTCy/Baltimore (1 yr)



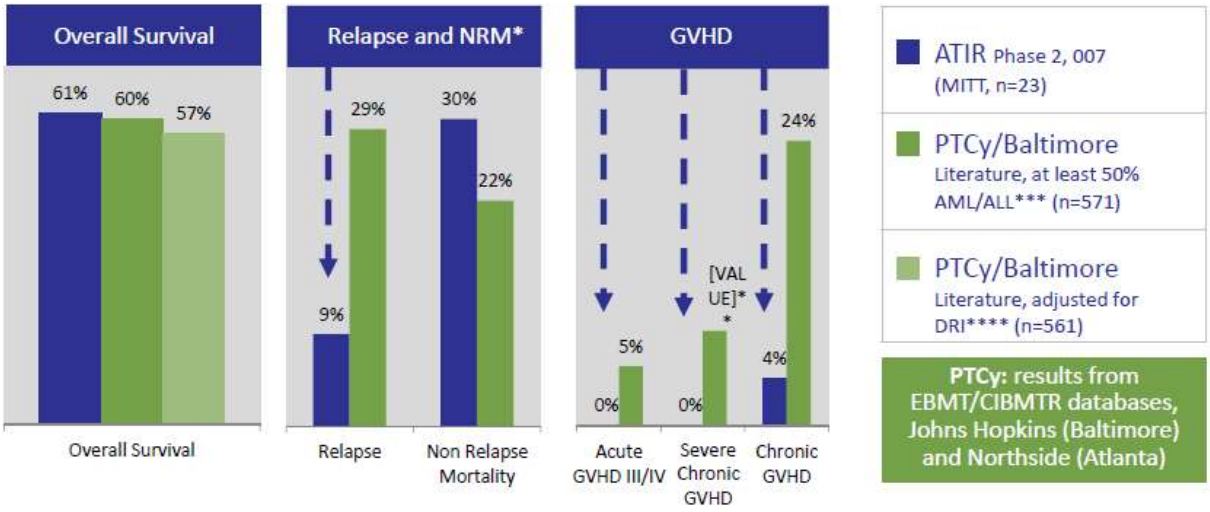
* 23 patients from CR-AIR 007 (study completed) plus 5 patients from CR-AIR 008 that have completed 1 year follow up with single dose

** Solh 2016 (Atlanta; DRI normalised GRFS 30%; n=128); McCurdy 2017 (Johns Hopkins; DRI normalised GRFS 38%; n=372)

Figure 7.8 (a) – Note: Comparison provided for illustrative purposes, based on literature comparison, NOT based on randomised controlled trials

To provide further insight to the results with the PTCy protocol versus ATIR101 ahead of the Phase III CR-AIR-009 head-to-head randomised controlled trial, Kiadis performed a screening of the available literature data for the Baltimore protocol. Publications were selected that were based on PTCy with at least 50% AML/ALL patients, that involved myeloablative conditioning and that dated from after 2008 (publications) or 2013 (posters). The average OS, relapse, GVHD grade III/IV and chronic GVHD rates for the PTCy protocol in those publications were calculated by taking the results in the different publications weighted by the number of patients. Differences in Disease Risk Index were assessed, and a normalisation for DRI performed for OS. Figure 7.8(b) below provides the outcome of the comparison. This literature comparison supports the conclusion that ATIR101 can offer an improvement versus PTCy.

Phase 2 (007): relapse & GVHD vs literature for PTCy (1 yr)



* PTCy: Relapse: of which 11% relapsed and 18% relapsed and died
** Solomon 2012; Ciurea 2012; Esquirol 2016
*** Ciurea 2015; Piemontese 2017; Solomon 2012; Ciurea 2012; Devillier 2016; Di Stasi 2014; Esquirol 2016; Sugita 2015
**** Ciurea 2015; McCurdy 2017; Devillier 2016; Sugita 2015 (normalisation based on Armand 2014); DRI CR-AIR-AIR-007: 53% high/47% intermediate

Figure 7.8(b) – Note: Comparison provided for illustrative purposes, based on literature comparison, NOT based on randomised controlled trials

The various post hoc analyses for OS and GRFS, based on ITT and MITT populations, for either CR-AIR-007 or CR-AIR-007 and CR-AIR-008 combined (with, for the CR-AIR-008, n=5, the patients with more than 1 year of follow-up) with DRI normalisations that match the DRI of these patient populations, are summarised in Figure 7.8(c) below.

Phase 2 (007/008) vs PTCy literature (1 yr)

* 23 AML/ALL patients from CR-AIR 007 (study completed) plus 5 AML/ALL patients from CR-AIR 008 that have completed 1 year follow up with single dose (008 data not all monitored and thus subject to change); for 28 AML/ALL 007/008 patients: Relapse rate 11% and NRM 25%, chronic GVHD 4%
** Ciurea 2015 (CIBMTR); McCurdy 2017 (Baltimore), Devillier 2016, Sugita 2015 (57% high DRI; normalisation based on Armand 2014)
*** Solh 2016 (Atlanta; DRI normalized GRFS 30%; n=128); McCurdy 2017 (Johns Hopkins; DRI normalized

GRFS 38%; n=372)

Figure 7.8(c) - Note: Comparison provided for illustrative purposes, based on literature comparison, NOT based on randomised controlled trials

Partially T-cell depleted grafts: Miltenyi

Another approach to enable haploidentical transplantations relies on the depletion of certain populations of T-cells that elicit GVHD from the donor material while preserving other populations of T-cells that do not elicit GVHD. The most prominent such approach is the elimination of T-cells carrying the α/β-receptor (α/β depleted-T-cells). α/β-T-cells are crucial for the specific attack of virus infected cells or cancerous cells. What remains after depletion of α/β-T-cells are so-called γ/δ-T-cells. Those cells still provide some immunity to the patient but at a more unspecific ("innate") level.

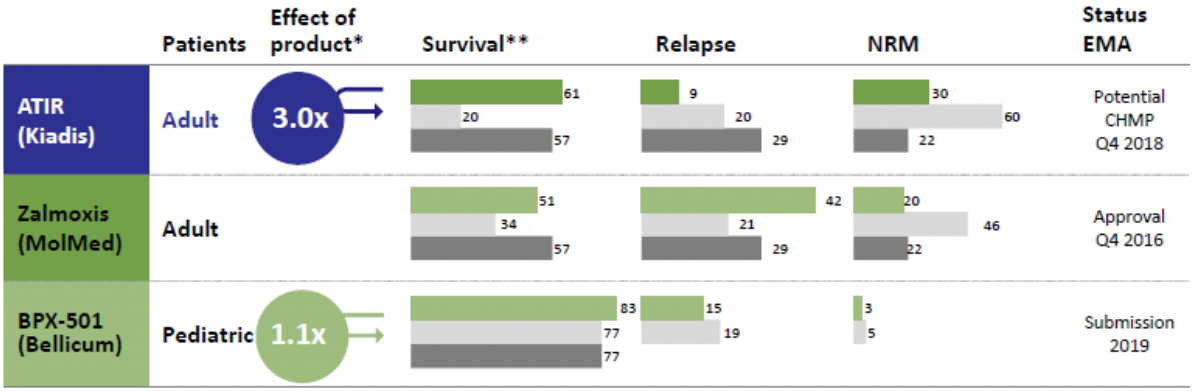
This approach is spearheaded primarily by an academic group at Tuebingen University in Germany, partially sponsored by Miltenyi, which develops and markets devices and tools for α/β-T-cell -depletion (the Clinimacs system). Investigators claim a superior result versus CD34+ selected stem cell grafts and results equivalent to MUD and cord blood in paediatric studies (*Lang et al., Bone Marrow Transplantation (2015); 50: S6-S10*). However, data in adult patients is still very limited.

ATIR can be combined as adjunctive product to an α/β -T-cell depleted HSCT. The first trial with ATIR201 will be performed with α/β-T-cell depleted grafts. Whereas studies with ATIR101 to date have been performed with a CD34+ selected stem cell only HSCT, Kiadis also aims to perform additional studies in blood cancers with α/β-T-cell depleted grafts. Of note is that Bellicum has performed studies both in CD34+ selected grafts and α/β-T-cell depleted grafts.

Other manipulated Donor Lymphocyte Infusion products as adjunctive to haploidentical HSCT: MolMed (Zalmoxis) and Bellicum (BPX-501)

Bellicum and MolMed are developing manipulated DLI product candidates to improve the outcome of haploidentical HSCT in cancer. Like Kiadis, the approach of Bellicum and MolMed relies on the infusion of a T-cell depleted haploidentical HSCT, either a CD34+ stem cell only graft (MolMed and Bellicum) or a α/β T-cell depleted graft (Bellicum), followed by a donor lymphocyte infusion to provide mature T-cells with immediate protection against infections and relapse.

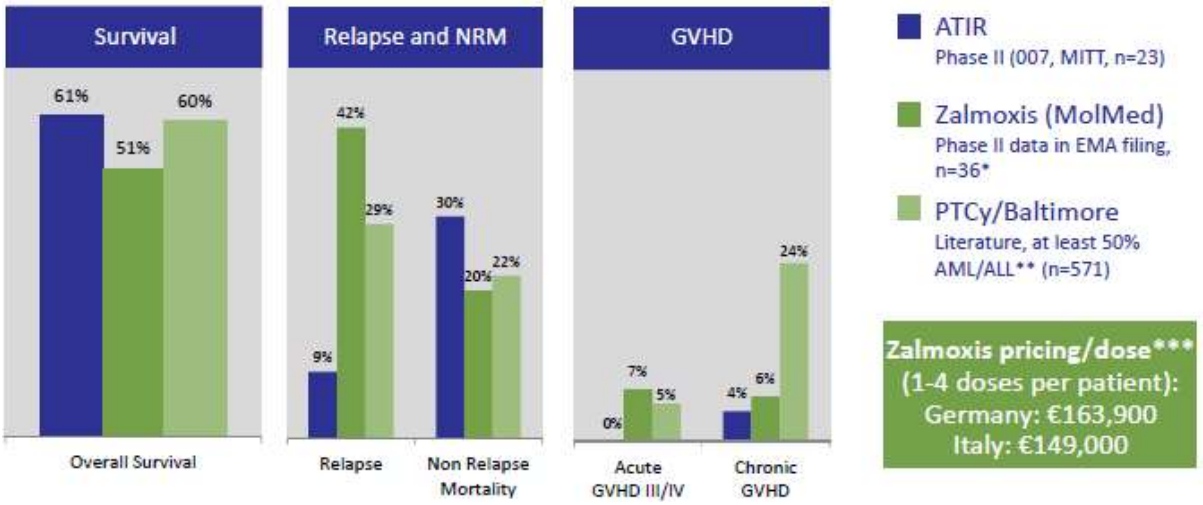
The difference between Kiadis and both MolMed and Bellicum is the approach towards manipulation of the T-cells in the DLI product. ATIR101 is depleted for alloreactive GVHD causing cells *ex vivo* (preventive strategy). Zalmoxis (MolMed) and BPX-501 (Bellicum) are genetically manipulated DLI products, resulting from the insertion of a suicide gene into the immune cells with a viral vector. Should the immune cells after dosing into the patient elicit GVHD, an agent can be infused to trigger suicide of the transplanted cells (treatment strategy). The agent to trigger the suicide switch is ganciclovir for Zalmoxis (an anti-viral agent commonly used to treat or prevent cytomegalovirus (CMV) infections) and rimiducid for BPX-501. Figure 7.8(d) below provides an overview of Zalmoxis, BPX-501 and ATIR data.



* ATIR 007 MITT data (N=23). Matched historical control for Zalmoxis includes T-cell replete and T-cell deplete, thus effect of product cannot be determined
** Leukemia Free Survival for BPX-501 (BPX-501 Overall Survival is 89%, Overall Survival not reported for controls);
*** Adults PTCy, pediatric MUD; except for ATIR not DRI adjusted/matched
Low GVHD for all three; 5% Grade III/IV for BPX-501 (resolved after rimiducid)
Source: CHMP Assessment report (Zalmoxis); Merli EHA 2017 (BPX-501); Locatelli 2017 (BPX-501)

Figure 7.8(d) – Note: Comparison provided for illustrative purposes, NOT based on randomised controlled trials

MolMed obtained conditional EMA approval for Zalmoxis as adjunctive to a haploidentical donor HSCT on 22 August 2016. Approval was granted on the basis of a comparison of Phase II data for 36 patients (mostly with leukaemia) with data from a matched historical control. Zalmoxis does not yet appear to have re-imbursement authorisation, however, it is currently priced in Italy at €149,000 and in Germany at €163,900 per dose (*See MolMed Press Releases dated 13 December 2017 and 16 January 2018*). A Phase III trial (TK008) was started in 2010 and is estimated to be completed in December 2018 (Clinicaltrials.gov; NCT00914628). Kiadis believes that ATIR101 is competitively positioned versus Zalmoxis, based on a comparison between the CR-AIR-007 and CR-AIR-008 results and the Zalmoxis data published by MolMed and included in the EMA CHMP Assessment report (23 June 2016, EMA/CHMP/589978/2016).



* CHMP Assessment report (aGVHD III/IV: Kempen 2017 report); CD34+ HSCT; 74% AML; 10% ALL; 16%MDS/NHL/HD; patients receiving Zalmoxis
** Ciurea 2015 (CIBMTR); Piemontese 2017 (EBMT), Solomon 2012 (Atlanta), Ciurea 2012; Devillier 2016; Di

Stasi 2014; Esquirol 2016; Sugita 2015
*** Prices as at 16 January 2018 and 13 December 2017, respectively

Figure 7.8(e) - Note: Comparison provided for illustrative purposes, based on literature comparison, NOT based on randomised controlled trials.

Bellicum is conducting several Phase I/II studies with BPX-501 as adjunctive to a haploidentical donor HSCT, in patients with blood cancers and inherited blood disorders, both paediatric and adult. To date, only data in paediatric patients has been communicated by Bellicum. The 1 year data for Bellicum's Phase II trial shows a survival rate of 80%, a relapse rate of 30% and non-relapse mortality rates at 0%, illustrating a low rate of GVHD at high doses of T-cells with 3 out of 4 patients treated with rimiducid (see Figure 7.8(d) above). Recently, Bellicum's Phase II study was put on clinical hold triggered by safety concerns (encephalopathy). Given the lack of available data in adult leukaemia, it is not possible to perform a like-for-like a comparison between ATIR101 and BPX-501.

The use of umbilical cord derived stem cells

Companies such as Gamida Cell Ltd. ("**Gamida Cell**") have been working to address the limited number of umbilical cord stem cells available by developing methods to expand them in the laboratory to have sufficient numbers for efficient transplantation and engraftment. Gamida Cell's lead product NiCord® is under development for patients that do not find a matching donor and as an alternative to haploidentical transplantation. Although this approach in principle may have promise and increase the likelihood of success of using cord blood, it will not resolve the problem that fully functional and pathogen specific memory and effector T-cells will not be present in cord-blood and hence not provide immediate immune protection to patients against certain opportunistic or other pathogens. Gamida Cell has initiated a Phase III study with NiCord® in patients with haematological malignancies in November 2016, which is estimated to be completed in August 2019 (Clinicaltrials.gov; NCT02730299).

Gene therapy approaches (inherited blood disorders): Bluebird Bio

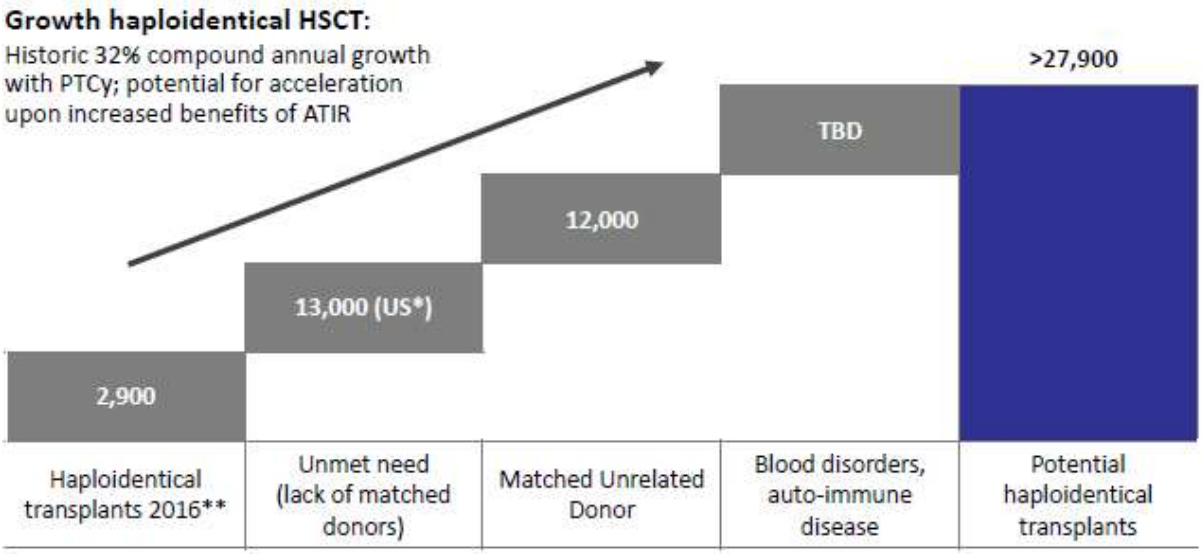
Bluebird Bio Inc. is focused on clinical studies for LentiGlobin 3305, a gene therapy inserting a functional human beta-globin gene into the patient's own stem cells *ex vivo* and then transplanting those modified cells into the patient through infusion into the bloodstream. The FDA has granted breakthrough therapy designation to LentiGlobin 3305 for the treatment of transfusion-dependent patients with β-thalassaemia major.

7.9 Market opportunity

Based on available scientific literature, Kiadis estimates that - in the future - up to approximately 27,900 patients each year in the EU and the United States combined could benefit from an improved haploidentical transplantation (see Figure 7.9 below). This estimate includes (i) 2,900 patients who received a haploidentical transplantation in 2015, (ii) 13,000 patients eligible for transplantation but no transplantation has yet occurred due to the lack of a matched donor as indicated by scientific literature (*Besse 2015* (U.S. only)), and (iii) 12,000 patients currently receiving MUD and cord blood transplantations, which may be replaced with haploidentical transplantations. Recent growth in the use of haploidentical HSCT (currently 32% annual growth in the U.S.) supports this estimation (see Figure 7.9 below). In addition, Kiadis believes there is also potential upside from broader HSCT application with ATIR based on an improved HSCT treatment, which could accelerate the upward trending

annual growth rates of haploidentical HSCT transplants (see Figure 7.9 below). Kiadis believes that this market landscape presents a sustainable opportunity for ATIR.

ATIR potential for (improved) haploidentical HSCT



* EU Not Known; ** EU 2000, US 900

Figure 7.9 - Source: CIBMTR 2017 Summary Slides; Passweg (2017); Besse (2015)

Different haploidentical transplantation approaches exist to serve these potential patients. In a survey conducted by Defined Health in 2013, transplant physicians and KOLs in the U.S. and the EU indicated that they would use ATIR in an average of 58% of their haploidentical transplantation patients (*ATIR Assessment, September 2013 by Defined Health*). Given the positive responses from treatment physicians and the overall size of potential patient population requiring treatment, Kiadis believes that ATIR101 could be the approach of choice for a significant portion of the available haplo HSTC market.

In the U.S., hospitals are typically not reimbursed for pharmaceuticals administered to the in-patient population. However, injectable medications administered in an out-patient setting could be eligible for reimbursement. Kiadis believes that in the U.S., ATIR could potentially be reimbursed as an out-patient infused drug, outside of the DRG (Diagnosis-related group) reimbursement system for the HSCT itself. This means that the cost of ATIR treatment can potentially be invoiced to third-party (including government) payers, with a mark-up. The costs of allogenic HSCTs and related complications per patient can be markedly high (see Figures 7.9(a) and (b) below) (excluding the lifelong costs for patients living with chronic GVHD) (*Broder 2017; Milliman 2017*). Third-party payers in the U.S. are increasingly examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. Kiadis believes that the aim of ATIR as a preventative treatment and the cost savings associated therewith strengthens its case for reimbursement.

Total HSCT costs	Period / Source
$401,000 (MA) $301,000 (RIC)	*100 days*; Broder 2017
$549,000 (MA) $432,000 (RIC)	*1 year*; Broder 2017
$893,000	*180 days;* Milliman 2017**

Figure 7.9(a)
* Includes inpatient/outpatient/pharmacy costs
** Includes different physician charges, graft procurement costs

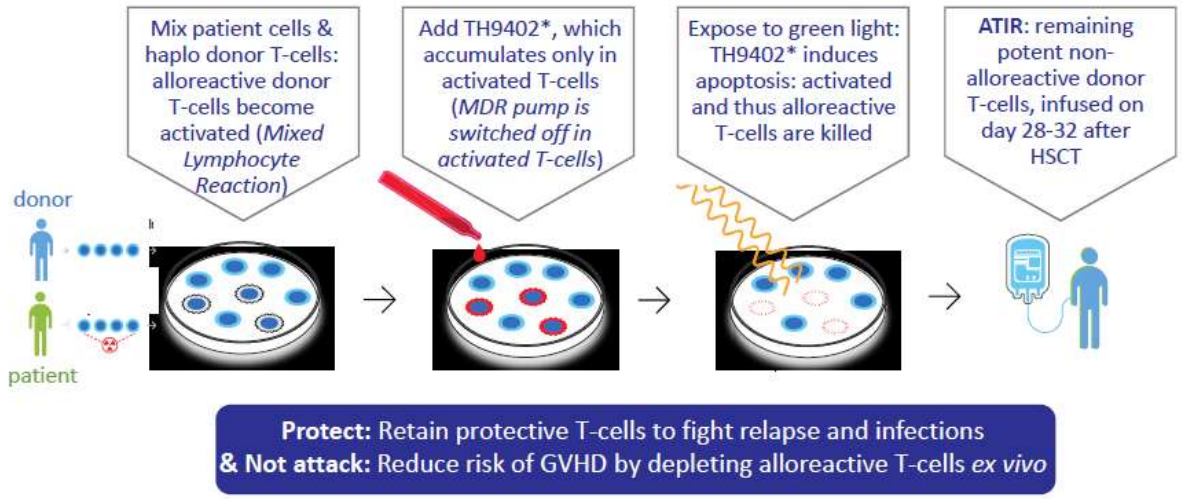
HSCT complications	Costs to healthcare system (US)
Cancer death	$165,000
Relapse	$69,000*
Hemorrhagic cystitis	$242,000*/**
Acute GVHD	$527,000*
Chronic GVHD moderate/mild	$124,000 ($14,400 per year***)
Chronic GVHD severe	$322,000 ($37,400 per year***)

Figure 7.9(b) - Sources: Mariotto 2011; Yu 2017; Broder 2017; Khera 2014; literature PTCy analysis
* Cost based on Broder total cost and cost multiplier Khera
** Side effect of cyclophosphamide
*** 10 years, discounted

7.10 Introduction to Kiadis' key technology – the Theralux platform

ATIR consists of donor T-cells that have been selectively depleted of those T-cells that recognise the patient as "non-self", but retain other T-cells able to fight relapse and infections.

The selective depletion of GVHD-causing T-cells from the donor graft occurs through Kiadis' Theralux platform technology. This T-cell manipulation technology is shown schematically in Figure 7.10(a) below.



* TH9402 – proprietary selective rhodamine derivative, modified to become cytotoxic under green light

Figure 7.10(a) – Source: *Kiadis Pharma N.V.*

The recognition of the patient as 'non-self' (i.e. foreign) by the donor T-cells is mimicked in the laboratory. This occurs through the activation of donor T-cells against the major histocompatibility complex (MHC) antigens on the irradiated recipient's cells through a one-way mixed lymphocyte reaction (MLR), in which irradiated patient cells are mixed with donor T-cells. This results in activation of those donor T-cells that recognise recipient cells as 'foreign', while the other T-cells remain unactivated.

Kiadis' photosensitising reagent TH9402 (a rhodamine derivative) is added to the cells after four days. In unactivated cells, a P-glycoprotein pump also involved in drug resistance of

cells transports foreign molecules such as TH9402 out of the cells. However, in activated T-cells this pump is switched off. This distinction between activated and unactivated T-cells, results in the retention and accumulation of TH9402 in those donor T-cells that recognise the patient cells as 'foreign'.

TH9402 is then transformed into its toxic form by exposing the cell culture to visible green light using Kiadis' Theralux device. The temperature controlled Theralux device operates at a fixed wavelength of 514nm to activate the photosensitive compound TH9402 with accurately and precisely dosed light (e.g. 5 J/cm^2). Upon absorption of a photon of the appropriate wavelength, the photosensitiser TH9402 enters an excited state, which results in the production of singlet molecular oxygen. If produced in sufficient quality, the singlet oxygen molecules induce cell death in the T-cells in which TH9402 was retained. Consequently, the toxic form of TH9402 kills those T-cells that have retained the dye because they were activated and attacking patient cells.

Thus, the mixture is depleted of immune cells that can cause GVHD. The remaining cells include immune cells that can fight infective agents, as well as T-cells that can fight any remaining tumour cells.

ATIR is formulated for infusion and cryopreserved by cooling to below minus 135C° until use. ATIR is infused into the patient 28 to 32 days after the transplantation of a haploidentical HSCT.

Figure 7.10(b) - Kiadis' Theralux device

7.11 Manufacturing

ATIR allows for central manufacturing with the potential for attractive COGS (cost of goods sold) versus genetically engineered cell therapy. It entails a five-day manufacturing process with only two operating days and without genetic engineering (which eliminates the need for viral vectors). As a result, manufacturing can be done in simple clean rooms with laminar flow cabinets (no requirement for Biosafety Level 2 (BL-2) facilities), with the potential for a modular facility buildout. Kiadis has established a GMP-compliant, robust manufacturing process that has been successfully transferred to multiple GMP-manufacturing sites. The manufacturing data and the development plan for future improvements have been submitted to the EMA and the EMA has awarded Kiadis an advanced therapy medicinal product (ATMP) certificate of quality and non-clinical data for ATIR in April 2015.

Kiadis has entered into an agreement to lease an existing commercial manufacturing facility,

which includes process development and quality control laboratories, as well as space for Kiadis' headquarters in Amsterdam, the Netherlands. The facility is located at Paasheuvelweg 25A in Amsterdam, the Netherlands. The in-house manufacturing capability will allow the Company to enhance flexibility and expand capacity, and will not affect the ongoing contract manufacturing collaborations. Manufacturing from this new facility is not expected to start in 2018.

7.11.1 Process development

The first clinical trial (CR-GVH-001) conducted in Montreal, Canada was performed with a labour-intensive manual process that included several steps that would not be compliant with current GMP. After the conclusion of this first study, Kiadis optimised the manufacturing process to allow for centralised manufacturing at a CMO. During this optimisation, no comparison of the old process versus the new process was conducted to compare the quality of the two processes directly. During clinical trial CR-AIR-004 (see paragraph 7.7.1 above), it was observed that the changed process resulted in a product with poor quality parameters that did not meet the key characteristics of ATIR101 and therefore did not qualify as ATIR101. Upon identifying this, the trial was terminated and the manufacturing process was completely abandoned. Kiadis abandoned the process changes that had been made to the initial process, re-visited the original manufacturing process used in the CR-GVH-001 study and used that process as the sole basis for further optimisation. Based on the original manufacturing process used in the first clinical trial, Kiadis has developed a robust manufacturing process that was used in the CR-AIR-007 Phase II clinical trial. Kiadis has gained valuable experience from the CR-AIR-004 clinical trial and believes it has overcome the initial manufacturing issues, as demonstrated by the EMA granting Kiadis a certification of quality and non-clinical data for ATIR for advanced therapy medicinal products, and as evidenced by the positive results of the Phase II CR-AIR-007 study.

The development of the successful GMP-compliant manufacturing process for CR-AIR-007 was guided by elements of Quality-by-Design that resulted in a clear definition of the critical quality attributes (CQAs) of ATIR101. For each of those quality attributes, an assay was developed and implemented that allows the monitoring of these essential characteristics of the cell therapy product. The assays monitoring the CQAs are routinely performed for the Quality Control release of ATIR101 for use in the clinical setting.

The continued CQA-guided development of Kiadis' product candidates has resulted in the successful establishment of further optimised manufacturing processes for clinical studies CR-AIR-008 and CR-AIR-009.

7.11.2 Product release assays

ATIR101 is a personalised cell based medicinal product that is manufactured on an individual basis from biological starting materials collected from the patients and the corresponding donor. Consequently, there is an inherent variation in the biological starting materials used, and thus an inherent variability in the manufacturing results.

A pivotal release assay is therefore the functional safety and potency assay as exemplified in Figure 7.11.2 below. This figure depicts the functional 'fingerprint' of ATIR101. The blue bars represent the immune-reactivity of cells from the donor prior to having been manufactured into ATIR101 and the green bars represent the immune-reactivity of ATIR101 (i.e. after the allo-depletion process); the y-axis (proliferation index) is a measure of immune-reactivity. The donor cells (blue) and ATIR101 (green) display little reactivity in the control setting, yet

the cells collected from the donor prior to manufacture react strongly to the cells of the recipient (patient), indicative of the potential to elicit GVHD. In contrast, ATIR101 no longer shows significant reactivity towards the recipient, an important confirmation of successful depletion of alloreactive T-cells and a measure of functional safety of the product. Both donor cells and ATIR101 still exhibit comparable immune-reactivity towards 3rd party antigens (i.e. cells from individuals other than the donor and patient) and towards a poly-clonal T-cells stimulus, anti-CD3/CD28, a measure of potency of the remaining T-cells in ATIR. Together, this data shows that after manufacturing, ATIR101 no longer responds to the patient cells (recipient) but has retained its reactivity towards other stimuli.

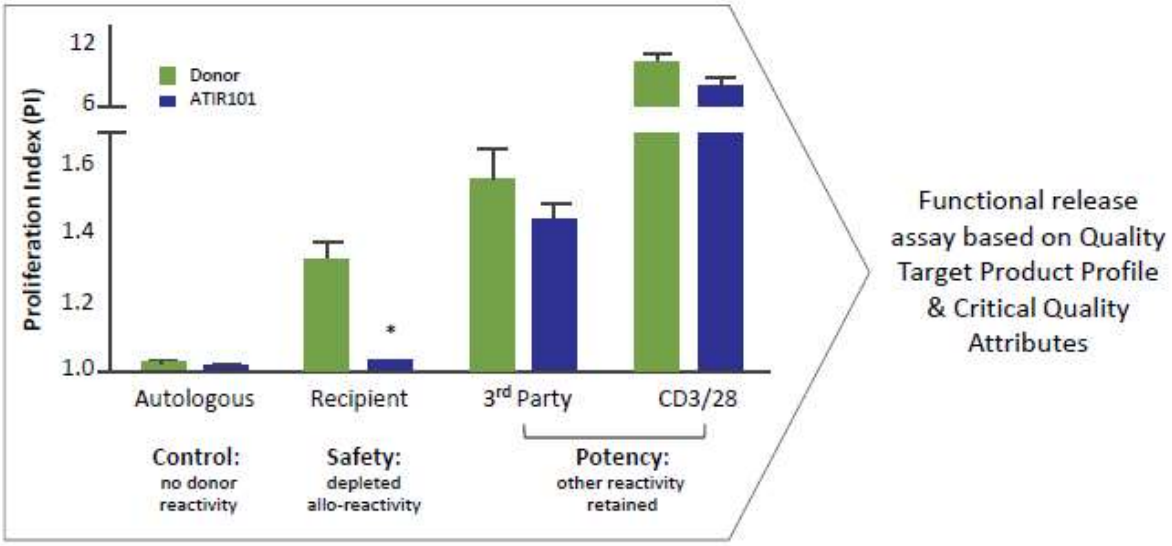


Figure 7.11.2 – Source: *Bonig ISCT 2017*

7.11.3 Manufacturing sites

Currently, Kiadis' manufacturing process is conducted at the:

GMP facility of the Blood-Donor Services Baden-Württemberg-Hessen of the German Red Cross in Frankfurt/Main, Germany.

The manufacturing process was first transferred into this facility in 2013 and has been included in the GMP manufacturing licence of this site by the local authorities in accordance with European Union regulations. This site manufactured ATIR101 for the European and Canadian clinical centres in clinical study CR-AIR-007, manufactures ATIR101 for the current Phase II clinical trial CR-AIR-008 and will manufacture ATIR101 for the Phase III clinical trial CR-AIR-009.

Kiadis' laboratories in Amsterdam, the Netherlands

Kiadis' laboratories in Amsterdam are run under its GMP licence for certain parts of ATIR-release analytics. Specifically, all potency testing of Kiadis' ATIR101 for the CR-AIR-007 trial and the CR-AIR-008 trial is conducted at this site and will be conducted at this site for the CR-AIR-009 trial.

Continuous development efforts are dedicated to the further optimisation of the manufacturing process, and to develop increasingly refined methodologies to assess quality

and potency of ATIR. Manufacturing at this site is solely done for development purposes and not under formal GMP conditions.

Future in-house and CMO manufacturing sites

Kiadis secured a lease to an existing commercial manufacturing facility in Amsterdam, which will be use for process development, ATIR release analytics and clinical and commercial manufacturing of ATIR. In addition, Kiadis is currently exploring the most suitable additional CMO manufacturers for its (future) trials and for ATIR production generally, if (conditional) marketing approval is obtained in the European Union. The number of suitable manufacturing sites and contract manufacturing organisations has been increasing during the last few years and Kiadis anticipates that the number of options will further increase, reflecting the rapid emergence of the cell-based therapeutics sector.

7.12 Biosimilars and Exclusivity

The 2010 Patient Protection and Affordable Care Act (the "**Act**") in the U.S. authorised the FDA to approve biosimilars. Under the Act, a manufacturer may submit an application for licensure of a biologic product that is "biosimilar to" or "interchangeable with" a previously approved biological product or "reference product." In order for the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and proposed biosimilar product. A finding of "interchangeability" requires that a product is determined to be biosimilar to the reference product, and that the product can be expected to produce the same clinical results as the reference product. Due to the personalised nature of Kiadis' ATIR products, being a cell based medicinal product that is manufactured on an individual basis from biological starting materials collected from the patients and the corresponding donor, Kiadis believes that under the current biosimilar regime approval by the FDA of products biosimilar to Kiadis' ATIR is unfeasible, offering Kiadis potential market exclusivity for ATIR if approved.

7.13 Orphan drug designations

7.13.1 Strategy

Kiadis' strategy is to initially apply its ATIR products and its Theralux technology to indications for which it currently has orphan drug status, or for which it expects to qualify for orphan drug status in the future. This will allow Kiadis to obtain market exclusivity for these products, in particular 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 (see also paragraph 8.2.1 below).

7.13.2 Orphan drug designations granted

To date, Kiadis has been granted five orphan drug designations. Two in the U.S. for ATIR101 (i) for immune reconstitution and prevention of GVHD following HSCT and (ii) for prevention (reduction) of TRM caused by GVHD or infections following partially matched (haploidentical) HSCT. In addition, Kiadis has been granted orphan drug designations in the European Union

for ATIR101 (i) for the prevention of GVHD, (ii) for the treatment of AML and (iii) for the treatment in HSCT, regardless of the underlying disease.

7.14 Intellectual property

7.14.1 Strategy

Intellectual property rights are of importance to the success of Kiadis' business. It is part of Kiadis' policy to actively seek patent protection for inventions it deems valuable. Thereto, Kiadis periodically evaluates the results of its research and development activities, and decides whether to apply for new patents. Kiadis keeps part of the results as confidential know-how.

Kiadis' research activities are performed by researchers employed by Kiadis (including its predecessors), as well as by external researchers. The employment contracts of Kiadis' employees and external researchers contain confidentiality and intellectual property assignment clauses. With respect to its personnel, this policy is also included in Kiadis' personnel handbook.

To avoid the potential risk of infringing patent rights of third parties, Kiadis has conducted freedom-to-operate analyses (FTO) for its product candidates. For example, an FTO was conducted for ATIR in 2014. If necessary, Kiadis will attempt to take the necessary action to license or acquire relevant third-party patent rights. As at the Registration Document Date, Kiadis has not identified any relevant third-party patent rights.

Kiadis aims for patent protection in key jurisdictions. The filing strategy usually comprises filing a first patent application with the U.S. Patent and Trademark Office, the Canadian Intellectual Property Office or the European Patent Office, to obtain a priority right. Within one year, this first filing is usually followed by an application under the Patent Cooperation Treaty (PCT). This PCT application forms the basis for further patent applications in selected jurisdictions. In the past, these included the United States, (a number of jurisdictions in) Europe, Japan, Australia, and Canada. In the future, Kiadis aims to seek patent protection in China and has in fact done so in respect of its P040 patent family (see below) where a patent application was submitted to the Chinese patent authorities in August 2017.

On becoming aware of an infringement of its intellectual property, Kiadis will evaluate the various options available to protect its position. Under its licence agreement with the University of Montreal and Maisonneuve-Rosemont Hospital (see paragraph 7.18 below), Kiadis is obliged to take all appropriate measures required to protect the intellectual property rights it has licensed under such agreement.

7.14.2 Patents and patent applications owned or licensed-in by Kiadis

In relation to the following families of patents and patent applications in connection with its Theralux platform based products, Kiadis has rights either as owner (P019 and P040) or as exclusive licensee (P015 and P016) within the scope of the relevant licence.

P015 family

Title	Registered in the name of	Patent number	Claimed priority date	Expiry date
Rhodamine derivatives for photodynamic diagnosis and treatment	Université de Montréal/Hôpital Maisonneuve-Rosemont	US 8,409,564 B2	5-10-1999	18-10-2021
Rhodamine derivatives for photodynamic diagnosis and treatment	Université de Montréal/Hôpital Maisonneuve-Rosemont	US 8,802,082 B2	5-10-1999	3-10-2020
Rhodamine derivatives for photodynamic diagnosis and treatment	Université de Montréal/Hôpital Maisonneuve-Rosemont	EP 1 267 931 B1	5-10-1999	3-10-2020

Family P015 comprises granted patents in Canada (CA 2,382,885), Australia (AU 781855), Japan (JP 4859319 and JP 5476342), Korea (KR 10-0697400), and Mexico (MX 263362) as well.

This family relates to methods of treatment for reducing or preventing GVHD and a pharmaceutical composition to be used in this method.

P016 family

Title	Registered in the name of	Publication number	Claimed priority date	Expiry date (if granted)
Immunologic compounds for prevention, protection, prophylaxis or treatment of immunological disorders, infections and cancer	Université de Montréal/Hôpital Maisonneuve-Rosemont	EP 1701740 A1[(1)]	5-12-2003	2-12-2024

[(1)] The application EP 1701740 A1 is currently under examination and, as with all applications, may or may not be granted.

Family P016 comprises granted patents in Canada (CA 2,548,468), Australia (AU 2004294243), Japan (JP 4901479) and Mexico (MX 299241). The expiry dates for these patents is 2 December 2024.

In addition to the pending applications in Europe, family P016 comprises granted patents in Canada (CA 2,548,468), Australia (AU 2004294243), Japan (JP 4901479) and Mexico (MX 299241).

This family relates to the use of fragments or supernatant from photodynamically treated cells for preparing vaccines against haematological tumours or for treating an immunological disorder.

P019 family

Title	Registered in the name of	Patent number	Claimed priority date	Expiry date
Halogenated rhodamine derivatives and applications thereof	Celmed Biosciences Inc.	US 7,560,574 B2	2-4-2001	28-01-2024
Halogenated rhodamine derivatives and applications thereof	Kiadis Pharma Canada Inc.	US 8,383,672 B2	2-4-2001	27-03-2022
Halogenated rhodamine derivatives and applications thereof	Kiadis Pharma Canada Inc.	US 9,636,363 B2	2-4-2001	27-03-2022

Family P019 comprises granted patents in Canada (CA 2,410,273), Australia (AU2002242560), Japan (JP4647187 and JP5277211) and Mexico (MX243689). The European patent application EP 1 276 734 A1 was deemed withdrawn and subsequently closed.

This family relates to more rhodamine derivatives, their synthesis and use.

P040 family

Title	Registered in the name of	Publication number	Claimed priority date	Expiry date (if granted)
Improved photodynamic process and product obtained therefrom	Kiadis Pharma Intellectual Property B.V.	WO2016/131960[(1)]	19-2-2015	19-2-2036

(1) The application is currently under examination and, as with all applications, may or may not be granted

Family P040 comprises applications in Europe, the US, Australia, Brazil, Canada, China, Israel, India, Japan, South Korea, Mexico, New Zealand, Russia, Saudi Arabia and Singapore.

This family relates to an improved photodynamic process leading to an ATIR product with improved functionalities.

NB1011 patents

In addition to the patents and patent applications in relation to the Theralux platform, Kiadis owns other patents including the NB1011 patents relating to phosphoramidate compounds for inhibiting the proliferation of cells. There is no product development or research activity in relation to these patents.

7.15 Trade secrets, confidential know-how and other proprietary rights

In addition to patent protection, Kiadis also relies on trade secrets and/or confidential know-how and continuing technological innovation to protect its proprietary position, especially where patent protection is believed to be limited.

Kiadis has taken steps to protect what it believes are trade secrets associated with the development and manufacturing of its products (including cell handling, formulation and

release assays), device components, the conduct of clinical trials, patient specific supply chain and communication (including storage and shipment) and the evaluation of clinical and scientific data. However, trade secrets and/or confidential know-how are difficult to protect. Kiadis attempts to maintain trade secrets and/or confidential know-how partly through contractual arrangements with its employees, consultants and collaborators. These arrangements may not provide meaningful protection. These contractual arrangements may also be breached, and Kiadis may not have an adequate remedy for any such breach. In addition, Kiadis' trade secrets and/or confidential know-how may become known or be independently developed by a third party, or misused by any collaborator to whom Kiadis discloses such information.

Kiadis' policy is to require its employees, consultants and advisors to execute confidentiality agreements in connection with their employment, consulting or advisory relationships with Kiadis. Kiadis also takes measures intended to require its employees, consultants and advisors that work on Kiadis' products to agree to disclose and assign to Kiadis (or Kiadis' licensors) all inventions conceived during their term of service, developed using Kiadis' property or which relate to Kiadis' business. Despite any measures taken to protect Kiadis' intellectual property, unauthorised parties may attempt to copy aspects of its products or to obtain or use information that it regards as proprietary.

7.16 Collaborations

Kiadis and its predecessors have been working since 1991 with the University of Montreal, Canada, and since 1996 with a group led by Prof. Denis Claude Roy at the Hospital Maisonneuve-Rosemont at Montreal, Canada (affiliated to the University of Montreal), in both cases for research projects relating to the Theralux technology. Professor Roy's research includes applications of the Theralux platform in various disease indications, basic research activity in the area of mechanism of action of ATIR, and development work to establish assays for the characterisation of cellular products. Kiadis intends to continue this collaboration.

7.17 Commercialisation

Kiadis' current strategy is to market ATIR in larger hospitals and specialised centres of excellence that currently cover the majority of HSCT treatments. These major centres are expected to be trained and set-up to most efficiently comply with the requirements for aphaeresis of donors and patients and the logistics and shipping involved in manufacturing and providing ATIR to the relevant patient.

Kiadis expects that at least two manufacturing sites will be required in the United States as well as two sites in Europe. Similarly, additional sites could be explored if approval is granted in other territories, such as Asia, the Middle East and South America.

Kiadis or its partners will look to establish a commercialisation organisation including a medical affairs department to build relationships with the sites, build a network of KOLs in the U.S. and Europe, plan and implement Phase IV clinical trials and perform other activities required for commercialisation of ATIR. Kiadis or its partners will set up commercial organisations for each territory to handle pricing and reimbursement and customer management. As ATIR treatment is expected to be done only in larger specialised centres, the number of medical and commercial staff and technical experts is expected to be small, especially when compared to drugs that need to be marketed and distributed at the local

physician level.

Kiadis is collecting data to provide insight into the pharmacoeconomic impact of ATIR versus alternatives and it will continue to do so during the upcoming clinical trials. Such data will not only consist of data regarding overall survival rates of patients, but include information on immunosuppression needed, incidence and severity of infections, relapse rates, quality of life and additional parameters that will support an appropriate pricing of ATIR.

Kiadis expects future pricing negotiations to be based upon improvements with ATIR101 over the Baltimore protocol (see paragraph 6.5 above), for which analysis of the Phase III data should provide the requisite input. However, until the moment that Phase III data becomes available, Kiadis will start pricing discussions with hospitals, payors and reimbursement agencies on the basis of more limited Phase II data, the outcome of which is uncertain.

Whether or not Kiadis commercialises ATIR on its own or with a partner, it believes the same underlying assumptions of the commercialisation strategy apply.

7.18 Licences, royalty and milestone payment obligations

Kiadis currently licenses some of the components used in its programs from third parties, particularly the Theralux product portfolio, for which Kiadis has an exclusive licence. Kiadis is subject to certain payment obligations in connection with the commercialisation of, among others, ATIR101.

License agreement - University of Montreal and Maisonneuve-Rosement Hospital

Between 1991 and 2015, Kiadis and its predecessors entered into a series of licensing agreements with the University of Montreal and Maisonneuve-Rosemont Hospital pursuant to which Kiadis is obliged to pay to the University of Montreal and Maisonneuve-Rosemont Hospital royalties of 5% of net sales of all products derived from the Theralux platform for the term of Kiadis' commercialisation of such products. Under this licence, Kiadis is required to, among other things, develop, obtain regulatory approval of, seek intellectual property protection for and commercialise products based on the Theralux technology. Kiadis' present development involving these compounds relies upon previous research conducted by third parties over whom Kiadis had no control. In order to receive regulatory approval for a product, Kiadis needs to present all relevant data and information obtained during its research and development, including research conducted prior to Kiadis licensing the product. Although Kiadis is not currently aware of any such problems, any problems that emerge from pre-clinical research and testing conducted prior to Kiadis in-licensing may affect future results or Kiadis' ability to document prior research and to conduct clinical trials.

Following the 2010 licence agreement with Hospira (see "Hospira Termination and Royalty Agreement" below) it was agreed and confirmed in writing between the parties in September 2012 that Kiadis would pay to the University of Montreal and Maisonneuve-Rosemont Hospital an amount of US$750,000, to be increased with 3.5% interest per annum as of 1 January 2011, as a royalty fee in relation to the sublicence granted to Hospira. The US$750,000 royalty fee and accrued interest are payable as follows: (i) 50% will be paid if Kiadis grants a sublicence to any of the products licensed by Kiadis under the licensing agreements with the University of Montreal and Maisonneuve-Rosemont Hospital provided (a) that the sublicence includes an upfront fee and (b) that the granting of an option to a sublicence will not trigger the repayment obligation, and (ii) 100% will be paid in case of the

acquisition of Kiadis by another company which results in a change of control over Kiadis (whichever of (i) and (ii) occurs first). The parties also agreed to a temporary increase in the royalty rate on net sales from 5% to 7.5% whereby the additional 2.5% would be used to pay the royalty fee (or its remainder). Upon repayment of the royalty fee, the royalty rate will return to 5%.

Hospira Termination and Royalty Agreement

In December 2010, Kiadis entered into a licence agreement with Hospira to develop and commercialise ATIR in certain territories. This agreement was terminated as of January 2012, when Hospira and Kiadis agreed to terminate both the exclusive license Kiadis had granted to Hospira related to products derived from the Theralux platform and Hospira's obligations with respect to such products.

Notwithstanding the termination, pursuant to the terms of the Hospira Termination and Royalty Agreement, Kiadis has agreed to use commercially reasonable efforts to commercialise the products derived from the Theralux platform. Kiadis also agreed to make payments to Hospira as follows: a milestone payment of US$3 million to Hospira upon the earlier of (i) the execution of a sub-license to the Theralux platform, or (ii) the first commercial sale of a product derived from the Theralux platform by Kiadis. Furthermore, Kiadis has agreed to pay a 5% royalty on worldwide net sales of products derived from the Theralux platform until a threshold amount has been paid, after which a 3% royalty on net sales in all countries (except for those in North America, South America and China, Mongolia, Tibet, Hong Kong, Macau and Antarctica) applies. The terms of the Hospira Termination and Royalty Agreement also grant Hospira a right of first negotiation should Kiadis wish to grant a sub-licence to any of its Theralux based products for human haematological therapy or for treatment of an orphan disease anywhere in the world.

Celmed milestone agreement

For a description of Kiadis' contingent liability for milestone payments to the original shareholders of Celmed in relation to Rhitol and NB1011, two product candidates which Kiadis ceased to develop in 2008, and certain security rights that have been vested in relation thereto, see note 20 to the audited consolidated financial statements for the year ended 31 December 2016, note 21 to the audited consolidated financial statements for the year ended 31 December 2015 and note 22 to the audited consolidated financial statements for the year ended 31 December 2014. Because these products are no longer in development, Kiadis does not expect that the approvals necessary to trigger these payment obligations will occur.

7.19 Facilities

Kiadis' headquarters are located at Paasheuvelweg 25A in Amsterdam, the Netherlands, where it leases approximately 3,700 square metres of office space and a commercial manufacturing facility, including process development and quality control laboratories, pursuant to a sublease agreement entered into on 7 December 2017. The sublease has a ten year term (until 31 December 2027) that is automatically extended for four years (until 31 December 2031), and thereafter for five years (until 31 December 2036), unless terminated by Kiadis at the end of a lease period with one year's notice. The second extension (i.e. the extension until 31 December 2036) is however also subject to the headlease between Kiadis' lessor and the head lessor being extended after 29 February 2032 for a period of five years.

Kiadis also leases approximately 550 square metres of laboratory and office space at the Science Park 406 in Amsterdam, the Netherlands, pursuant to a lease agreement originally dated October 2015. The lease is automatically extended each year with a one-year term, unless terminated at the end of a lease period with three months' notice.

7.20 Legal proceedings

In the ordinary course of its business, Kiadis may become involved in litigation arising from claims against Kiadis or brought by it against others to enforce Kiadis' rights. Kiadis is not currently involved, nor has it been involved during the twelve-month period immediately prior to the Registration Document Date, in any governmental, legal or arbitration proceedings which may have or have had a material effect on its business, financial position or profitability, and Kiadis is not aware of any such proceedings which are currently pending or threatened.

8 Regulation

8.1 Medicinal product regulations

In each country where it conducts its research and intends to market its products and product candidates, Kiadis has to comply with laws and regulations including regulations laid down by regulatory agencies and by other national or supra-national regulatory authorities (hereinafter, collectively the "**Competent Authorities**"), as well as industry standards, that regulate nearly all aspects of Kiadis' activities. The Competent Authorities include – among others – the EMA in the European Union, the national competent authorities of each Member State of the European Union, the FDA in the U.S. and the TPD in Canada.

8.2 Regulatory incentives

8.2.1 Orphan designation

There is a need for the development of medicines for rare diseases, and intended for small numbers of patients (i.e. orphan drugs), and since the pharmaceutical industry has limited commercial incentive, under normal market conditions, in developing and marketing such medicines, both the European Union and the United States offer a range of incentives to encourage the development of these medicines. In order for the pharmaceutical industry to profit from these incentives it has to comply with the orphan drug regulations.

Marketing authorisation for an orphan drug leads to a ten year market exclusivity in the European Union. This period may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation, including among other things, if the product is sufficiently profitable so that market exclusivity is no longer justified. In order to be eligible for incentives made available by the European Union and by the Member States to support research into, and the development and availability of, orphan drugs the medicinal product needs to be designated as an orphan drug pursuant to Regulation (EC) No 141/2000, as amended. Regulation (EC) No 141/2000, as amended, states that a medicinal product shall be designated as an orphan medicinal product if its manufacturer can establish:

- that it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the European Union when the application is made or that it is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that the marketing of the medicinal product in the European Union would generate sufficient return to justify the necessary investment; and

- that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorised in the community or, if such method exists, the medicinal product will be of significant benefit to those affected by that condition.

In the United States, an orphan drug designation qualifies the manufacturer for certain tax credits and leads to market exclusivity for seven years following the date of the drug's marketing approval by the FDA. CFR21§316 states that a drug shall be designated as an

orphan drug if its manufacturer can establish that the drug is for a condition:

- that affects fewer than 200,000 individuals in the United States; or

- that affects more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available the drug for the disease or condition will be recovered from sales of the drug in the United States.

In both the European Union and the United States, a manufacturer may request orphan drug designation of a previously unapproved drug or new orphan indication for a different use for an already marketed drug. In addition, a manufacturer of a drug that is otherwise the same drug as an already approved orphan drug may seek and obtain orphan drug designation for the subsequent drug for the same rare disease or condition if it can present a plausible hypothesis that its drug may be clinically superior to the first drug. However, an orphan drug designation cannot be approved for the same drug made by another manufacturer for the same indication during the market exclusivity period unless it has the consent of the original manufacturer or the original manufacturer is unable to provide sufficient quantities. More than one manufacturer may receive orphan drug designation for the same drug for the same rare disease or condition, but each manufacturer seeking orphan drug designation must file a complete request for designation.

An application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. The period of exclusivity begins on the date that the marketing application is approved. The exclusivity is limited to the indication for which the drug has been designated.

8.2.2 SME

In the European Union, manufacturers may benefit from further incentives including a certification procedure for ATMPs under development (see paragraph 8.4 below), and/or administrative and procedural assistance and fee reductions when they are classified as a micro or a small or medium-sized enterprise ("**SME**"). Within the SMEs, medium enterprises are defined as those which employ fewer than 250 persons, and which have an annual turnover not exceeding €50 million and/or an annual balance sheet total not exceeding €43 million; a small enterprise is defined as an enterprise which employs fewer than 50 persons and whose annual turnover and/or annual balance sheet total does not exceed €10 million; and a microenterprise is defined as an enterprise which employs fewer than ten persons and whose annual turnover and/or annual balance sheet total does not exceed €2 million.

Administrative, regulatory and financial support is available to companies assigned SME status by EMA, including:

- direct assistance by phone, email, teleconference or through briefing meetings on regulatory aspects of the pharmaceutical legislation;

- fee exemptions and reductions for pre- and post-authorisation regulatory procedures, including scientific advice, inspections and pharmacovigilance;

- assistance with translations of product information into all official EU languages;

- inclusion in an online SME register, which is an important source of information

on EU-based SMEs involved in the manufacturing, development or marketing of medicines and promotes partnering and networking between SMEs;

- guidance on clinical data publication and a free redaction tool license;

- liaison with academic investigators in paediatric-medicine research through the European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA); and

- workshops and training sessions.

8.2.3 Development of medicines for children

Several incentives for the development of medicines for children are available in the European Union:

- medicines that have been authorised across the European Union with the results of paediatric investigational plan ("**PIP**") studies included in the product information are eligible for an extension of their patent protection by six months. This is the case even when the studies' results are negative;

- for orphan medicines, the incentive is an additional two years of market exclusivity;

- scientific advice and protocol assistance at the EMA are free of charge for questions relating to the development of medicines for children; and

- medicines developed specifically for children that are already authorised but are not protected by a patent or supplementary protection certificate, can apply for a paediatric-use marketing authorisation ("**PUMA**"). If a PUMA is granted, the product will benefit from ten years of market protection as an incentive.

8.3 Regulatory and development

Kiadis' pharmaceutical product candidates are subject to substantial requirements that govern, among other things, their testing, manufacturing, quality control, safety, efficacy, labelling, storage, record keeping, marketing approval, advertising, promotion and pricing. The process of maintaining continued compliance with the regulatory requirements requires the expenditure of substantial amounts of time and money.

ATMPs are medicines for human use that are based on gene therapy, somatic-cell therapy or tissue engineering. They offer ground-breaking new opportunities for the treatment of disease and injury. Competent Authorities are generally aware of the specificities of these novel cell-based product candidates, and give much attention to their upfront characterisation and the development of assays to measure their biological activity (potency). The pre-clinical and clinical development paths for product candidates are broadly similar in the European Union, the United States and Canada.

8.3.1 Non-clinical studies

Development of the product candidates starts with non-clinical studies which include laboratory tests to develop a robust product manufacturing process including formulation and

stability. In addition further non clinical studies are conducted to evaluate the mode of action and in vivo tests are conducted until adequate proof of safety is established (e.g. toxicity studies in animals). The conduct of the non-clinical tests and formulation of the compounds for testing must comply with regulations and requirements set by the Competent Authorities. Upon successful completion of non-clinical studies clinical development can be initiated.

8.3.2 Clinical studies

Prior to initiating clinical trials a request for clinical trial authorisation (Canada and national competent authorities in the European Union) or an Investigational New Drug application (IND in the United States), need to be approved by the relevant Competent Authorities for such trials to be allowed to start. These submissions must be supported by an investigational medicinal product dossier or equivalent as detailed in applicable guidance documents. The results of the preclinical tests, together with manufacturing information and analytical data, are included in these applications. Manufacturing of investigational products is subject to authorisation and must be carried out in accordance with applicable GMP. Furthermore, a clinical trial may only be started after a competent ethics committee (European Union and Canada) or institutional review board (United States.) has issued a favourable opinion on the clinical trial application. Clinical trials are typically conducted in sequential phases, Phases I, II and III, with Phase IV trials being conducted after marketing approval. Phase IV trials are generally required for products that receive conditional or accelerated approval to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit (see also paragraph 8.5 below). These phases may be compressed, may overlap or may be omitted in some circumstances.

8.3.3 Paediatric Regulation

On 26 January 2007, the Paediatric Regulation (Regulation (EC) No 1901/2006 and Regulation (EC) No 1902/2006) came into force in the European Union. Its objective is to improve the health of children in the European Union by facilitating the development and availability of medicines for children from birth up to 18 years of age, ensuring that medicines for use in children are of high quality, ethically researched and authorised appropriately and improving the availability of information on the use of medicines for children. The aim is to achieve this without subjecting children to unnecessary trials or delaying the authorisation of medicines for use in adults. The Paediatric Regulation established the Paediatric Committee (PDCO), which is responsible for coordinating the Agency's work on medicines for children. The Committee's main role is to determine the studies that companies must carry out on children as part of PIPs. At least an approved Paediatric Investigation Plan (PIP) needs to be in place before applying for marketing authorisation. The PDCO grants deferrals for some medicines, allowing a company to delay development of the medicine in children until there is enough information to demonstrate its effectiveness and safety in adults. The PDCO also grants waivers when development of a medicine in children is not needed or is not appropriate, such as for diseases that only affect the elderly population. When the approved PIP contains studies that need to be performed, the proposed study design and timelines need to be adhered to.

8.4 Marketing authorisation

8.4.1 European Union

The EMA's Committee for Advanced Therapies ("**CAT**") provides a certification procedure for ATMPs under development by SMEs as defined in the ATMP regulation (EC) No 1394/2007,

as amended. This is an opportunity for SMEs to get an assessment of the data they have generated and to obtain some degree of comfort that they are on the right track for successful development. The certification procedure involves the scientific evaluation of data quality and, when available, non-clinical data that SMEs have generated at any stage of the ATMP development process. It aims to identify potential issues early on, so that these can be addressed prior to the submission of a marketing-authorisation application. After the assessment, the CAT may recommend issuing a certification confirming the extent to which the available data comply with the standards that apply for evaluating a marketing-authorisation application. Following the CAT recommendation, the EMA issues a certification. The evaluation and certification procedure takes ninety days.

The EMA and the European Commission apply a centralised authorisation procedure. Pursuant to Regulation (EC) No 726/2004, as amended, this procedure is mandatory for ATMPs, products containing a new active substance for the treatment of acquired immune deficiency syndrome, cancer, neurodegenerative disorders or diabetes, all drugs that are designated as orphan drugs pursuant to Regulation (EC) No 141/2000, as amended, and pharmaceutical products containing a new chemical substance for the treatment of auto-immune diseases, other immune dysfunctions and viral diseases. When a centralised authorisation is granted, the authorisation is automatically valid in all Member States of the European Union.

Under the centralised authorisation procedure, the EMA's Committee for Medicinal Products for Human Use, ("**CHMP**"), serves as the scientific committee that renders opinions about the safety, efficacy and quality of human products on behalf of the EMA. The CHMP is composed of experts nominated by the Competent Authority of each European Union Member State, one of them to be appointed to act as rapporteur for the co-ordination of the evaluation with the possible assistance of a further member of the CHMP acting as a co-rapporteur. The CHMP has 210 days, or longer if additional information is requested, to give its opinion to the EMA as to whether a marketing authorisation should be granted. This process is complex and involves extensive consultation with the Competent Authorities of the Member States of the European Union and a number of experts.

A marketing authorisation that has been granted in the European Union may be suspended of withdrawn if ongoing regulatory requirements are not met or if safety problems are identified. Among other things, marketing authorisation holders are required to have risk management plans that use risk minimisation strategies beyond product labelling to ensure that the benefits of certain prescription drugs outweigh their risks.

8.4.2 United States

The results of drug candidate development, preclinical testing and clinical trials are submitted to the FDA as part of an NDA or in case of a biological drug therapeutic, a Biologic License Application ("**BLA**"). A BLA must contain extensive manufacturing information, detailed information on the composition of the product and proposed labelling; filing of a BLA also and requires payment of a user fee. Once the submission has been accepted for filing, the FDA begins an in-depth review of the BLA. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act ("PDUFA"), the FDA has twelve months in which to complete its initial review of a standard BLA and respond to the applicant, and eight months for a priority BLA. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs. The review process is often significantly extended by FDA requests for additional information or clarification. The review process and the PDUFA goal date may be extended by three months if the FDA requests (or the BLA sponsor otherwise provides)

additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

If the FDA's evaluations of the BLA and the clinical and manufacturing procedures and facilities are favourable, the FDA may issue an approval letter. If the FDA's evaluation of the BLA submission and the clinical and manufacturing procedures and facilities are not favourable, the FDA may refuse to approve the BLA and issue a complete response letter. Companies that receive a complete response letter may submit to the FDA information that represents a response to the issues identified by the FDA in the complete response letter.

The FDA may refer the BLA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of the advisory committee, but it generally follows such recommendations. The FDA may deny approval of a BLA if the applicable regulatory criteria are not satisfied, or it may require additional clinical data or an additional pivotal Phase III clinical trial. Even if such data are submitted, the FDA may ultimately decide that the BLA does not satisfy the criteria for approval. Once issued, the FDA may withdraw a drug approval if ongoing regulatory requirements are not met or if safety problems occur after the drug reaches the market. In addition, the FDA may require further testing (including Phase IV clinical trials), and/or risk management plans that use risk minimisation strategies beyond drug labelling to ensure that the benefits of certain prescription drugs outweigh their risks. The FDA has the power to prevent or limit further marketing of a drug based on the results of these post-marketing programs. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label. Further, if there are any modifications to a drug, including changes in indications, labelling or manufacturing processes or facilities, a new BLA or BLA supplement may be required to be submitted to obtain FDA approval which may require the development of additional data or the conduct additional preclinical studies and clinical trials.

8.4.3 Canada

In Canada upon completion of all clinical studies, the results are submitted to the TPD of Health Canada as part of a New Drug Submission ("**NDS**"). If, at the completion of a new drug review, it is concluded that the benefits outweigh the risks and that the risks can be mitigated or managed, the product is issued a letter known as a notice of compliance which permits marketing of the product in Canada. The review process typically takes between 12 and 24 months from the date an NDS is submitted.

Even after marketing approval has been obtained, further studies are required to provide additional data on safety and efficacy in order to gain approval for the use of a drug as a treatment for clinical indications other than those for which the product was initially tested. Critical analyses of adverse drug reactions must be conducted annually or whenever requested to do so by the director of Health Canada, and a report must be provided. The TPD must also be informed of, among other things, any changes to a previously authorised Clinical Trial Application and of any updates made to an investigator's brochure. In addition, any product that is manufactured or distributed pursuant to the TPD approval is subject to extensive continuing regulation, including record-keeping and labelling requirements and reporting of adverse events with the product. If any modifications to a product are proposed, including changes in the manufacturing process, manufacturing facility or labelling, a supplement to the NDS is required to be submitted to the TPD.

The TPD conducts post-market surveillance programs to monitor a product's side effects.

Results of post-marketing programs may limit or expand the further marketing of products. A serious safety or efficacy problem involving an approved drug or medical device may result in regulatory withdrawal of the product from the market.

8.5 Accelerated assessment procedures

Speeding the availability of drugs that treat serious diseases is in everyone's interest, especially when the drugs are the first available treatment or if the drug has advantages over existing treatments. Both the European Union and FDA have developed four distinct and successful approaches to making such drugs available as rapidly as possible.

8.5.1 European Union

When an application is submitted for a marketing authorisation in the European Union in respect of drugs for human use which is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation, the applicant may request an accelerated assessment procedure pursuant to article 14, paragraph 9 of Regulation (EC) No 726/2004, as amended. Applicants requesting an accelerated assessment procedure should justify that the medicinal product is expected to be of major public health interest. Based on the request, the justifications presented, and the recommendations of the rapporteurs, the CHMP will formulate a decision. Such a decision will be taken without prejudice to the CHMP opinion (positive or negative) on the granting of a marketing authorisation. If the CHMP accepts the request, the timeframe for the evaluation will be reduced to 150 days.

In the European Union conditional marketing authorisation may be requested by an applicant or proposed by the CHMP for medicinal products which aim at:

- the treatment, prevention or medical diagnosis of seriously debilitating or life-threatening diseases; or
- medicinal products to be used in emergency situations in response to public health threats recognised either by the World Health Organisation or by the European Union in the framework of Decision No 2119/98/EC; or
- medicinal products designated as orphan medicinal products in accordance with Regulation (EC) No 141/2000, as amended.

A conditional marketing authorisation may be granted where the CHMP finds that, although comprehensive clinical data referring to the safety and efficacy of the medicinal product have not been supplied, all the following requirements are met:

- the risk-benefit balance of the medicinal product, as defined in Article 1(28a) of Directive 2001/83/EC, as amended, is positive;
- it is likely that the applicant will be in a position to provide the comprehensive clinical data;
- unmet medical needs will be fulfilled (no existing satisfactory methods or the medicinal product provides major therapeutic advantage); or
- the benefit to public health of the immediate availability on the market of the

medicinal product concerned outweighs the risk inherent in the fact that additional data are still required.

The legal basis for a conditional marketing authorisation is Article 14 (7) of Regulation (EC) No 726/2004, as amended. The provisions for the granting of such an authorisation are laid down in Regulation (EC) No 507/2006. Conditional marketing authorisations are valid for one year, on a renewable basis. The holder will be required to complete ongoing studies or to conduct new studies with a view to confirming that the benefit-risk balance is positive. In addition, specific obligations may be imposed in relation to the collection of pharmacovigilance data. The granting of a conditional marketing authorisation will allow medicines to reach patients with unmet medical needs earlier than might otherwise be the case, and will ensure that additional data on a product are generated, submitted, assessed and acted upon.

In addition, authorisation under exceptional circumstances may be requested when it is not possible to provide comprehensive data on the efficacy and safety under normal conditions of use, because:

- the indications for which the product in question is intended are encountered so rarely that the applicant cannot reasonably be expected to provide comprehensive evidence; or

- in the present state of scientific knowledge, comprehensive information cannot be provided; or

- it would be contrary to generally accepted principles of medical ethics to collect such information.

The legal basis for the marketing authorisation under exceptional circumstances is article 14 (8) of Regulation (EC) No 726/2004, as amended, and the relevant documentation for applications in exceptional circumstances are laid down in Part II of Annex I of Directive 2001/83/EC, as amended. The authorisation under exceptional circumstances is granted subject to a requirement for the applicant to meet certain conditions, in particular concerning the safety of the medicinal product, notification to the Competent Authorities of any incident relating to its use, and action to be taken. The renewal of the marketing authorisation of a medicinal product under exceptional circumstances follows the same rules as a "normal" marketing authorisation. After five years, the marketing authorisation will then be renewed under exceptional circumstances for an unlimited period, unless the Competent Authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal.

8.5.2 Food and Drug Authority

The FDA has four expedited programs representing efforts to address unmet medical needs in the treatment of serious conditions. These are: regenerative medicine advanced therapy designation, breakthrough therapy designation, fast track designation, accelerated approval and priority review. For regenerative medicine therapies/ATMPs, recently a fifth option has been added: Regenerative Medicine Advanced Therapy Designation (RMAT designation).

8.5.2.1 Breakthrough Therapy

The FDA's breakthrough therapy designation is intended to expedite the development and

review of drugs which may demonstrate substantial improvement over available therapy. A drug that receives breakthrough therapy designation is eligible for all fast track designation features, intensive guidance on an efficient drug development program, beginning as early as Phase 1 and organisational commitment involving senior managers. Breakthrough Therapy designation is requested by the manufacturer. If a manufacturer has not requested breakthrough therapy designation, the FDA may suggest that the sponsor consider submitting a request if:

- after reviewing submitted data and information (including preliminary clinical evidence), the FDA thinks the drug development program may meet the criteria for breakthrough therapy designation; and

- the remaining drug development program can benefit from the designation.

Ideally, a breakthrough therapy designation request should be received by FDA no later than the End-of-Phase II meetings if any of the features of the designation are to be obtained. Because the primary intent of breakthrough therapy designation is to develop evidence needed to support approval as efficiently as possible, FDA does not anticipate that breakthrough therapy designation requests will be made after the submission of an original BLA or NDA or a supplement. FDA will respond to breakthrough therapy designation requests within sixty days of receipt of the request.

8.5.2.2 Fast track

Fast track designation can be requested early in the development process, if evidence of activity in a non-clinical model, a mechanistic rationale or pharmacologic data demonstrates the potential to address an unmet medical need. In the later stages of development, a company will need to provide clinical data to demonstrate the potential to address an unmet medical need.

Fast track designation gives opportunities for applicants to have frequent interactions with the relevant review teams including meetings with the FDA. In addition, a fast track product can be eligible for priority review if supported by clinical data at the time of an NDA or BLA.

If the FDA determines, after preliminary evaluation of clinical data submitted by a sponsor, that a fast track product may be effective, it may consider reviewing portions of a marketing application before the sponsor submits the complete application.

Fast track designation can be requested when the IND is first submitted or at any time thereafter but before receiving marketing approval of a BLA or NDA. As a practical matter, FDA should ordinarily receive a fast track designation request no later than the sponsor's pre-BLA or pre-NDA meeting with the agency because many of the features of fast track designation will not apply after that time.

FDA will respond to fast track designation requests within sixty calendar days of receipt of the request.

8.5.2.3 Accelerated approval

Accelerated approval may be granted for a product upon determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is

reasonably likely to predict an effect on irreversible morbidity or mortality (IMM) or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. The endpoint can be either a surrogate endpoint that is considered reasonably likely to predict clinical benefit or a clinical endpoint that can be measured earlier than the IMM that is reasonably likely to predict an effect on IMM or other clinical benefit.

For drugs granted accelerated approval, post-marketing confirmatory trials will be required to verify and describe the anticipated effect on the IMM or other clinical benefit.

The accelerated approval pathway has been used primarily in settings in which the disease course is long and an extended period of time would be required to measure the intended clinical benefit of a drug.

Accelerated approval is also potentially useful in acute disease settings where the intended clinical benefit can be demonstrated only in a very large study because the clinical event that would need to be evaluated to demonstrate clinical benefit occurs rarely.

The FDA may withdraw approval of a drug or indication approved under the accelerated approval pathway if e.g. the confirmatory trial fails to verify the predicted clinical benefit, the evidence demonstrates that the product is not shown to be safe and effective under the conditions used, the applicant fails to conduct the post-approval trials with due diligence or the applicant disseminates false or misleading promotional materials related to the product.

8.5.2.4 Priority review designation

A priority review designation is intended to direct overall attention and resources to the evaluation of an application that treats, prevents or is used in the diagnosis of a serious condition and if approved would provide a significant improvement in safety or effectiveness. This is determined by the FDA at the time of an NDA or BLA or efficacy supplement filing. A priority review designation means the FDA's goal is to take action on the marketing application within six months of receipt (as compared to within ten months under standard review).

The FDA determines whether an application qualifies for priority review (versus standard review) for every application, not just when priority review is requested by the applicant. However, an applicant may expressly request priority review. The FDA will inform the applicant in writing of a priority review designation by day sixty of the review.

8.5.3 RMAT designation

In the 21st Century Cures Act, signed into law on 13 December 2016, the U.S. Congress included several provisions related to regenerative medicine. One of these provisions established a new program to help foster the development and approval of these products: Regenerative Medicine Advanced Therapy (RMAT) Designation building on the FDA's existing expedited programs available to regenerative medicine products which are described above.

Sponsors of RMAT-designated products are eligible for increased and earlier interactions with the FDA, similar to those interactions available to sponsors of breakthrough-designated therapies. In addition, they may be eligible for priority review and accelerated approval. The meetings with sponsors of RMAT-designated products may include discussions of whether

accelerated approval would be appropriate based on surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites.

Once approved, when appropriate, the FDA can permit fulfilment of post-approval requirements under accelerated approval through the submission of clinical evidence, clinical studies, patient registries, or other sources of real world evidence such as electronic health records; through the collection of larger confirmatory datasets; or through post-approval monitoring of all patients treated with the therapy prior to approval.

8.5.4 Therapeutic Products Directorate

In Canada an applicant may request priority review for a serious, life-threatening or severely debilitating disease or condition for which there is substantial evidence of clinical effectiveness that the drug provides:

- effective treatment, prevention or diagnosis of a disease or condition for which no drug is presently marketed in Canada; or

- a significant increase in efficacy and/or significant decrease in risk such that the overall benefit/risk profile is improved over existing therapies, preventatives or diagnostic agents for a disease or condition that is not adequately managed by a drug marketed in Canada.

In order to qualify for priority review status, the product must not only be intended for patients suffering from a serious, life-threatening or severely debilitating disease or condition but must also be indicated to treat, prevent or diagnose a serious symptom or manifestation of the condition. For example, a product indicated for alleviating a minor skin irritation in a patient with cancer would not be eligible for priority review status although the condition (cancer) itself is clearly life-threatening.

Priority review status allows for the insertion of eligible drug submissions into the TPD's submission workload on the basis of a shortened review target of 180 calendar days. As such, qualifying submissions may undergo review in advance of non-eligible submissions in accordance with approaching target dates.

8.6 Manufacturing

The manufacturing of authorised drugs, for which a separate manufacturer's licence is mandatory, must be conducted in strict compliance with applicable GMP requirements and comparable requirements of regulatory bodies, which mandate the methods, facilities and controls used in manufacturing, processing and packing of drugs to assure their safety and identity. Therefore, all establishments engaged in fabrication, packaging or labelling, importation, distribution, wholesale or operation of a testing laboratory are required to hold an establishment licence unless expressly exempted by the regulations.

8.6.1 European Union

The EMA enforces GMP requirements through mandatory registration of facilities and inspections of those facilities. The EMA may have a co-ordinating role for these inspections but the responsibility for carrying them out rests with the Competent Authority of the Member State of the European Union under whose responsibility the manufacturer falls. Failure to

comply with these requirements could interrupt supply and result in delays, unanticipated costs and lost revenues, and could subject the applicant to potential legal or regulatory action, including but not limited to warning letters, suspension of manufacturing, seizure of product, injunctive action or possible civil and criminal penalties.

8.6.2 United States

Satisfactory completion of an FDA inspection of the manufacturing facility or facilities, including those of third-parties, at which the product is produced to assess compliance with strictly enforced current GMP is generally required for marketing of a new drug.

8.6.3 Canada

The TPD enforces GMP by regular inspection of the establishments to verify whether they are in compliance with current GMP. Importers must demonstrate that the products they import originate from sites that comply with current GMP.

8.7 Marketing and promotion

8.7.1 European Union

The marketing and promotion of authorised medicinal products, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs, are strictly regulated in the European Union, notably under, among others, Directive 2001/83/EC, as amended, guidance published by the European Commission and the EMA, laws, regulations and guidance set out by the Member States of the European Union and industry wide codes of conduct. The applicable regulatory framework aims to ensure that information provided by holders of marketing authorisations regarding their products is truthful, balanced and accurately reflects the safety and efficacy claims authorised by the EMA or by the Competent Authority of the authorising Member State. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Marketing and promotion of medicinal products which are available by prescription only, aimed at consumers or patients (directly or indirectly) is strictly forbidden.

8.7.2 United States

All promotional materials, including promotional labelling as well as advertisements need to be submitted to the FDA. Advertising and promotional labelling materials are regulated by the advertising and promotional labelling branch (APLB). APLB is responsible for protecting the public health by:

- regulating advertising and promotional labelling materials for Center for Biologics Evaluation and Research (CBER) products to ensure that the information about the risks and benefits of regulated products are communicated in a truthful, accurate, science-based, non-misleading and balanced manner and is in compliance with pertinent federal laws and regulations; and

- evaluating proposed proprietary names to avoid potential medication errors related to look-alike and sound-alike proprietary names and mitigating other factors that contribute to medication errors, such as unclear label abbreviations,

acronyms, dose designations, and error prone label and packaging design.

Any person who disseminates or causes another party to disseminate a false or misleading direct to consumer (DTC) ad shall be liable for a civil penalty of up to $250,000 for the first violation, and up to $500,000 for subsequent violations in a three year period (Sec. 901 of Title IX of the Food and Drug Administration Amendments Act).

8.7.3 Canada

In Canada health product advertisements need to comply with the requirements of the Food and Drugs Act and its regulations, and the Controlled Drugs and Substances Act. The preclearance of advertising for marketed health products is administered through an independent, self-regulatory and voluntary system. These advertising preclearance agencies (APAs) are independent entities which review and pre-clear advertising material to help interested parties ensure compliance with the regulatory guidance developed by the TPD. Complaints received directly by the TPD or referred to the TPD by the APAs are evaluated for non-compliance and subjected to a health risk assessment. Once non-compliance and the health risk level of an advertisement is determined, immediate risk management actions may be taken by the TPD and may include but is not limited to: warning letter to the advertising sponsor and/or broadcaster, requesting immediate cessation of the advertisement, contacting and/or referral to the APAs, issuance of a risk communication, suspension or cancellation of marketing authorisation/product licence, or prosecution. Risk management actions can be taken alone or in combination, and sequentially or simultaneously. Further information on regulatory measures available to the TPD in order to achieve compliance by regulated parties are described in the TPD's Compliance and Enforcement Policy (POL-0001).

8.8 Regulatory data protection and market exclusivity

8.8.1 European Union

In the European Union, all applications for marketing authorisation receive an 8+2+1 year data/market exclusivity regime if submitted on or after 20 November 2005 as regards applications via the centralised procedure or if submitted on or after 30 October 2005 as regards applications via other authorisation procedures. This regime consists of (i) a regulatory data protection period and market exclusivity period of eight years, (ii) a market exclusivity period of an additional two years after the eight year period and (iii) an extended market exclusivity period of one year after the ten year period if, during the first eight years of those ten years, the marketing approval holder obtains an approval for one or more new therapeutic indications which, during the scientific evaluation prior to their approval, are determined to bring a significant clinical benefit in comparison with existing therapies. Under the current rules, a third party may reference the preclinical and clinical data of the original sponsor beginning eight years after first approval in the European Union, but the third party may market a generic version after only ten (or, where applicable, eleven) years have lapsed.

Medicines that still meet the criteria for orphan designation benefit from the incentive of ten years of market exclusivity once they are approved for marketing in the European Union. This protects them from market competition with similar medicines with similar indications once they are approved. Market exclusivity is awarded by the European Commission and is specifically linked to one specific orphan designation for which a marketing authorisation has been granted. Each orphan designation carries the potential for one market exclusivity for a

particular indication. A medicine that has several separate orphan designations for different indications can have several separate market exclusivities if these refer to separate designated conditions. The period of market exclusivity is extended by two years for medicines that also have complied with an agreed PIP. A designated orphan medicinal product shall be removed from the European Union's Community register of orphan medicinal products at the end of the period of market exclusivity. See also above for more details on orphan drugs.

8.8.2 United States

A new chemical entity that was approved by the FDA after 24 September 1984, in an application submitted under section 505(b) of the Food, Drug and Cosmetic Act receives market exclusivity for a period of five years from the date of approval of the first approved new drug application. After approval of a sponsor's marketing application for a designated orphan-drug product for treatment of the rare disease or condition concerning which orphan-drug designation was granted, exclusivity is granted for seven years from the date of approval (see also paragraph 8.2.1 above for more details on orphan drugs). As provided by section 351(m) of the PHS Act, the period will be extended by six months if the sponsor conducts paediatric studies that meet the requirements for paediatric exclusivity pursuant to section 505A of the Federal Food, Drug, and Cosmetic Act.

In August 2014 FDA released a new draft guidance document "Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the Public Health Service Act (PHS Act)". In this draft guidance biological products approved under Section 351(a) of PHS Act are given a period of market exclusivity of twelve years beginning at a date of first licensure. However, the date of first licensure does not include the date of licensure of (and a new period of exclusivity shall not be available for) a biological product licensed under section 351(a) of the PHS Act if the licensure is for:

- a supplement for the biological product that is the reference product; or
- a subsequent application filed by the same sponsor or manufacturer of the biological product that is the reference product (or a licensor, predecessor in interest, or other related entity) for
- a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or
- a modification to the structure of the biological product that does not result in a change in safety, purity, or potency.

As provided by section 351(m) of the PHS Act, an additional six month period of exclusivity will attach to the 12-year period if the sponsor conducts paediatric studies that meet the requirements for paediatric exclusivity pursuant to section 505A of the Federal Food, Drug, and Cosmetic Act.

8.8.3 Canada

Innovative drugs, as defined in section C.08.004.1 of the Food and Drug Regulations, are entitled to an eight-year term of data protection. Where the drug has qualified for the

paediatric extension, the term is extended to eight and a half years.

8.9 Post-approval regulation

If regulatory approval for marketing of a product or new indication for an existing product is obtained, Kiadis will be required to comply with a number of post-approval requirements. Kiadis will be required to report certain adverse reactions and production problems, provide updated safety and efficacy information to the Competent Authorities of the jurisdictions in which a marketing authorisation has been granted and comply with the relevant requirements concerning advertising and promotional labelling requirements. Drug manufacturers and certain of their subcontractors are required to register their establishments with the Competent Authorities and certain state agencies, and are subject to periodic unannounced inspections by the Competent Authorities and certain state agencies for compliance with ongoing regulatory requirements, including current GMP, good pharmacovigilance practice, regulations and guidance, which impose certain procedural and documentation requirements upon drug manufacturers. Accordingly, Kiadis and its third-party manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with current GMP and other regulatory requirements. Discovery of problems with a product after approval for marketing may result in restrictions on a product, manufacturer, or holder of an approved NDA or marketing authorisation holder, including withdrawal of the product from the market.

8.10 Price review

8.10.1 European Union

The pricing of prescription pharmaceuticals in each of the Member States of the European Union is subject to strict governmental control. Each country in the European Economic Area has its own pricing and reimbursement regulations and may have other regulations related to the marketing and sale of pharmaceutical products in the country. Generally, prior to the commencement of any commercial sales of a medicinal product, any obligatory or commercially necessary pricing and reimbursement negotiations will have been concluded. Some European Union Member States require the conduct of a clinical trial or other studies that compare the cost-effectiveness of a medicinal product to other available therapies in order to obtain or maintain reimbursement or pricing approval.

8.10.2 United States

The U.S. has low levels of price regulation. The FDA has no legal authority to investigate or control the prices charged for marketed drugs. Manufacturers, distributors and retailers establish these prices. The FDA recognises that other factors beyond its purview, including insurance coverage and drug pricing, can determine patient access to drugs. These factors have been receiving increasing public attention and public debate.

8.10.3 Canada

In Canada the Patented Medicine Prices Review Board, or PMPRB, is an independent quasi-judicial administrative agency that is responsible for regulating the price charged by patentees for prescription and non-prescription patented drugs sold to wholesalers, hospitals or pharmacies for human and veterinary use to ensure that they are not excessive. The PMPRB regulates the price of each patented drug product, including the price for each

strength of each dosage form of each patented medicine sold in Canada.

Under the Patented Medicines Regulations, patentees are required to file price and sales information twice a year for each strength of each dosage form of each patented medicine sold in Canada for price regulation purposes. Patentees are also required to file research and development expenditures once a year for reporting purposes. Manufacturers must inform the PMPRB of their intention to sell a new patented medicine but are not required to obtain prior approval of the price.

Patentees are required to comply with the Patent Act to ensure that prices of patented medicines sold in Canada are not excessive. In the event that the PMPRB finds, after a public hearing, that a price is excessive in any market, it may order the patentee to reduce the price and take measures to offset excess revenues it may have received.

In Canada the provincial and territorial governments are responsible, among other things, for providing public drug benefit plans to certain segments of their population (all provinces and territories provide coverage to seniors and those receiving social assistance) and managing the list of drugs for which public reimbursement from government drug plan is available. In some cases, drugs have a restricted status limiting coverage to particular types of patients or situations.

9 Management, Supervisory Board and Employees

9.1 General

Set out below is a summary of relevant information concerning the Management Board, the Supervisory Board, Senior Management and Kiadis' employees and a brief summary of certain significant provisions of Dutch corporate law and the Articles of Association in respect of the Management Board and the Supervisory Board.

This summary does not purport to give a complete overview and should be read in conjunction with the Articles of Association and the relevant provisions of Dutch law, and does not constitute legal advice regarding these matters and should not be considered as such. The full text of the Articles of Association is available, in Dutch and English, via Kiadis' website www.kiadis.com.

9.2 Management structure

The Company has a two-tier board structure consisting of a Management Board (*Raad van Bestuur*) and a Supervisory Board (*Raad van Commissarissen*).

The Management Board is responsible for the day-to-day management which includes, among other things, formulating strategies and policies, and setting and achieving the Company's objectives. The Supervisory Board supervises and advises the Management Board.

Each member of the Management Board and Supervisory Board owes a duty to the Company to properly perform the duties assigned to such member and to act in the Company's corporate interest. Under Dutch law, a company's corporate interest extends to the interests of all of the company's stakeholders, including its shareholders, creditors, employees and clients.

9.3 Management Board

9.3.1 Responsibility, powers and function

The Management Board is responsible for the day-to-day management of the operations under the supervision of the Supervisory Board. In performing its duties, the Management Board must carefully consider and act in accordance with the interests of the Company and the business connected with it, taking into consideration the interest of all the stakeholders of the Company (which includes but is not limited to its customers, its employees and the Shareholders).

The Management Board is required to keep the Supervisory Board informed, consult with the Supervisory Board on important matters and submit certain important decisions to the Supervisory Board for its approval, as more fully described below. The Management Board shall inform the Supervisory Board at least once a year in writing of the general outline of the strategy, the general and financial risks and the management and control system of Kiadis.

The Management Board may perform all acts necessary or useful for achieving the Company's corporate purposes, save for those acts that are prohibited by law or by the Articles of Association. The Management Board as a whole is authorised to represent the Company, as is each member of the Management Board acting individually. The number of

members of the Management Board will be determined by the Supervisory Board and will consist of a minimum of one member.

9.3.2 Management Board Rules

In accordance with the Articles of Association, the Management Board has adopted internal rules regulating its decision-making process and working methods ("**Management Board Rules**"), in addition to the relevant provisions of the Articles of Association. These Management Board Rules have been published on Kiadis' website www.kiadis.com.

9.3.3 Appointment, dismissal and suspension

The Articles of Association provide that the Company's general meeting of shareholders (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 and the Supervisory Board may suspend Management Board members at any time, and that the General Meeting may dismiss Management Board members at any time. A resolution of the General Meeting to suspend or 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.

9.3.4 Meetings and decision-making

The Management Board holds, in principle, one meeting every week, or more (or less) often as deemed necessary or desirable for the proper functioning of the Management Board. If no larger majority is stipulated by Dutch law or pursuant to the Articles of Association or the Management Board Rules, the Management Board may adopt resolutions with an absolute majority of the votes cast at the meeting. Resolutions of the Management Board may, instead of at a meeting, be passed in writing, provided that all members of the Management Board are familiar with the resolution to be passed and none of them objects to this decision-making process.

A member of the Management Board may not participate in deliberating or decision-making within the Management Board, if with respect to the matter concerned he has a direct or indirect personal interest that conflicts with the interests of the Company and the business connected with it. If, as a result hereof, the Management Board cannot make a decision, the Supervisory Board will resolve the matter. All transactions in which there is a conflict of interest with one or more members of the Management Board shall be agreed on terms that are customary in the sector concerned and disclosed in the Company's annual report. Decisions to enter into transactions in which there are conflicts of interest with one or more

members of the Management Board that are of material significance to the Company require the approval of the Supervisory Board.

Resolutions of the Management Board identified in the Management Board Rules or identified pursuant to a resolution of the Supervisory Board from time to time on the basis of the relevant provisions in the Articles of Association require the prior approval of the Supervisory Board.

Under the Articles of Association, the resolutions of the Management Board that must be approved by the Supervisory Board include:

- the issue and acquisition of any of the Company's shares or debt instruments, or of debt instruments issued by a limited partnership or general partnership of which the Company is a fully liable partner;
- the application or the withdrawal for quotation in the listing on any stock exchange of the Company's shares or debt instruments, or of debt instruments issued by a limited partnership or general partnership of which the Company is a fully liable partner;
- the entry into or termination of a permanent cooperation of the Company or a dependent company with another legal entity or company or as fully liable partner in a limited partnership or general partnership, if such cooperation or termination is of major significance to the Company;
- the participation for a value of at least one-fourth of the amount of the issued capital with the reserves according to the most recent adopted balance sheet (whether consolidated or not) with explanatory notes of the Company or by a dependent company in the capital of another company, as well as a significant increase or reduction of such a participation;
- investments involving an amount equal to at least the sum of one-fourth of the Company's issued capital plus the reserves as shown in its most recent adopted balance sheet (whether consolidated or not);
- a proposal to amend the Company's articles of association;
- a proposal to dissolve (*ontbinden*) the Company;
- a proposal to conclude a legal merger (*juridische fusie*) or a demerger (*splitsing*);
- application for bankruptcy (*faillissement*) or for suspension of payments (*surséance van betaling*);
- the termination of the employment of a considerable number of employees of the Company or of a dependent company at the same time or within a short period of time;
- far-reaching changes in the employment conditions of a significant number of employees of the Company or of a dependent company; or

- a proposal to reduce the issued share capital.

Dutch law and the Articles of Association provide that decisions of the Management Board involving a significant change in the Company's identity or character are subject to the approval of the General Meeting. Such changes include:

- the transfer of all or substantially all of the Company's business to a third party;
- the entry into or termination of a longstanding joint venture with other legal entities or companies, or of the Company's position as a fully liable partner in a limited partnership or a general partnership, if such a joint venture is of major significance to the Company; or
- the acquisition or disposal of a participation in the capital of a company worth at least one-third of the amount of the assets according to the balance sheet with explanatory notes thereto, or if the Company prepares a consolidated balance sheet, according to such consolidated balance sheet with explanatory notes according to the last adopted annual accounts of the Company, by the Company or a subsidiary.

9.3.5 Members of the Management Board

The Management Board is currently composed of the following members:

Name	Age	Position	Member since	Term
Arthur Lahr	49	Chief Executive Officer	2017	2021
Robbert van Heekeren	47	Chief Financial Officer	2012[(1)]	2019

(1) Mr Van Heekeren was appointed to the management board of Kiadis Pharma B.V. (a company that has merged as disappearing entity with the Company in 2016, see paragraph 10.3.3 below) in 2012 which is the date referred to in this table. He has been member of the Management Board since the Company's incorporation on 12 June 2015.

The Company's registered address serves as the business address for the members of the Management Board (see paragraph 10.1 below).

Arthur Lahr

Mr. Lahr was appointed as a member of the Management Board on 4 April 2017 and is acting as Kiadis' Chief Executive Officer since 1 April 2017. Prior to joining Kiadis, Mr. Lahr was Chief Strategy Officer and member of the Management Committee at Crucell from 2004 until its acquisition by Johnson & Johnson in 2011. Before that he was, amongst others, a consultant at McKinsey & Company and an engineer at Unilever. Mr. Lahr holds a master's degree in Applied Physics from the University of Delft, the Netherlands, and an MBA from INSEAD, Fontainebleau, France.

At present, Mr. Lahr also serves as a member of the supervisory board of Sanquin, the Dutch national plasma and blood product supplier.

Robbert van Heekeren

Mr. Van Heekeren was appointed as a member of Kiadis Pharma B.V.'s management board (a company that merged as disappearing entity with the Company in 2016, see paragraph 10.3.3 below) on 22 February 2012 and has acted as Kiadis' Chief Financial Officer since 1 May 2008. He has been a member of the Management Board since the Company's incorporation on 12 June 2015. Prior to joining Kiadis, Mr. Van Heekeren was Executive Director, Head Global Finance & Control at Organon, the former pharmaceutical business unit of AkzoNobel. Mr. Van Heekeren worked for Organon for more than ten years in various international management positions. Mr. Van Heekeren 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.

During the last five years Mr. Van Heekeren held the position of member of the supervisory board of Odysee Mobile (2009 - 2015) and of Ceronco Biosciences (2011 - 2015).

9.4 Supervisory Board

9.4.1 Responsibility, powers and function

The Supervisory Board is responsible for supervising the conduct of the management and of the general course of affairs of the Company and of any affiliated enterprise. Furthermore, the Supervisory Board assists the Management Board by rendering advice. The members of the Supervisory Board are not authorised, however, to represent the Company in dealings with third parties.

In performing their duties, the members of the Supervisory Board are required to be guided by the interests of the Company and the enterprise connected therewith and to take into account the relevant interests of all Kiadis' stakeholders as well as the corporate social responsibility issues that are relevant to the business. The Supervisory Board is responsible for the quality of its own performance. The Supervisory Board may, at the Company's expense, seek the advice which it deems desirable for the correct performance of its duties.

9.4.2 Supervisory Board Rules

Pursuant to the Articles of Association, the Supervisory Board has adopted internal rules regulating its decision-making process and working methods ("**Supervisory Board Rules**"), in addition to the relevant provisions of the Articles of Association. The Supervisory Board Rules include a profile for the size and composition of the Supervisory Board, which profile takes into account the nature of Kiadis' business, the Supervisory Board's activities and the desired expertise and background of the members of the Supervisory Board.

9.4.3 Appointment, dismissal and suspension

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 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 number of members of the Supervisory Board will be determined by the General Meeting and will consist of a minimum of three members. Only natural persons (not legal entities) may be appointed as members of the Supervisory Board. The current members of the Supervisory Board have been appointed for the term set out in the table set out in paragraph 9.4.6 below. The Supervisory Board appoints a chairman and a deputy chairman from among its members.

The Articles of Association provide that the General Meeting and the Supervisory Board may suspend Supervisory Board members at any time, and that the General Meeting may dismiss Supervisory Board members at any time. Under the Articles of Association, a resolution of the General Meeting to suspend or dismiss members of the Supervisory Board pursuant to a proposal by the Supervisory Board requires 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 of the Supervisory Board requires an absolute majority of the votes cast representing more than 50% of the Company's issued share capital.

The Articles of Association provide that each member of the Supervisory Board shall be appointed for a maximum period of four years. A member of the Supervisory Board may be re-appointed for a total of three consecutive four-year terms. The members of the Supervisory Board must retire periodically in accordance with a rotation plan to be drawn up by the Supervisory Board. A member's term of office shall not lapse later than on the day after the first General Meeting to be held during the fourth year after such member's (re)appointment.

9.4.4 Meetings and decision-making

The Supervisory Board holds at least four meetings per year, or more often as deemed necessary or desirable by one or more members of the Supervisory Board or the Management Board. If no larger majority is stipulated by Dutch law or pursuant to the Articles of Association or the Supervisory Board Rules, the Supervisory Board may adopt resolutions with an absolute majority of the votes cast at the meeting. In the event of a tie in voting, the chairman will have a deciding vote. The Supervisory Board is only entitled to make decisions if at least half of its members are present or represented.

Resolutions of the Supervisory Board may, instead of at a meeting, be passed in writing, provided that all members of the Supervisory Board are familiar with the resolution to be passed and none of them objects to this decision-making process.

A member of the Supervisory Board may not participate in deliberating or decision-making within the Supervisory Board, if with respect to the matter concerned he has a direct or indirect personal interest that conflicts with the interests of the Company and the business connected with it. If, as a result hereof, the Supervisory Board cannot make a decision, the General Meeting will resolve the matter. All transactions in which there is a conflict of interest with one or more members of the Supervisory Board shall be agreed on terms that are customary in the sector concerned and disclosed in the Company's annual report. Decisions to enter into transactions in which there are conflicts of interest with one or more members of the Supervisory Board that are of material significance to the Company require the approval

of the Supervisory Board.

9.4.5 Supervisory Board committees

The Supervisory Board has appointed from among its members an Audit Committee and a Remuneration and Nominating Committee.

9.4.5.1 Audit Committee

The Audit Committee shall consist of at least two members. At least one member of the Audit Committee shall be a financial expert, in the sense that the member in question has relevant knowledge and experience of financial administration and accounting for listed companies or other large legal entities. The members of the Audit Committee shall be appointed and may be replaced at any time by the Supervisory Board. The Supervisory Board shall appoint one of the members of the Audit Committee as Chairman of the Audit Committee. The Audit Committee shall not be chaired by the chairman of the Supervisory Board or by a former member of the Management Board. The term of office of a member of the Audit Committee will generally not be set beforehand. It will, *inter alia*, depend on the composition of the Supervisory Board as a whole and that of other Committees from time to time.

The Audit Committee is charged in particular with:

- the supervision of the Management Board with respect to (i) the operation of the internal risk management and control systems, including supervision of the enforcement of the relevant legislation and regulations and supervision of the operation of codes of conduct; (ii) the provision of financial information by the Company (including but not limited to the choice of accounting policies, application and assessment of the effects of new rules, information about the treatment of estimated items in the financial statements, forecasts and the work of internal (if present) and external auditors); (iii) compliance with recommendations and observations of internal (if present) and external auditors; (iv) the role and functioning of the internal audit function, if present; (v) the tax principles of the Company; (vi) relations with the external auditor, including, in particular, his independence and remuneration; (vii) the financing of the Company; and (viii) the application of information and communication technology;

- giving advice to the Supervisory Board on the nomination by the Supervisory Board to the General Meeting for the appointment of the external auditor;

- where necessary, making proposals to the Supervisory Board on the policy applied in respect of the independence of the external auditor and possible (potential) conflicts of interest between the external auditor and the Company; and

- preparing meetings of the Supervisory Board with the Management Board to discuss the annual report, the annual accounts and the half-yearly figures of the Company.

The Audit Committee consists of Mr. Berndt Modig as chairperson and Mr. Martijn Kleijwegt as member.

9.4.5.2 Remuneration and Nominating Committee

The Nomination and Remuneration Committee shall consist of at least two members. No more than one member of the Nomination and Remuneration Committee shall be a member of the management board of another Dutch listed company. The members of the Nomination and Remuneration Committee shall be appointed and may be replaced at any time by the Supervisory Board. The Supervisory Board shall appoint one of the members of the Nomination and Remuneration Committee as Chairman of the Nomination and Remuneration Committee. The Nomination and Remuneration Committee shall not be chaired by the chairman of the Supervisory Board or by a former member of the Management Board, or by a Supervisory Board member who is a member of the management board of another listed company. The term of office of a member of the Nomination and Remuneration Committee will generally not be set beforehand. It will, *inter alia*, depend on the composition of the Supervisory Board as a whole and that of other Committees from time to time.

The Nomination and Remuneration Committee is charged in particular with:

- drawing up selection criteria and appointment procedures for Supervisory Board members and Management Board members;
- periodically assessing the size and composition of the Supervisory Board and the Management Board, and making proposals for a composition profile of the Supervisory Board;
- periodically assessing the functioning of individual Supervisory Board members and Management Board members, and reporting on this to the Supervisory Board;
- making proposals for appointments and reappointments;
- supervising the policy of the Management Board on the selection criteria and appointment procedures for senior management;
- drafting proposals to the Supervisory Board for the remuneration policy to be pursued for members of the Management Board;
- drafting proposals for the remuneration of the individual members of the Management Board; and
- preparing an annual Remuneration Report on behalf of the Supervisory Board, which contains an account of the manner in which the remuneration policy has been implemented in the past financial year for the Management Board, as well as an overview of the remuneration policy for Management Board planned by the Supervisory Board for the next financial year and subsequent years.

The Nomination and Remuneration Committee consists of Mr. Martijn Kleijwegt as chairperson and Mr. Robert Soiffer as member.

9.4.6 Members of the Supervisory Board

The Supervisory Board is composed of the following five members:

Name	Age	Position	Member since	Term
Mark Wegter[(1)]	48	Supervisory director – Chairman	2001[(3)]	2019
Martijn Kleijwegt[(1)]	63	Supervisory director	2006[(3)]	2019
Stuart Chapman[(1)]	48	Supervisory director	2013[(3)]	2019
Robert Soiffer[(2)]	60	Supervisory director	2016	2020
Berndt Modig[(2)]	59	Supervisory director	2016	2020

(1) Non-independent member of the Supervisory Board within the meaning of the Dutch Corporate Governance Code (the "**Corporate Governance Code**").

(2) Independent member of the Supervisory Board within the meaning of the Corporate Governance Code.

(3) The presented information refers to the year of appointment to the supervisory board of Kiadis Pharma B.V. (a company that merged as disappearing entity with the Company in 2016, see paragraph 10.3.3 below). Each of these 3 members has been member of the Supervisory Board since the Company's incorporation on 12 June 2015.

The Company´s registered address serves as the business address for all members of the Supervisory Board (see paragraph 10.1 below).

The Supervisory Board has nominated Dr. Otto Schwarz and Mr. Subhanu Saxena as new members of the Supervisory Board to be appointed by the General Meeting.

Dr. Schwarz is an industry veteran, with significant global operational and commercial leadership experience. Most recently, Dr. Schwarz served as Executive Vice-President, Chief Operating Officer and a member of the Executive Committee of Actelion Pharmaceuticals Inc. ("**Actelion**"), up to its recent acquisition by Johnson & Johnson. Prior to joining Actelion, Dr. Schwarz served as Executive Vice-President of Commercial Operations at Nycomed and as an Executive Board Member at Altana Pharma. From 1984 to 2003 he held various positions at Schering-Plough and Eli Lilly in Austria, Switzerland, Canada, the U.S. and Germany. Dr. Schwarz holds a PhD in pharmaceutical chemistry from Vienna University, Austria.

During the last five years, he held a board seat at the Max7 Foundation (June 2016 – present).

Mr. Saxena currently serves as a Regional Director with the Bill & Melinda Gates Foundation as well as a Partner at New Rhein Healthcare and a Senior Advisor to Bain Capital. Mr. Saxena served as the Managing Director and Global Chief Executive Officer of Cipla, a publicly listed, Indian pharmaceutical and biotech company, and was with Cipla from February 2013 to February 2017. Prior to joining Cipla, Mr. Saxena was Head of Global Product Strategy and Commercialisation and member of the Executive Committee at Novartis. Mr. Saxena also previously served as CEO of Novartis UK. Prior to joining the pharma industry, Mr. Saxena worked with leading global companies including Citicorp, the Boston Consulting Group and PepsiCo across markets in Europe, North America, Africa and Asia. Mr. Saxena holds a graduate degree in Engineering from Oxford University and an MBA from INSEAD, Fontainebleau, France.

During the last five years, he held a board seat at Cipla (2013 – 2016).

Mark Wegter

Mr. Wegter became a member and chairman of the supervisory board of Kiadis Pharma B.V. (a company that has merged as disappearing entity with the Company in 2016, see paragraph 10.3.3 below) in 2001. He has been a member of the Supervisory Board and its chairman since the incorporation of the Company on 12 June 2015. In 1998, Mr. Wegter joined Life Sciences Partners, becoming a General Partner in 2001. In that same year, Mr. Wegter established Life Sciences Partners' office in Munich, Germany. Mr. Wegter also holds positions at various Life Sciences Partners entities that manage Life Sciences Partner funds. Mr. Wegter graduated from the Erasmus University of Rotterdam, the Netherlands, with a degree in economics.

During the last five years, he held a board position at VitrOmics Healthcare (2000 – 2015).

Martijn Kleijwegt

Mr. Kleijwegt became a member of the supervisory board of Kiadis Pharma B.V. (a company that has merged as disappearing entity with the Company in 2016, see paragraph 10.3.3 below) in 2006. He has been a member of the Supervisory Board since the incorporation of the Company on 12 June 2015. Mr. Kleijwegt founded Life Sciences Partners in 1998 and has been Managing Partner of Life Sciences Partners ever since. Mr. Kleijwegt is the Managing Director of the Company's significant Shareholders Life Sciences Partners B.V. and Life Sciences Partners II B.V. (see paragraph 11.1 below) and holds positions at various Life Sciences Partners entities that manage Life Sciences Partner funds. He is also a current member of the board of the European Venture Capital Association. Mr. Kleijwegt graduated from the University of Amsterdam, the Netherlands, with a degree in economics.

During the last five years, he held a board seat at Prosensa (2007 – 2014).

Stuart Chapman

Mr. Chapman became a member of the supervisory board of Kiadis Pharma B.V. (a company that has merged as disappearing entity with the Company in 2016, see paragraph 10.3.3 below) in 2013. He has been a member of the Supervisory Board since the incorporation of the Company on 12 June 2015. After having worked at 3i Group and Cazenove Private Equity, in 2006 Mr. Chapman co-founded DFJ Esprit (now named Draper Esprit) and has been a board member and Managing Partner of Draper Esprit ever since. Mr. Chapman holds a degree in economics from the University of Loughborough, United Kingdom.

Robert Soiffer

Dr. Soiffer became a member of the Supervisory Board on 28 June 2016. Dr. Soiffer is currently a Professor at Harvard University Medical School, Chief of the Division of Hematologic Malignancies at the DFCI and Co-director of the Adult Stem Cell Transplantation Program at the DFCI. Dr. Soiffer joined the Dana-Farber Cancer Institute (DFCI) in 1988, after completing a medical oncology fellowship. Dr. Soiffer sits on the board of the U.S. National Marrow Donor Program (NMDP) and on the Massachusetts Board of the Leukemia and Lymphoma Society. He is also Chairman of the Advisory Committee for

International Blood and Marrow Research.

Berndt Modig

Mr. Modig became a member of the Supervisory Board on 28 June 2016. Mr. Modig was previously Chief Financial Officer of Prosensa and before that Chief Financial Officer at Jerini AG and Surplex GmbH. He is also currently a Board Member of Axovant Sciences Ltd., Auris Medical Holding AG and Affimed N.V., and CEO of Pharvaris B.V. Holds a degree in business administration, economics and German from the University of Lund, Sweden and received his MBA from INSEAD, Fontainebleau, France.

During the last five years, he held board seats at Mobile Loyalty Plc (until 2013), Onkobiotek (until 2017) and Schoodic Management B.V.

9.5 Senior Management

Kiadis' Senior Management supports the Management Board in the day-to-day management of the operations. It currently consists of the senior officers listed below.

Name	Age	Position and practice area
Andrew Sandler	53	Chief Medical Officer
Jan Feijen	62	Chief Operations Officer
Margot Hoppe	53	General Counsel & Corporate Secretary
Karl Hård	55	Head of Investor Relations and Communications

The terms of the appointment of the Senior Management members do not contain an expiration date.

The Company´s registered address serves as the business address for Senior Management (see paragraph 10.1 below).

Andrew Sandler

Dr. Sandler was appointed in 2017 as Kiadis' Chief Medical Officer. Dr. Sandler has over 20 years of experience within the healthcare industry, dedicated to haematologic malignancies and solid tumours. He has served as the senior medical executive in multiple global NASDAQ listed oncology companies. Most recently, Dr. Sandler was Senior Vice President, Medical Affairs, at Medivation (now part of Pfizer). Prior to that he served as Chief Medical Officer at Dendreon Pharmaceuticals and Spectrum Pharma. He has also held senior-level positions with several other leading biotechnology and pharmaceutical companies, including Bayer Healthcare, Berlex Laboratories, Inc. and Seattle Genetics, Inc. Dr. Sandler is also a board certified medical oncologist in the U.S. Dr. Sandler holds a degree in medicine from Mount Sinai School of Medicine, New York and has completed a fellowship in medical oncology at the University of California San Francisco.

Jan Feijen

Mr. Feijen was appointed in 2017 as Kiadis' Chief Operations Officer. Prior to joining Kiadis, he was Vice President Manufacturing and Technical Operations, Platform Lead Vaccines and Advanced Therapies at Janssen: Pharmaceutical Companies of Johnson & Johnson. Prior to that, Mr. Feijen held various executive positions at Crucell, Avebe U.A. and Gist-Brocades International B.V. (Gist-Brocades). He holds a master's degree in applied physics from the University of Delft, the Netherlands.

During the last five years, Mr. Feijen held board seats at Janssen Vaccines Korea Corporation (2011 – 2017), Janssen Vaccines Switzerland AG (2011 – 2016), JFE Group, Inc. (2009 – 2016) and PhoAzie, Inc. (2013 – 2016).

Margot Hoppe

Ms. Hoppe was appointed as Kiadis' General Counsel & Corporate Secretary in 2008. She has over 20 years of experience in corporate legal affairs and worked for various biotechnology companies including Gist-Brocades and Koninklijke DSM N.V. (DSM). Ms. Hoppe holds master's degrees in law and political science from the Erasmus University of Rotterdam, the Netherlands.

Karl Hård

Mr. Hård was appointed in 2017 as Kiadis' Head of Investor Relations and Communications. He spent almost 20 years at AstraZeneca PLC based in Sweden and the UK where he held various senior roles within investor relations and ultimately as head of Investor Relations. Prior to that, he worked as Global Program Director, establishing new external collaborations, and as a Director in Biological Chemistry, leading research into novel pharmacological targets. Prior to joining AstraZeneca, Mr. Hård was an Assistant Professor of Chemistry at Leiden University, the Netherlands. Mr. Hård received a master's degree in biochemistry from the Helsinki University, Finland, and holds a PhD in Chemistry from Utrecht University, the Netherlands.

9.6 Remuneration and equity holdings

The Supervisory Board establishes the remuneration of the individual members of the Management Board in accordance with the principles laid down in the Management Board remuneration policy as adopted by the General Meeting. The Supervisory Board presents to the General Meeting for approval any proposal providing for the remuneration of the members of the Management Board in the form of shares or options. This proposal must include the number of shares and/or options that may be granted to the Management Board and which criteria apply to a grant or modification. The general principles on which the Company´s current remuneration policy is based and the objectives that it seeks to accomplish are:

- to provide competitive compensation so as to enable Kiadis to recruit, motivate and retain qualified and expert individuals that Kiadis needs in order to achieve its strategic and operational objectives;

- to focus management on the creation of sustainable added value, taking into account the interests of all stakeholders, by having total compensation significantly driven by variable performance dependent

income components;

- to provide for variable income consisting of short-term (cash bonus) and long-term incentives (options and stock appreciation rights), whereby the distribution between short-term and long-term incentives aims to achieve a proper balance between short-term results and long-term value creation;

- to align the economic interest of the Management Board as related to long-term incentives with the economic interest of the Shareholders.

9.6.1 Remuneration

9.6.1.1 Management Board

The total remuneration costs in 2017 in relation to the members of the current Management Board amounted to €1,179,941, as set forth in the following table:

Name	Base salary	Employer's pension contributions	Annual cash bonus	Share-based payments[(1)]	Social security and other payments
Arthur Lahr	€232,500	€5,535	€70,000	€539,603	€9,559
Robbert van Heekeren	€173,350	€6,504	€39,000	€94,331	€9,559

(1) Expenses of share-based payments incurred in 2017 relate to the SARs granted to Mr. Lahr and the options granted to Mr. van Heekeren.

At the Registration Document Date, there are no amounts reserved or accrued by the Company or its subsidiaries to provide pension, benefit, retirement or similar benefits for current members of the Management Board.

9.6.1.2 Supervisory Board

The remuneration of the members of the Supervisory Board is determined by the General Meeting, which has determined that the chairman of the Supervisory Board, if independent, will receive an annual remuneration of €50,000 and each other member of the Supervisory Board, if independent, will receive an annual remuneration of €40,000. The total remuneration in relation to 2017 amounted to €80,000.

At the Registration Document Date, there are no amounts reserved or accrued by the Company or its subsidiaries to provide pension, benefit, retirement or similar benefits for current members of the Supervisory Board.

9.6.1.3 Senior Management

The total remuneration costs in relation to 2017 to current Senior Management amounted to €849,463. It is noted that Mr. Feijen joined Kiadis on 1 April 2017, Mr. Hård on 1 September 2017 and Mr. Sandler on 28 September 2017. Consequently the aforementioned amount does not include a full year's remuneration paid to them. Similarly, the aforementioned amount does not include the remuneration paid in 2017 to Dr. Jeroen Rovers, who was succeeded in 2017 as Kiadis' Chief Medical Officer and member of Senior Management by Mr. Sandler.

9.6.2 Equity holdings and interests

At the Registration Document Date, the number of Shares, options (see paragraph 9.11.1 below) and stock appreciation rights ("**SARs**") (see paragraph 9.11.2 below) held by the Management Board, Senior Management and Supervisory Board are as follows:

Name	Shares	Options	SARs
Arthur Lahr	-	-	300,000
Robbert van Heekeren	127,995	33,903	-
Andrew Sandler	-	100,000	-
Jan Feijen	-	65,000	-
Margot Hoppe	53,190	25,000	-
Karl Hård	-	25,000	
Mark Wegter[(1)]	-	-	-
Martijn Kleijwegt[(2)]	-	-	-
Stuart Chapman	-	-	-
Robert Soiffer	-	-	-
Berndt Modig	-	-	-

(1) Mr. Wegter does not hold Shares directly, but he is (i) a 22.95% shareholder in LSP Management Group B.V., a company that holds a capital interest of 16.27% and a voting interest of 16.27% in Lenildis Holding B.V., which latter company in turn, as at the Registration Document Date, holds a substantial holding in the Company. See also paragraph 11.1 below.

(2) Mr. Kleijwegt does not hold Shares directly, but (i) is a 31.15% shareholder and managing director of LSP Management Group B.V., a company that holds a capital interest of 16.27% and a voting interest of 16.27% in Lenildis Holding B.V., and (ii) through Pro-Ventures I B.V., a company of which Mr. Kleijwegt is the sole shareholder and managing director, he has an a capital interest of 22.24% and a voting interest of 22.24% in Lenildis Holding B.V. Lenildis Holding B.V. in turn, as at the Registration Document Date, holds a substantial holding in the Company. See also paragraph 11.1 below.

(3) For completeness sake it is noted that Dr. Schwarz does not hold any Shares, options or SARs, and that Mr. Saxena holds 5,200 Shares (but no options nor SARs).

9.7 Employment, service and severance agreements

The current members of the Management Board have entered into a service agreement with the Company. The main elements of each of these service agreements are the following:

- a term of four years;
- a fixed base salary;
- no fixed expenses;
- an annual pension contribution;

- an annual cash bonus;
- options or stock appreciation rights; and
- severance pay equal to the annual fixed base salary (including in case of a change of control).

The members of the Supervisory Board do not have an employment, service or severance contract with the Company, except that Dr. Robert Soiffer and Mr. Bernd Modig have an agreement with the Company relating to their position as member of the Supervisory Board.

9.8 Potential conflicts of interest and other information

Mr. Kleijwegt is managing director of the Company's significant Shareholders Life Sciences Partners B.V. and Life Sciences Partners II B.V. (see paragraph 11.1 below).

Mr. Van Heekeren and Ms. Hoppe hold Shares and Mr. Kleijwegt and Mr. Wegter have an indirect interest in Shares, Mr. Van Heekeren, Dr. Sandler, Mr. Feijen, Ms. Hoppe and Mr. Hård hold options and Mr. Lahr holds SARs (see paragraph 9.6.2 above).

Mr. Wegter and Mr. Kleijwegt have been nominated as members of the Supervisory Board by significant Shareholders Life Sciences Partners B.V. and Life Sciences Partners II B.V. respectively and hold various positions at Life Sciences Partners. Mr. Chapman has been nominated as a member of the Supervisory Board by significant Shareholder Esprit Nominees Ltd. and also holds a position at Draper Esprit. As a consequence hereof, Mr. Wegter, Mr. Kleijwegt and Mr. Chapman are "not independent" within the meaning of the Corporate Governance Code (see paragraph 9.4.6 above).

Other than these circumstances, Kiadis is not aware of any other circumstance that may lead to a potential conflict of interest between the private interests or other duties of members of the Management Board, the Supervisory Board (including, for the purposes of this statement, Dr. Schwarz and Mr. Saxena) or Senior Management vis-à-vis Kiadis. No family ties exist among the members of the Management Board, Supervisory Board (including, for the purposes of this statement, Dr. Schwarz and Mr. Saxena) or Senior Management.

With respect to each of the members of the Supervisory Board (including, for the purposes of this statement, Dr. Schwarz and Mr. Saxena), the Management Board and Senior Management, Kiadis is not aware of (i) any convictions in relation to fraudulent offences in the last five years, (ii) any bankruptcies, receiverships or liquidations of any entities in which such members held any office, directorships or senior management positions in the last five years, or (iii) any official public incrimination or sanctions of such person by statutory or regulatory authorities (including designated professional bodies), or disqualification by a court from acting as a member of the administrative, management or supervisory bodies of an issuer or from acting in the management or conduct of the affairs of any issuer for at least the previous five years.

Other than disclosed in this paragraph 9.8, Kiadis is not aware of any arrangement or understanding with significant Shareholders, suppliers, customers or others pursuant to which any member of the Management Board or Supervisory Board was selected as a member of such management or supervisory bodies.

9.9 Directors' indemnification and insurance

Under Dutch law, members of the Management Board and the Supervisory Board may be liable to the Company for damages in the event of improper or negligent performance of their duties. They may be jointly and severally liable for damages to the Company and to third parties for infringement of the Articles of Association or of certain provisions of Dutch law. In certain circumstances, they may also incur additional specific civil and criminal liabilities. Members of the Management Board, members of the Supervisory Board, Senior Management and certain other officers of Kiadis and certain subsidiaries are insured under an insurance policy against damages resulting from their conduct when acting in the capacities as such members or officers.

The Articles of Association provide for an indemnity for members of the Management Board and the Supervisory Board. Kiadis indemnifies any member who was or is in his capacity as member of the Management Board or the Supervisory Board a party, or is threatened to be made a party, to any threatened, pending or completed action, suit or proceeding against any and all liabilities including all expenses, judgments, fines, amounts paid in settlement and other financial losses actually and reasonably incurred. No indemnification shall be made if a member of the Management Board or the Supervisory Board shall have been adjudged in a final and non-appealable judgment by a Dutch court to be liable for gross negligence or wilful misconduct in the performance of his duty (unless and only to the extent that the judge before whom such action or proceeding was brought or any other Dutch judge having appropriate jurisdiction shall determine upon application that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to a compensation which the judge before whom such action or proceeding was brought or such other judge having appropriate jurisdiction shall deem proper) or if costs and losses have been insured under any insurance and the insurance company has reimbursed the costs and losses to such member.

9.10 Employees and key technical staff

As at the Registration Document Date, Kiadis has 61 employees, all primarily located in Amsterdam. Kiadis' employees are classified as follows: management, chemistry/manufacturing/control (CMC), clinical development, research, quality assurance, medical/regulatory affairs, finance, IT and support staff.

Kiadis had an average of 61 employees for the year ended 31 December 2017, 39 employees for the year ended 31 December 2016, 27 employees for the year ended 31 December 2015 and 21 employees for the year ended 31 December 2014. During the year ended 31 December 2016, Kiadis did not employ a significant number of temporary employees.

Kiadis' key scientific and technical staff consists of the Chief Medical Officer, the Chief Operations Officer, the Vice President CMC, the Head of Technology and Development, the Head of Project Management, the Head of Manufacturing, the Head of Analytics and Validation and the Head of Regulatory Affairs. The key technical staff's relevant collective expertise and experience encompasses clinical development, process development and manufacturing in the pharmaceutical industry, as well as a relevant education background for working in the pharmaceutical industry.

9.11 Incentive plans

9.11.1 Share Option Plan

In order to advance the interests of the Company and the Shareholders by enhancing the Company's ability to attract, retain and motivate persons who are expected to make important contributions to Kiadis, and by providing such persons with equity ownership opportunities that are intended to better align the interests of such persons with those of the Company and the Shareholders, the Kiadis Pharma N.V. 2016 Share Option Plan was created. Under this plan, employees, Management Board and Supervisory Board members and advisors may be offered options to purchase Shares whereby each (vested) option grants the right to acquire one Share.

The option exercise price shall be the closing sales price at which Shares are traded on the day prior to the day the option is granted. Vesting of the options may take place on one date or in part over time, but all options granted up to the Registration Document Date have vested as follows: one third on the first anniversary of the date the options are granted, one third on the second anniversary of the date the options are granted, and one third on the third anniversary of the date the options are granted. The members of the Management Board who have been granted options prior to the Registration Document Date may not exercise such options, if vested, within the first three years after the date the options were granted. In addition, options for the Management Board may be settled in cash. Options granted to the Management Board shall be related to certain performance targets in accordance with the principles laid down in the Management Board remuneration policy as adopted by the General Meeting. Granted options have a duration of ten years. The plan contains so-called good leaver provisions whereby the good leaver shall remain entitled to vested options with the non-vested options lapsing and vested options to be exercised within one year, and bad leaver provisions, whereby a bad leaver shall lose all options, whether vested or not.

The option pool shall not exceed 3.5% of the number of Shares in issue immediately prior to a grant date, and within this option pool, the Management Board may in total be granted options to at most 2% of the number of Shares in issue.

At the Registration Document Date, the total number of options held by the Management Board, Senior Management, Supervisory Board and other (former) employees is 477,377. None of these options have been exercised.

9.11.2 Stock Appreciation Right Plan

In order to advance the interests of the Company and the Shareholders by enhancing the Company's ability to attract, retain and motivate persons who are expected to make important contributions to Kiadis, and by providing such persons with long-term incentives that are intended to better align the interests of such persons with those of the Company and the Shareholders, the Kiadis Pharma N.V. 2017 Stock Appreciation Right Plan was created. Under this Plan, employees and Management Board and Supervisory Board members may receive a cash payment equal to the increase in value of a stated number of Shares over a specific period of time. The Plan also allows in the granting of SARs to advisors, which in particular enables the Company to incentivise personnel that is not engaged on the basis of an employment agreement but on the basis of a consultancy or other arrangement.

The initial price of a SAR shall be the closing sales price at which Shares are traded on the day prior to the day the SARs is granted. Vesting of the SARs may take place on one date or

in part over time, but all SARs granted up to the Registration Document Date have vested as follows: one third of the SARs vests on the first anniversary of the date on which the SARs was granted, one third of the SARs vests on the second anniversary of the date on which the SARs was granted, and one third of the SARs vests on the third anniversary of the date on which the SARs was granted. The members of the Management Board who have been granted a SARs prior to the Registration Document Date may not exercise such SARs, if vested, within the first three years after the date on which the SARs was granted. SARs granted to the Management Board shall be related to certain performance targets in accordance with the principles laid down in the Management Board remuneration policy as adopted by the General Meeting. Granted SARs have a duration of ten years. The plan contains so-called good leaver provisions whereby the good leaver shall remain entitled to the vested part of his SARs with the non-vested part of his SARs lapsing and the vested part of the SARs is to be exercised within one year, and bad leaver provisions, whereby a bad leaver shall lose his SARs, whether vested or not.

The SARs pool shall not exceed 3% of the number of Shares in issue immediately prior to a grant date.

At the Registration Document Date, the total number of Shares in respect of which SARs have been granted to the Management Board, Senior Management, Supervisory Board and other (former) employees is 300,000. None of these SARs have been exercised.

9.12 Pension schemes

As per 2011, Kiadis provides its employees with a collective pension plan based on a defined-contribution agreement. Both members of the Management Board participate in this pension scheme. Kiadis provides its employees with collectively negotiated health and retirement benefits in line with market practices in the Netherlands.

A defined-contribution plan is a post-employment benefit plan under which Kiadis pays fixed contributions into a separate entity (Delta Lloyd) administering the pension scheme. Kiadis has no legal or constructive obligations to pay further contributions if the fund does not hold sufficient assets to pay all employees the benefits relating to employee service in the current and prior periods.

10 Description of Share Capital and Corporate Governance

10.1 General

The Company was incorporated on 12 June 2015 as a public limited liability company (*naamloze vennootschap*) under the laws of the Netherlands. The Company is registered with the Trade Register of the Chamber of Commerce of Amsterdam, the Netherlands, under number 63512653. The Company's registered address is in Amsterdam, the Netherlands and its business address is at Paasheuvelweg 25A, 1105 BP Amsterdam, the Netherlands (tel: +31 - 20 – 2402550). The Company's commercial name is Kiadis Pharma.

Set out below is a summary of certain information concerning the Company's share capital and certain significant provisions of Dutch corporate law and a brief summary of certain provisions of the Articles of Association.

This summary does not purport to give a complete overview and should be read in conjunction with the Articles of Association and the relevant provisions of Dutch law, and does not constitute legal advice regarding these matters and should not be considered as such. The full text of the Articles of Association is available, in Dutch and English, at the Company´s business address in Amsterdam during regular business hours. The Articles of Association are available in Dutch and English at Kiadis' website www.kiadis.com (see paragraph 2.4 above).

10.2 Corporate purpose

Pursuant to article 3 of the Articles of Association, the objects of the Company are:

- to develop and subsequently market or license new pharmaceutical products with a primary focus on oncology;
- to participate in, to finance, to collaborate with, to conduct the management of companies and other enterprises and provide advice and other services;
- to acquire, use and/or assign industrial and intellectual property rights and real property;
- to invest funds;
- to provide security for the obligations of the Company, group companies or third parties; and
- to undertake all that which is connected to the foregoing or in furtherance thereof,

all in the widest sense of the words.

10.3 Share capital

10.3.1 Authorised and issued share capital

The Company's authorised share capital pursuant to the Articles of Association amounts to €5,000,000 and is divided into 50,000,000 ordinary shares, each with a nominal value of €0.10. All of the Company's authorised shares will, when issued and outstanding, be created

under Dutch law.

On the Registration Document Date, the Company´s issued capital amounts to €1,751,509.20 and is divided into 17,515,092 Shares, each with a nominal value of €0.10.

At the Registration Document Date, neither the Company nor any of its subsidiaries hold any Shares. As at the Registration Document Date, all the Shares are fully paid up.

10.3.2 Warrants, options and stock appreciation rights

The Company has issued three classes of warrants to acquire Shares: two classes that are exercisable until 15 June 2022 (the "**2022-I Warrants**" and the "**2022-II Warrants**", collectively the "**2022 Warrants**") and one class that is exercisable until 31 August 2027 (the "**2027 Warrants**").

On the Registration Document Date, the following warrants are outstanding.

	Outstanding	**exercise price**	**Exercise period**
2022-I Warrants	246,186	€7.307	Until 15 June 2022
2022-II Warrants	3,731	€7.312	Until 15 June 2022
2027 Warrants	253,617	€6.358	Until 31 August 2027

In connection with the Company's €5.0 million equity raise in June 2017 (see paragraph 10.3.3 below), 746,269 2022-I Warrants and 55,970 2022-II Warrants were issued. In the period up to the Registration Document Date, 500,083 2022-I Warrants were exercised and 52,239 2022-II Warrants were exercised.

The 2027 Warrants were issued to Kreos Expert in connection with the debt financing arrangements that Kiadis entered into with Kreos Capital in August 2017 (see paragraph 5.7 above). Of these 253,617 2027 Warrants, 211,348 were issued in August 2017 when the first tranche of the loan provided by Kreos Capital was drawn down, and 42,269 were issued in October 2017 when the second tranche of the loan was drawn down.

If the Company subdivides its Shares into a greater number of shares, the number of shares purchasable upon the exercise of the warrants shall be proportionately increased and the exercise price shall be proportionately decreased. If the Shares are combined or consolidated into a lesser number of shares, the exercise price shall be proportionately increased and the number of shares purchasable upon the exercise of the warrants shall be proportionately decreased. Upon any event whereby all of the Shares are reclassified, exchanged, combined, substituted, or replaced for, into, with or by Company securities of a different class and/or kind, then from and after the consummation of such event, the warrants will be exercisable for the number, class and kind of Company securities that the holder of a warrant would have received had the shares purchasable upon the exercise of the warrant been outstanding on and as of the consummation of such event. This adjustment shall similarly apply to successive reclassifications, exchanges, combinations, substitutions, replacements or other similar events.

If the Company in the period up to 17 August 2018 issues any Shares as part of an equity financing raise at a subscription price per Share of less than €6.358, then the exercise price of the 2027 Warrants shall be reduced to such equity financing raise's subscription price. In the event that the exercise price has been adjusted in the period up to 17 August 2018 as per the aforementioned, any possible subsequent equity financing raise during such period

shall not result in further adjustment of the exercise price.

If the Company in the period between 17 August 2018 and 17 August 2019 issues any Shares as part of an equity financing raise at a subscription price per Share of less than €6.358 (or, if the exercise price is reduced in the period up to 17 August 2018 as per the aforementioned, such lower amount), then the exercise price of the 2027 Warrants shall be reduced to such equity financing raise's subscription price. In the event that the exercise price has been adjusted in the period between 17 August 2018 and 17 August 2019 as per the aforementioned, any possible subsequent equity financing raise during such period shall not result in further adjustment of the exercise price. The exercise price adjustment provisions set out in this paragraph do not apply to the issuance of shares other than pursuant to or in the context of an equity finance raise, including Shares issued to employees, advisors, officers or directors of the Company pursuant to any agreement or incentive plan duly adopted for such purpose by the Management Board and Supervisory Board of the Company in the ordinary course and consistent with past practice approved by the Supervisory Board and Shares issued to finance or pursuant to acquisitions, licenses or strategic transactions approved by the Management Board and Supervisory Board of the Company and conducted by the Company on a basis consistent with capital raising transactions by comparable companies.

In relation to the 2022 Warrants exercise price adjustment provisions similar to those set out in the paragraph above applied. Based on these provisions, as a consequence of the issuance of the 2027 Warrants the exercise price of the 2022-I Warrants was adjusted to €7.307 and the exercise price of the 2022-II Warrants was adjusted to €7.312. Since and as a consequence of these adjustments, the relevant exercise price adjustment provisions have ceased to be applicable to the 2022 Warrants.

On the Registration Document Date, the Management Board, Senior Management, Supervisory Board and other (former) employees together hold 477,377 options and 300,000 SARs. None of these options or SARs has been exercised.

10.3.3 History of share capital

The Company was incorporated on 12 June 2015 in the context of the Capital Restructuring.

At the Company's incorporation, 10,694,508 Shares were issued. Subsequently, as part of the Company's IPO in 2015, a total of 2,777,136 Shares were issued in July and August 2015.

At the beginning of 2016, Kiadis Pharma B.V., as disappearing entity, merged into the Company as a result of which 290 Shares were issued to the shareholders of Kiadis Pharma B.V. (but excluding the Company which prior to the merger already held 97.52% of the shares of Kiadis Pharma B.V.). In February and July 2016, an aggregate number of 156,328 Shares were issued to The Leukemia & Lymphoma Society, Inc., which invested into the Company to further finance the clinical development of ATIR101, Kiadis' principal product. In June 2016, a total of 338,239 Shares were issued to the participants of the Kiadis 2013 Exit Participation Plan (the "**2013 Exit Participation Plan**"), a bonus share plan to provide incentives to certain executives and key employees of Kiadis, which plan was closed after the Company's IPO in 2015 and settled by means of the aforementioned June 2016 issuance of Shares. On 15 June 2017, the Company issued 746,269 new Shares pursuant to a private placement with a group of existing and new institutional investors in which it raised €5 million in gross proceeds. In connection with the June 2017 equity raise, the 2022 Warrants were

issued, of which 552,322 were exercised since. On 12 October 2017, the Company issued 2,250,000 new Shares pursuant to a private placement with a group of existing and new institutional investors in which it raised €18 million in gross proceeds.

10.3.4 Issue of Shares

Under the Articles of Association, the Company may issue Shares, or grant rights to subscribe for Shares, only pursuant to a resolution of the General Meeting upon proposal of the Management Board, subject to the prior approval of the Supervisory Board.

The Articles of Association provide that the General Meeting or the Articles of Association may designate the authority to issue Shares, or grant rights to subscribe for Shares, to the Management Board, subject to the approval by the Supervisory Board. Pursuant to Dutch law and the Articles of Association, the period of designation may not exceed five years. Such designation may be renewed by a resolution of the General Meeting for a subsequent period of up to five years each time. Unless the resolution determines otherwise, the designation is irrevocable. At the designation, the number of Shares which may be issued by the Management Board must be determined.

On 8 June 2017 a General Meeting was held at which it was resolved to authorise the Management Board, subject to the approval of the Supervisory Board, to issue Shares for a period of five years following 8 June 2017, or grant rights to subscribe for Shares, up to a maximum of 50% of the number of Shares that were outstanding on 8 June 2017 and to exclude pre-emptive rights in relation thereto. On the basis of these authorisations, the Company issued new Shares in the context of the June 2017 and October 2017 equity raisings (see paragraph 10.3.3), granted the 2022 Warrants and the 2027 Warrants (see paragraph 10.3.2) and granted 274,200 options pursuant to the Kiadis Pharma N.V. 2016 Share Option Plan (see paragraph 9.11.1), and excluded the pre-emptive rights in relation thereto.

No resolution of the General Meeting or the Management Board is required for an issue of Shares pursuant to the exercise of a previously granted right to subscribe for Shares.

10.3.5 Pre-emptive Rights

Dutch company law and the Articles of Association in most cases give shareholders pre-emptive rights to subscribe on a pro rata basis for any issue of new shares or upon a grant of rights to subscribe for shares. Exceptions to these pre-emptive rights include the issue of shares and the grant of rights to subscribe for shares (i) to the Company's employees or the employees of a group company as defined in section 2:24b of the Dutch Civil Code, (ii) in return for non-cash consideration, or (iii) the issue of shares to persons exercising a previously granted right to subscribe for shares.

A Shareholder may exercise pre-emptive rights during a period of at least two weeks from the date of the announcement of the issue or grant. The General Meeting or the Management Board, if so designated by the General Meeting, may restrict the right or exclude pre-emptive rights. A resolution of the General Meeting to restrict or exclude pre-emptive rights, or to designate the Management Board with such authority, requires a majority of at least two-thirds of the votes cast, if less than 50% of the Company's issued share capital is represented. Unless the Management Board is designated to restrict or to exclude pre-emptive rights, a resolution to restrict or to exclude pre-emptive rights will be passed by the General Meeting on the proposal of the Management Board, with the prior

approval of the Supervisory Board. A resolution by the General Meeting, or by the Management Board, to restrict or to exclude pre-emptive rights is subject to the prior approval of the Supervisory Board. See paragraph 10.3.4 above for the resolution that authorised the Management Board, subject to Supervisory Board approval, to exclude pre-emptive rights that the General Meeting took on 8 June 2017.

10.3.6 Reduction of share capital

Under the Articles of Association, upon a proposal from the Management Board, after approval by the Supervisory Board and in compliance with articles 2:99 and 2:100 of the Dutch Civil Code, the General Meeting may resolve to reduce the Company's issued and outstanding share capital by cancelling Shares, or by amending the Articles of Association to reduce the nominal value of the Shares. A resolution for cancellation of Shares may only relate to Shares held by the Company itself or of which it holds the depositary receipts.

The decision to reduce the Company's share capital requires a majority of at least two-thirds of the votes cast if less than 50% of its issued share capital is present or represented at the General Meeting.

10.3.7 Acquisition of Shares by the Company

The Company cannot subscribe for Shares in its own capital at the time Shares are issued. Any acquisition by the Company of its Shares that are not fully paid-up shall be null and void. The Company can acquire fully paid-up Shares in its own capital for no consideration, or if (i) the shareholders' equity less the acquisition price is not less than the sum of the paid-in and called-up part of the Company's capital and the reserves that it is required to maintain by law, (ii) the nominal value of the Shares to be acquired in its own capital, which the Company holds or hold in pledge, or which are held by one of its subsidiaries is not more than 50% of the issued capital, such in accordance with section 2:98 of the Dutch Civil Code and (iii) the acquisition is authorised by the General Meeting. A subsidiary cannot subscribe for its own account or acquire Shares in the capital of the Company.

Authorisation from the General Meeting to acquire the Shares must specify the number and class of Shares that may be acquired, the manner in which Shares may be acquired and the price range within which Shares may be acquired. Such authorisation will be valid for no more than eighteen months.

The Company may not cast votes on, and is not entitled to dividends or other distributions paid on, Shares held by it nor will such Shares be counted for the purpose of calculating a voting quorum. For the computation of the profit distribution, the Shares held by the Company in its own capital shall not be included. The Management Board is authorised, subject to approval of the Supervisory Board, to dispose of the Company's own Shares held by it.

On 8 June 2017, a General Meeting was held which resolved to authorise the Management Board, subject to the approval of the Supervisory Board, to acquire Shares for a period of 18 months following 8 June 2017, by way of purchase, via the stock exchange or otherwise, up to a maximum of 10% of the issued capital and for a consideration of at least €0.01 per Share and which may not exceed the average closing price of the Shares on Euronext during five consecutive trading days preceding the date of repurchase increased by 10%.

10.4 Dividends and other distributions

10.4.1 General

Pursuant to Dutch law and the Articles of Association, the distribution of profits will take place following the adoption of the Company's annual accounts by the General Meeting, and only to the extent that those accounts show sufficient profits to make the contemplated distribution. The Company may only make distributions to the Shareholders, whether from profits or from its freely distributable reserves, insofar as its shareholders' equity exceeds the sum of the paid-up and called-up share capital plus the reserves required to be maintained by Dutch law or pursuant to its Articles of Association.

10.4.2 Right to reserve

Subject to the approval of the Supervisory Board and subject to Dutch law and the Articles of Association, the Management Board may determine which part of the Company's profits will be added to the reserves. The remaining part of the profits after the addition to the reserves will be at the disposal of the General Meeting.

10.5 General Meetings

General Meetings must be held in Amsterdam, Rotterdam, Utrecht, or Haarlemmermeer (Schiphol) the Netherlands. The annual General Meeting must be held at least once a year, no later than in June. Extraordinary General Meetings may be held, as often as the Management Board or the Supervisory Board deem desirable. In addition, pursuant to Dutch law and the Articles of Association, one or more Shareholders, who solely or jointly represent at least one-tenth of the issued capital, may request that a General Meeting be convened, the request setting out in detail matters to be considered. If no General Meeting has been held within eight weeks of the Shareholder(s) making such request, the Shareholders will be authorised to request in summary proceedings a District Court to convene a General Meeting. Furthermore, within three months of it becoming apparent to the Management Board that the equity of the Company has decreased to an amount equal to or lower than one-half of the paid-up part of the capital, a General Meeting must be held to discuss any requisite measures.

The convocation of the General Meeting must be published through an announcement by electronic means. The convening notice must include, among other items, an agenda indicating the location and time of the General Meeting, the record date, the manner in which persons entitled to attend the General Meeting may register and exercise their rights, the time on which registration for the meeting must have occurred ultimately, as well as the place where the meeting documents may be obtained. The convening notice must be given at least 42 days prior to the day of the meeting.

The agenda for the annual General Meeting must contain certain subjects, including, among other things, the adoption of the financial statements, the discussion of any substantial change in the corporate governance structure of the Company and the allocation of the profit, insofar as this is at the disposal of the General Meeting. In addition, the agenda shall include such items as have been included therein by the Management Board, the Supervisory Board or Shareholders (with due observance of Dutch law as described below). If the agenda of the General Meeting contains the item of granting discharge to the members of the Management Board and the Supervisory Board concerning the performance of their duties in the financial year in question, the matter of the discharge shall be mentioned on the agenda as separate

items for the Management Board and the Supervisory Board respectively. The agenda shall also include such items as one or more Shareholders and others entitled to attend General Meetings, representing at least 3% of the issued and outstanding share capital, have requested the Management Board with a motivated request to include in the agenda, at least sixty days before the day of the General Meeting. No resolutions may be adopted on items other than those which have been included in the agenda.

Shareholders who, individually or with other Shareholders, hold Shares that represent at least 1% of the issued and outstanding share capital or a market value of at least €250,000, may request the Company to disseminate information that is prepared by them in connection with an agenda item for a General Meeting. The Company can only refuse disseminating such information, if received less than seven business days prior to the General Meeting, if the information gives or could give an incorrect or misleading signal or if, in light of the nature of the information, the Company cannot reasonably be required to disseminate it.

The General Meeting is chaired by the chairman of the Supervisory Board, or, in his absence by the deputy chairman of the Supervisory Board. If both are absent, the General Meeting shall appoint a chairman. The members of the Management Board and the Supervisory Board may attend a General Meeting. In these General Meetings, they have an advisory vote. The chairman of the General Meeting may decide at his discretion to admit other persons to the General Meeting.

Each Shareholder may attend the General Meeting, address the General Meeting and exercise voting rights pro rata to his shareholding, either in person or by proxy. Shareholders may exercise these rights, if they are the holders of Shares on the record date as required by Dutch law, which is currently the 28th day before the day of the General Meeting, and they or their proxy have notified the Company of their intention to attend the General Meeting in writing or by any other electronic means that can be reproduced on paper at least seven days prior to the General Meeting, specifying such person's name and the number of Shares for which such person may exercise the voting rights and/or meeting rights at such General Meeting. The convocation notice shall state the record date and the manner in which the persons entitled to attend the General Meeting may register and exercise their rights.

10.6 Voting rights

Each Share confers the right to cast one vote in the General Meeting.

Resolutions of the General Meeting are taken by an absolute majority, except where Dutch law or the Articles of Association prescribe a larger majority. Matters requiring a majority of at least two-thirds of the votes cast, if less than 50% of the issued share capital is represented, include:

- a resolution of the General Meeting regarding restricting and excluding pre-emptive rights or a resolution to designate the Management Board as the body authorised to exclude or restrict pre-emptive rights;
- a resolution of the General Meeting to reduce the Company´s outstanding share capital; and
- a resolution of the General Meeting to have the Company merge or demerge.

Pursuant to Dutch law, no votes may be cast at a General Meeting in respect of Shares

which are held by the Company.

10.6.1 Identity of Shareholders

The Company may request Euroclear Netherlands, admitted institutions, intermediaries, institutions abroad, and managers of investment institutions, to provide certain information on the identity of its Shareholders. Such request may only be made during a period of sixty days up to the day on which a General Meeting will be held. No information will be given on Shareholders with an interest of less than 0.5% of the issued share capital. A Shareholder who, individually or together with other Shareholders, holds an interest of at least 10% of the issued share capital may request the Company to establish the identity of the Shareholders. This request may only be made during a period of sixty days until (and not including) the 42nd day before the day on which a General Meeting will be held.

10.7 Amendment of the Articles of Association

On proposal by the Management Board which has been approved by the Supervisory Board, the General Meeting may resolve to amend the Articles of Association. A proposal to amend the Articles of Association must be included in the agenda. A copy of the proposal, containing the verbatim text of the proposed amendment, must be deposited with the Company for the inspection of every Shareholder until the end of the General Meeting. A copy of the proposal shall be made available free of charge to those who are entitled to attend the General Meeting.

10.8 Dissolution and liquidation

Under the Articles of Association, the Company may be dissolved by a resolution of the General Meeting, subject to a proposal by the Management Board which has been approved by the Supervisory Board.

In the event of dissolution, the Company´s business will be liquidated in accordance with Dutch law and the Articles of Association and the liquidation shall be arranged by the Management Board under supervision of the Supervisory Board, unless the General Meeting has designated other liquidators. During liquidation, the provisions of the Articles of Association will remain in force as far as possible.

The balance of the Company´s remaining equity after payments of debts and liquidation costs will be distributed to holders of the Shares, in proportion to the aggregate nominal value of the Shares held by them.

10.9 Corporate governance code

On 9 December 2003, the Dutch Corporate Governance Committee, also known as the Tabaksblat Committee, released the Dutch Corporate Governance Code. With effect from 1 January 2009, the Corporate Governance Code has been amended by the Frijns Committee. In December 2016, the Van Manen Committee published a revised version of the Corporate Governance Code, which has since come into force.

The Corporate Governance Code contains principles and best practice provisions for the management board, the supervisory board, shareholders and general meetings of shareholders and audit and financial reporting. 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, and to all large companies whose registered offices are in the Netherlands (balance sheet value > €500 million) and whose shares or depositary receipts for shares have been admitted to trading on a multilateral trading facility or a comparable system, are required under Dutch law to disclose in their annual reports whether or not they apply the provisions of the Corporate Governance Code that relate to the management board or supervisory board and, if they do not apply, to explain the reasons why.

Pursuant to article 2:391(5) of the Dutch Civil Code, the Corporate Governance Code applies to the Company. Kiadis acknowledges the importance of good corporate governance and agrees with the principles of the Code and has taken and will take further steps it considers appropriate to implement the Corporate Governance Code.

10.9.1 Non-compliance with the Corporate Governance Code

The practices where the Company is not in compliance with the revised Corporate Governance Code are the following:

1 Best practice provision 2.1.1 – Profile

The supervisory board should prepare a profile, taking account of the nature and the activities of the enterprise affiliated with the company. The profile should address: (i) the desired expertise and background of the supervisory board members; (ii) the desired diverse composition of the supervisory board, referred to in best practice provision 2.1.5; (iii) the size of the supervisory board; and (iv) the independence of the supervisory board members. The profile should be posted on the company´s website.

The Supervisory Board has prepared a profile which is posted on the Company´s website, but this profile does not address the size of the Supervisory Board nor the desired diverse composition of the Supervisory Board in terms of nationality, age, gender and education. This provision was departed from as the overriding principles for the Company are (a) 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, and (b) that the Company should have flexibility in attracting Supervisory Board members who will be able to provide such contribution to the Company, given its small size and specificity in terms of focus, strategy and stage of development. These overriding principles are shown by the new Supervisory Board members that have been (or who have been announced will be) appointed as of when the Company was listed at Euronext Amsterdam and Brussels in 2015 and who are diverse in nationality, age, educational background and work background.

For the reasons provided above, the Company does not intend to comply with this best practice provision.

2 Best practice provision 2.1.5 - Diversity policy

The supervisory board should draw up a diversity policy for the composition of the management board, the supervisory board and, if applicable, the executive committee. The policy should address the concrete targets relating to diversity

and the diversity aspects relevant to the company, such as nationality, age, gender, and education and work background.

The reasons for the departure from this provision in respect of the Supervisory Board are set out above in relation to best practice provision 2.1.1. The reason for this departure in respect of the Management Board and Senior Management is similar, in that the Company´s overriding principle is that the Management Board and Senior Management should have a diverse composition with their members specifically having the necessary expertise, education and work background in the industry in which the Company is active and that the Company should have flexibility in attracting Management Board and Senior Management members who will be able to provide a valuable contribution to the Company, given its small size and specificity in terms of focus, strategy and stage of development. This overriding principle is shown by the new members of the Management Board and Senior Management that have been joint the Company in 2017 and who are diverse in nationality, age, educational background and work background.

For the reasons provided above, the Company does not intend to comply with this best practice provision.

3 Best practice provision 2.1.7 - Independence of the supervisory board

The composition of the supervisory board is such that the members are able to operate independently and critically vis-à-vis one another, the management board, and any particular interests involved. In order to safeguard its independence, the supervisory board is composed in accordance with the following criteria: (i) any one of the criteria referred to in best practice provision 2.1.8, sections i. to v. inclusive should be applicable to at most one supervisory board member; (ii) the total number of supervisory board members to whom the criteria referred to in best practice provision 2.1.8 are applicable should account for less than half of the total number of supervisory board members; and (iii) for each shareholder, or group of affiliated shareholders, who directly or indirectly hold more than ten percent of the shares in the company, there is at most one supervisory board member who can be considered to be affiliated with or representing them as stipulated in best practice provision 2.1.8, sections vi. and vii.

The Supervisory Board is not independent as three of the five present members of the Supervisory Board are not independent within the meaning of best practice provisions 2.1.7 and 2.1.8. These Supervisory Board members are employed by and have been appointed upon nomination of three of the significant Shareholders. These three significant 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 Kiadis. 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, Kiadis deems continuity in the composition of the Supervisory Board to be of great importance, also taking into account the small size of the Company and its specificity in terms of focus, strategy and stage of development.

For the reasons provided above, the Company does not intend to comply with this best practice provision.

4 Best practice provision 2.1.9 - Independence of the chairman of the supervisory board

The chairman of the supervisory board should not be a former member of the management board of the company and should be independent within the meaning of best practice provision 2.1.8.

Prior to Mr. Wegter, chairman of the Supervisory Board, being appointed as member of the Supervisory Board as per 12 June 2015, he was a member of the management board of Kiadis Pharma B.V. from 4 September 2009 through 22 February 2012. The Supervisory Board considers that Mr. Wegter's contributions outweigh any perceived disadvantage of non-independence or of being a former member of the management board of Kiadis Pharma B.V. In addition, the Company deems continuity in the position of chairman to be of great importance, also taking into account the small size of the Company and its specificity in terms of focus, strategy and stage of development.

For the reasons provided above, the Company does not intend to comply with this best practice provision.

5 Best practice provision 2.2.4 - Succession

The supervisory board should ensure that the company has a sound plan in place for the succession of management board and supervisory board members that is aimed at retaining the balance in the requisite expertise, experience and diversity. Due regard should be given to the profile referred to in best practice provision 2.1.1 in drawing up the plan for supervisory board members. The supervisory board should also draw up a retirement schedule in order to avoid, as much as possible, supervisory board members retiring simultaneously. The retirement schedule should be published on the company's website.

There is not yet a sound plan in place for the succession of the Management Board and Supervisory Board members. In addition, the Supervisory Board has not drawn up a retirement schedule for itself yet. The reason is that it is the first term on the listed Company for all Supervisory Board and Management Board members. In addition, with regard to the Supervisory Board, three members were appointed upon the incorporation of the Company in June 2015, a further two members were appointed in June 2016 and the Company has announced that two more members will be proposed for appointment during the 2018 Annual General Meeting. As all of these members have a term of four years, there is already a natural succession plan/retirement schedule in place for the Supervisory Board.

The Company intends to comply with this best practice provision by drawing up such succession plans/retirement schedule before the first term will have ended.

6 Best practice provision 2.2.6 - Evaluation by the supervisory board

At least once per year, outside the presence of the management board, the

supervisory board should evaluate its own functioning, the functioning of the various committees of the supervisory board and that of the individual supervisory board members, and should discuss the conclusions that are attached to the evaluation. In doing so, attention should be paid to: (i) substantive aspects, the mutual interaction and the interaction with the management board; (ii) events that occurred in practice from which lessons may be learned; and (iii) the desired profile, composition, competencies and expertise of the supervisory board.

The Supervisory Board did not evaluate its functioning and the functioning of its committees and its individual members in 2017.

The Company does not intend to comply with this best practice provision.

Best practice provision 2.2.7 - Evaluation of the management board

At least once per year, outside the presence of the management board, the supervisory board should evaluate both the functioning of the management board as a whole and that of the individual management board members, and should discuss the conclusions that must be attached to the evaluation, such also in light of the succession of management board members. At least once annually, the management board, too, should evaluate its own functioning as a whole and that of the individual management board members.

The Management Board did not evaluate its own functioning and that of its individual members in 2017.

The Company intends to comply with this best practice provision by the end of 2018.

8 Best practice provision 2.3.1 - Supervisory board's terms of reference

The division of duties within the supervisory board and the procedure of the supervisory board should be laid down in terms of reference. The supervisory board's terms of reference should include a paragraph dealing with its relations with the management board, the general meeting, the employee participation body (if any) and the executive committee (if any). The terms of reference should be posted on the company's website.

The Supervisory Board's terms of reference do not yet contain a paragraph dealing with its relations with the employee participation body as there is no such body, nor with the executive committee.

The Company intends to comply with this best practice provision by the end of 2018.

9 Best practice provision 2.3.4 - Composition of the committees

The audit committee or the remuneration committee should not be chaired by the chairman of the supervisory board or by a former member of the management board of the company. More than half of the members of the committees should

be independent within the meaning of best practice provision 2.1.8.

More than half of the members of the Audit Committee and of the Nomination and Remuneration Committee are not independent as Mr. Kleijwegt, a member of both two-person committees, is not independent. The reason is that the appointments to these committees took place in June 2016, prior to the revised Corporate Governance Code becoming effective.

The Company expects it will comply with this best practice provision after the appointment in 2018 of the new (independent) Supervisory Board members who have been announced to be appointed, assuming these members will join one or more of the Supervisory Board committees.

10 Best practice provision 4.2.3 - Meetings and presentations

Analyst meetings, analyst presentations, presentations to institutional or other investors and press conferences should be announced in advance on the company's website and by means of press releases. Analysts' meetings and presentations to investors should not take place shortly before the publication of the regular financial information. All shareholders should be able to follow these meetings and presentations in real time, by means of webcasting, telephone or otherwise. After the meetings, the presentations should be posted on the company's website.

Kiadis does not announce, for practical reasons, meetings with analysts and presentations to analysts and (institutional) investors, nor does Kiadis provide for shareholders to follow these meetings and presentations in real time. However, the presentation used by Kiadis for its meetings with analysts and (institutional) investors is the Company presentation that is posted on its website and regularly updated and which is therefore a public document.

Kiadis will have meetings with analysts and give presentations to (institutional) investors also shortly before the publication of its regular financial information, but such meetings and presentations will not regard such regular financial information.

For the reasons provided above, the Company does not intend to comply with this best practice provision.

11 Best practice provision 4.2.5 - Management board contacts with press and analysts

The contacts between the management board on the one hand and the press and financial analysts on the other should be handled and structured carefully and with due observance of the applicable laws and regulations. The company should not do anything that might compromise the independence of analysts in relation to the company and vice versa.

Some analysts have as their business model that they are paid by a company for their research reports. If the Company would pay such an analyst to carry out research for a report or for the production or publication of an analyst report, the report will mention this, i.e. "this rapport has been commissioned by the

company".

For the reason provided above, the Company does not intend to comply with this best practice provision.

12 Best practice provision 4.3.3 - Cancelling the binding nature of a nomination or dismissal

The general meeting of shareholders of a company not having statutory two-tier status (structuurregime) 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. It may be provided that this majority should represent a given proportion of the issued capital, which proportion may not exceed one-third. If this proportion of the capital is not represented at the meeting, but an absolute majority of the votes cast is in favour of a resolution to cancel the binding nature of a nomination, or to dismiss a board member, a new meeting may be convened at which the resolution may be passed by an absolute majority of the votes cast, regardless of the proportion of the capital represented at the meeting.

The Articles of Association state that a resolution of the General Meeting to appoint or dismiss a member of the Management Board or Supervisory Board not in conformity with or without a proposal 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 Company deems this appropriate considering the remaining shareholdings and involvement of the Company's current significant Shareholders.

10.10 Liability, insurance and indemnity

Under Dutch law, members of the Management Board and the Supervisory Board may be liable to the Company for damages in the event of improper or negligent performance of their duties. They may be jointly and severally liable for damages to the Company and to third parties for infringement of the Dutch law or the Articles of Association. Members of the Management Board and the Supervisory Board and certain other of Kiadis' officers are insured under an insurance policy against damages resulting from their conduct when acting in the capacities as such members or officers. Furthermore, the Articles of Association provide for an indemnity for members of the Management Board and the Supervisory Board (see paragraph 9.9 above).

10.11 Disclosure rules

10.11.1 Home member state for purposes of the EU Transparency Directive

The Netherlands is the Company´s home member state for the purposes of the European Union Transparency Directive (Directive 2004/109/EC, as amended). As a result, upon listing, the Company will be subject to financial and other reporting obligations under the Financial Supervision Act and the Dutch Financial Reporting Supervision Act (*Wet toezicht financiële verslaggeving*) (the "**Financial Reporting Supervision Act**"), which both implement the EU Transparency Directive in the Netherlands.

10.11.2 Disclosure of financial information

The Company is required to publish its financial statements (consisting of the audited annual accounts, the directors' report and the responsibility statement) within four months after the end of each financial year and its half-yearly figures within two months after the end of the first six months of each financial year.

10.11.3 Financial Reporting Supervision Act

On the basis of the Financial Reporting Supervision Act, the AFM supervises the application of financial reporting standards by, among others, companies whose corporate seat is in the Netherlands and whose securities are listed on a regulated market, as defined in the Financial Supervision Act, or a foreign stock exchange.

Pursuant to the Financial Reporting Supervision Act, the AFM has an independent right to (i) request an explanation from the Company regarding its application of the applicable financial reporting standards and (ii) recommend to the Company the making available of further explanations. If the Company does not comply with such a request or recommendation, the AFM may request that the Enterprise Chamber of the Amsterdam Court of Appeal (*Ondernemingskamer van het Gerechtshof te Amsterdam*, the "**Enterprise Chamber**") orders the Company to (i) provide an explanation of the way the Company has applied the applicable financial reporting standards to its financial statements or (ii) prepare its financial reports in accordance with financial reporting requirements following the Enterprise Chamber's instructions.

10.11.4 Shareholder disclosure and reporting obligations

Pursuant to the Financial Supervision Act, each Shareholder who holds a substantial holding in the Company should forthwith notify the AFM of such substantial holding. Substantial holding means the holding of at least 3% of the shares or the ability to vote on at least 3% of the total voting rights. Any person who, directly or indirectly, acquires or disposes of an interest in the share capital or voting rights must give notice to the AFM without delay, if, as a result of such acquisition or disposal, the percentage of capital interest or voting rights held by such person, directly or indirectly, reaches, exceeds or falls below any of the following thresholds: 3%, 5%, 10%, 15%, 20%, 25%, 30%, 40%, 50%, 60%, 75% and 95%. In addition, if, as a result of such change, a person's direct or indirect interest in the share capital or voting rights passively reaches, exceeds or falls below the abovementioned thresholds, the person in question must give notice to the AFM no later than the fourth trading day after the AFM has published the change in the share capital and/or voting rights in the public register.

For the purpose of calculating the percentage of capital interest or voting rights, among others, the following interests must be taken into account: (i) shares or depositary receipts for shares or voting rights directly held (or acquired or disposed of) by any person, (ii) shares or depositary receipts for shares or voting rights held (or acquired or disposed of) by such person's controlled undertakings or by a third party for such person's account or by a third party with whom such person has concluded an oral or written voting agreement (including a discretionary power of attorney), (iii) voting rights acquired pursuant to an agreement providing for a temporary transfer of voting rights against a payment, (iv) shares or depositary receipts for shares or voting rights which such person, or any controlled undertaking or third party referred to above, may acquire pursuant to any option or other right held by such person (including, but not limited to, on the basis of convertible bonds), and (v)

shares which determine the value of certain cash settled instruments, whereby the increase in value of the financial instruments is dependent on the increase in value of the (underlying) shares or related dividends.

For the same purpose of calculating the percentage of capital interest or voting rights, the following instruments qualify as 'shares': (i) financial instruments of which the value depends on the increase in value of the shares or dividend rights and which will be settled other than in those shares, (ii) rights to acquire shares or depositary receipts, and (iii) negotiable instruments which provide for an economic position similar to the economic position of a holder of shares or depositary receipts.

The notification to the AFM should indicate whether the interest is held directly or indirectly, and whether the interest is an actual or a potential interest.

A person is deemed to hold the interest in the share capital or voting rights that is held by its controlled undertakings as defined in the Financial Supervision Act. The controlled undertaking does not have a duty to notify the AFM because the interest is attributed to the undertaking in control, which as a result has to notify the interest as an indirect interest. Any person, including an individual, may qualify as an undertaking in control for the purposes of the Financial Supervision Act. A person who has a 3% or larger interest in the share capital or voting rights and who ceases to be a controlled undertaking for purposes of the Financial Supervision Act must without delay notify the AFM. As of that moment, all notification obligations under the Financial Supervision Act will become applicable to the former controlled undertaking itself.

A holder of a right of pledge or usufruct in respect of shares or depositary receipts for shares can also be subject to the reporting obligations of the Financial Supervision Act, if such person has, or can acquire, the right to vote on the shares or, in the case of depositary receipts for shares, the underlying shares. If a pledgee or usufructuary acquires the voting rights on the shares or depositary receipts for shares, this may trigger a corresponding reporting obligation for the holder of the shares or depositary receipts for shares. Special rules apply with respect to the attribution of shares or depositary receipts for shares or voting rights which are part of the property of a partnership or other community of property.

Each person holding a gross short position in relation to the issued share capital of a Dutch listed company that reaches, exceeds or falls below any one of the following thresholds: 3%, 5%, 10%, 15%, 20%, 25%, 30%, 40%, 50%, 60%, 75% and 95%, must immediately give notice to the AFM. If a person's gross short position reaches, exceeds or falls below one of the above mentioned thresholds as a result of a change in the Company's issued share capital, such person is also required to make a notification no later than the fourth trading day after the AFM has published the Company's notification in the public register of the AFM. Shareholders are advised to consult with their own legal advisers to determine whether the gross short-selling notification obligation applies to them.

In addition, pursuant to Regulation (EU) No 236/2012, each person holding a net short position attaining 0.2% of the issued share capital of a Dutch listed company is required to notify such position to the AFM. Each subsequent increase of this position by 0.1% above 0.2% must also be notified. Each net short position equal to 0.5% of the issued share capital of a Dutch listed company and any subsequent increase of that position by 0.1% will be made public via the AFM short-selling register. To calculate whether a natural person or legal person has a net short position, their short positions and long positions must be set off. A short transaction in a share can only be contracted if a reasonable case can be made that

the shares sold can actually be delivered, which requires the confirmation of a third party that the shares have been located. The notification shall be made no later than 3:30pm Central European (Summer) Time ("**CEST/CET**") on the following trading day.

Under the Financial Supervision Act, the Company is required to notify the AFM without delay of any changes in its share capital if its share capital has changed by 1% or more compared to the previous disclosure in respect of its share capital. The Company is also required to notify the AFM without delay of any changes in the voting rights, insofar as it has not already been notified at the same time as a related change in its share capital. Changes in share capital and voting rights of less than 1% must also be notified; these changes can be notified at any time but at the latest within eight days after the end of each calendar quarter. The AFM will publish such notifications in a public register.

In addition, every holder of 3% or more of the shares or voting rights whose interest has a different composition as a result of (for example) an exchange of options for depositary receipts for shares or shares, or the exercise of rights under an agreement to acquire voting rights whereby in comparison to the previous notification a threshold is reached, exceeded or fallen below without this affecting the total percentage of the previously notified holding, must notify the AFM of this change within four trading days after the date on which he becomes aware of this or should have become aware of this.

The AFM keeps a public register of all notifications made pursuant to these disclosure obligations and publishes all notifications received by it. The notifications referred to in this paragraph should be made in writing by means of a standard form or electronically through the notification system of the AFM.

10.11.5 Non-compliance with disclosure obligations

Non-compliance with the disclosure obligations set out in the paragraph above is an economic offence (*economisch delict*) and may lead to the imposition of criminal prosecution, administrative fines, imprisonment or other sanctions. The AFM may impose administrative penalties or a cease-and-desist order under penalty for non-compliance. If criminal charges are pressed, the AFM is no longer allowed to impose administrative penalties and vice versa, the AFM is no longer allowed to seek criminal prosecution if administrative penalties have been imposed. Furthermore, a civil court can impose measures against any person who fails to notify or incorrectly notifies the AFM of matters required to be correctly notified. A claim requiring that such measures be imposed must be instituted by the Company and/or one or more Shareholders who alone or together with others represent(s) at least 3% of the issued share capital or are able to exercise at least 3% of the voting rights. The measures that the civil court may impose include:

(i) an order requiring the person violating the disclosure obligations under the Financial Supervision Act to make appropriate disclosure;

(ii) suspension of voting rights in respect of such person's shares for a period of up to three years as determined by the court;

(iii) voiding a resolution adopted by a General Meeting, if the court determines that the resolution would not have been adopted but for the exercise of the voting rights of the person who is obliged to notify, or suspension of a resolution until the court makes a decision about such voiding; and

(iv) an order to the person violating the disclosure obligations under the Financial Supervision Act to refrain, during a period of up to five years as determined by the court, from acquiring the shares and/or voting rights in the shares.

10.12 Takeover regulations

10.12.1 European Union takeover regulations

The European Directive on Takeover Bids (2004/25/EC) (the Takeover Directive) has been implemented in Dutch legislation in the Financial Supervision Act and the Public Takeover Bids Decree (*Besluit openbare biedingen Wft*).

10.12.2 Mandatory takeover offers

Pursuant to the Financial Supervision Act, a shareholder who (individually or acting in concert with others) directly or indirectly obtains control of a Dutch company whose shares are listed on a regulated market within the European Union or European Economic Area is required to make a public offer for all issued and outstanding shares in that company's share capital. Such control is deemed present if a (legal) person is able to exercise, alone or acting in concert, at least 30% of the voting rights in the general meeting of shareholders. The legislation also applies to persons acting in concert who jointly acquire 30% of the voting rights. An exemption exists if such shareholder or group of shareholders reduces its holding below 30% within 30 days of the acquisition of controlling influence provided that (i) the reduction of its holding was not effected by a transfer of shares or depositary receipts to an exempted party and (ii) during this period such shareholder or group of shareholders did not exercise its voting rights.

10.12.3 Squeeze out procedures

Pursuant to articles 2:92a of the Dutch Civil Code, a shareholder who for his own account contributes at least 95% of the issued capital may institute proceedings before the Enterprise Chamber against the other shareholders jointly for the transfer of their shares to the claimant. The proceedings are held before the Enterprise Chamber and can be instituted by means of a writ of summons served upon each of the minority shareholders in accordance with the provisions of the Dutch Code of Civil Procedure (*Wetboek van Burgerlijke Rechtsvordering*). The Enterprise Chamber may grant the claim for squeeze out in relation to all minority shareholders and will determine the price to be paid for the shares, if necessary upon the advice of one or three experts. In the event that a shareholder has acquired at least 95% of the shares held by him, representing at least 95% of the total voting rights, each remaining minority Shareholder is entitled to demand a squeeze out. This procedure must be initiated with the Enterprise Chamber within three months after the end of the period for tendering shares in the public offer. With regard to the price per share to be paid by the majority shareholder, the same procedure as for squeeze out proceedings initiated by the offeror, as set out in the previous paragraph, applies.

The offeror under a public offer is also entitled to start squeeze-out proceedings if, following the public offer, the offeror contributes at least 95% of the outstanding share capital and represents at least 95% of the total voting rights. The claim of a takeover squeeze-out needs to be filed with the Enterprise Chamber within three months following the expiry of the acceptance period of the offer. The Enterprise Chamber may grant the claim for squeeze-out in relation to all minority shareholders and will determine the price to be paid for the shares, if necessary, after appointment of one or three experts who will offer an opinion to the

Enterprise Chamber on the value to be paid for the shares of the minority shareholders. In principle, the offer price is considered reasonable if the offer was a mandatory offer or if at least 90% of the shares to which the offer related were received by way of voluntary offer.

The Dutch takeover provisions of the Dutch Financial Supervision Act also entitle those minority shareholders that have not previously tendered their shares under an offer to transfer their shares to the offeror, provided that the offeror has acquired at least 95% of the outstanding share capital and represents at least 95% of the total voting rights. With regard to price, the same procedure as for takeover squeeze-out proceedings initiated by an offeror applies. The claim also needs to be filed with the Enterprise Chamber within three months following the expiry of the acceptance period of the offer.

10.13 Insider trading and market manipulation rules

10.13.1 Reporting of insider transactions

Recently, the regulatory framework on market abuse within Europe has been amended and extended. These revisions are laid down in the Market Abuse Directive (2014/57/EU) (MAD II) as implemented in Dutch and Belgian law and the Market Abuse Regulation (no. 596/2014) (MAR) which is directly applicable in the Netherlands and Belgium.

Pursuant to the MAR, no natural or legal person is permitted to: (a) engage or attempt to engage in insider dealing in financial instruments listed on a regulated market or for which a listing has been requested, such as the Shares, (b) recommend that another person engages in insider dealing or induce another person to engage in insider dealing, or (c) unlawfully disclose inside information relating to the Shares or the Company. Furthermore, no person may engage in or attempt to engage in market manipulation.

The Company is required to inform the public as soon as possible and in a manner which enables fast access and complete, correct and timely assessment of the information, of inside information which directly concerns the Company. Pursuant to the MAR, inside information is knowledge of concrete information directly or indirectly relating to the issuer or the trade in its securities which has not yet been made public and publication of which could significantly affect the trading price of the securities (i.e. information a reasonable investor would be likely to use as part of the basis of his investment decision). An intermediate step in a protracted process can also be deemed to be inside information. The Company is required to post and maintain on its website all inside information for a period of at least five years. Under certain circumstances, the disclosure of inside information may be delayed, which needs to be notified to the AFM after the disclosure has been made. Upon request of the AFM, a written explanation needs to be provided setting out why a delay of the publication was considered permitted.

Persons discharging managerial responsibilities, as well as persons closely associated with them (within the meaning of the MAR) are obliged to notify the Company and the AFM, ultimately on the third trading day after the transaction date, of every transaction conducted on their own account relating to the shares or debt instruments of (or other financial instruments linked to) the Company, once the threshold of €5,000 has been reached within a calendar year.

Furthermore, a person discharging managerial responsibilities is not permitted to (directly or indirectly) conduct any transactions on its own account or for the account of a third party, relating to Shares or debt instruments of the Company or other financial instruments linked

thereto, during a closed period of thirty calendar days before the announcement of an half-yearly report or an annual report of the Company.

Persons discharging managerial responsibilities within the meaning of the MAR include: (a) members of the Management Board and Supervisory Board, or (b) members of the senior management who have regular access to inside information relating directly or indirectly to that entity and the authority to take managerial decisions affecting the future developments and business prospects of the Company. A person closely associated means: (a) a spouse, or a partner considered to be equivalent to a spouse in accordance with national law, (b) a dependent child, in accordance with national law, (c) a relative who has shared the same household for at least one year on the date of the transaction concerned, or (d) a legal person, trust or partnership, the managerial responsibilities of which are discharged by a person discharging managerial responsibilities or by a person referred to in point (a), (b) or (c), which is directly or indirectly controlled by such a person, which is set up for the benefit of such a person, or the economic interests of which are substantially equivalent to those of such a person.

10.13.2 Non-compliance with the market abuse rules

In accordance with the MAR, the AFM has the power to take appropriate administrative sanctions, such as fines, and/or other administrative measures in relation to possible infringements.

Non-compliance with the market abuse rules set out above could also constitute an economic offense and/or a crime (*misdrijf*) and could lead to the imposition of administrative fines by the AFM. The public prosecutor could press criminal charges resulting in fines or imprisonment. If criminal charges are pressed, it is no longer allowed to impose administrative penalties and vice versa.

The AFM shall in principle also publish any decision imposing an administrative sanction or measure in relation to an infringement of the MAR.

The Company has adopted a code of conduct in respect of the reporting and regulation of transactions in the Company's securities by members of the Management Board and Supervisory Board and the Company's employees. The Company and any person acting on its behalf or on its account is obligated to draw up an insiders list, to promptly update the insider list and provide the insider list to the AFM upon its request. The Company and any person acting on its behalf or on its account is obligated to take all reasonable steps to ensure that any person on the insider list acknowledges in writing the legal and regulatory duties entailed and is aware of the sanctions applicable to insider dealing and unlawful disclosure of inside information.

11 Substantial Holdings and Related Party Transactions

11.1 Substantial holdings

According to notifications made to the AFM as set out in the AFM register on substantial holdings as at the day immediately preceding the Registration Document Date, the following parties held a substantial holding of at least 3% of the share capital and/or voting rights in the Company.

Name	# of Shares	# of voting rights	% of Shares[1]	% of voting rights[2]	Capital interest	Voting interest	Holding	Notified on
Esprit Nominees Limited	3,342,647	3,342,647	24.81	24.81	Actual	Actual	Direct	04 August 2015
Achmea Pensioen- en Levensverzekeringen N.V.	2,208,607	2,208,607	12.78	12.78	Actual	Actual	Indirect[3]	12 October 2017
Life Sciences Partners II B.V.	1,656,458	1,656,458	9.58	9.58	Actual	Actual	Direct	12 October 2017
Lenildis Holding B.V.[4]	1,214,027	1,214,027	8.69	8.69	Actual	Actual	Direct	28 February 2017
Alta Partners Management VIII, LLC	940,035	940,035	7.06	7.06	Actual	Actual	Direct	02 July 2015

(1) Percentage regards the number of Shares notified on the date of notification indicated in the last column of the table, related to the total number of shares outstanding on such date.
(2) Percentage regards the number of voting rights notified on the date of notification indicated in the last column of the table, related to the total number of voting rights outstanding on such date.
(3) Interest held indirectly via Life Sciences Partners B.V.
(4) Lenildis Holding B.V. is a pooling entity that holds its interest in the Company on behalf of amongst others Pro-Ventures I B.V., a company of which Mr. Martijn Kleijwegt is the sole shareholder and managing director, and LSP Management Group B.V., a company of which (i) Mr. Mark Wegter is shareholder and (ii) Mr. Martijn Kleijwegt is shareholder and a managing director (see paragraph 9.6.2 above).

The table above sets out the information on substantial holdings of each of the named parties as at the date indicated in the last column of the above table. For an overview of applicable notification requirements see paragraph 10.11.4 above. The number of Shares or voting rights as well as the percentage of Shares or voting rights held by these parties at Registration Document Date may be different.

Except as disclosed above, Kiadis is not aware of any other person or legal entity that, as of the Registration Document Date, has a direct or indirect capital or voting interest in the Company of 3% or more. None of the parties listed above has voting rights that differ from other holders of Shares. Each Share entitles the holder thereof to one vote at the General Meeting.

Kiadis is not aware of any party, or parties acting in concert that, directly or indirectly, control the vote at any General Meeting, nor is Kiadis aware of any arrangement, the operation of which may result in a change of control of the Company.

11.2 Related party transactions

During the period covered by the historical financial information included in this Registration Document, and the subsequent period up to the Registration Document Date, the members

of the Management Board and Supervisory Board and enterprises controlled by them were considered related parties of Kiadis. Furthermore, the Company's significant shareholders that have a significant influence over the Company were regarded as such.

Other than compensation paid to members of the Management Board and the Supervisory Board, the grant of options under the Kiadis Pharma N.V. 2016 Share Option Plan, the grant of SARs under the Kiadis Pharma N.V. 2017 Stock Appreciation Right Plan (see paragraphs 9.6.2 and 9.11 above), the issuance of Shares pursuant to the settlement of the 2013 Exit Participation Plan as described in note 8 to the audited consolidated financial statements for the financial year ended 31 December 2016 and the participation of the Company's significant shareholders and Messrs. Rüdiger, Van Heekeren and Kleijwegt in financing rounds during the period covered by the historical financial information included in this Registration Document as set out in note 24 to the audited consolidated financial statements for the financial year ended 31 December 2015 and note 25 to the audited consolidated financial statements for the financial year ended 31 December 2014, there have not been any transactions with related parties during the period covered by the historical financial information included in this Registration Document, and the subsequent period up to the Registration Document Date.

12 Independent Auditors

KPMG, independent auditors with their address at Laan van Langerhuize 1, 1186 DS Amstelveen, the Netherlands, has audited and rendered an unqualified auditor's report on the audited consolidated financial statements and notes thereto for the financial years ended 31 December 2016, 2015 and 2014 incorporated by reference in this Registration Document.

The unaudited consolidated interim financial statements and the notes thereto for the six-month period ended 30 June 2017 incorporated by reference in this Registration Document have not been audited nor reviewed.

The unaudited consolidated interim financial statements and the notes thereto for the nine-month period ended 30 September 2017 included in this Registration Document have not been audited nor reviewed.

KPMG has given, and not withdrawn, its written consent to the inclusion of its auditor's reports in this Registration Document in the form and context in which they are included. As the Shares have not been and will not be registered under the U.S. Securities Act, KPMG has not filed a consent under the U.S. Securities Act.

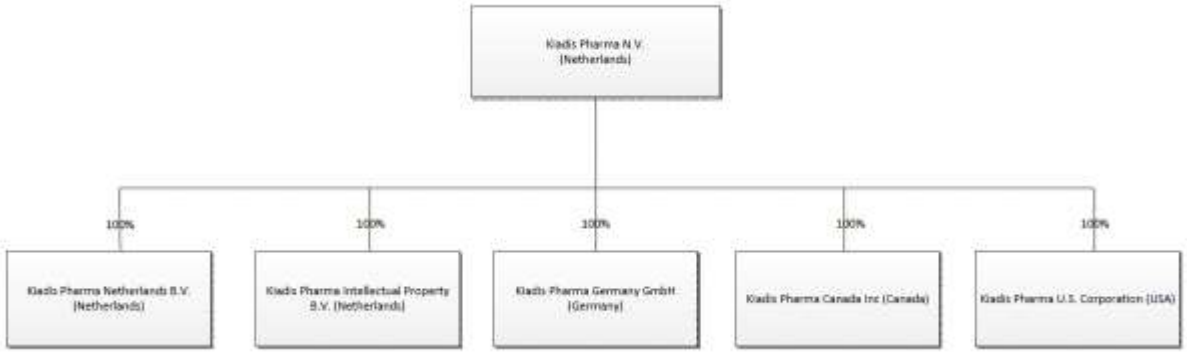
KPMG is governed by Dutch law in the Netherlands and is subject to inspection by the AFM. The AFM has granted KPMG a license to perform financial statement audits of public interest entities.

The auditor who signs on behalf of KPMG is a member of the Dutch Professional Organization for Accountants (*Nederlandse Beroepsorganisatie van Accountants*).

13 General Information

13.1 Organisational structure

The Company is a holding company at the head of the Kiadis corporate group. The below organisational chart lists all subsidiaries of Kiadis Pharma N.V.



13.2 Material contracts

Save as disclosed in paragraphs 5.7 and 5.10 above, Kiadis has not entered into any contracts (not being contracts entered into in the ordinary course of business) within the two years immediately preceding the Registration Document Date which are material, or at any other time and containing provisions under which Kiadis has an obligation or entitlement that is material as of the Registration Document Date.

14 Definitions and Glossary

In this Registration Document, the following defined terms are used

"AFM"	the Netherlands Authority for the Financial Markets (*Stichting Autoriteit Financiële Markten*)
"Act"	2010 Patient Protection and Affordable Care Act
"Actelion"	Actelion Pharmaceuticals Inc.
"Articles of Association"	the Company's articles of association (*statuten*) as they read on the Listing Date
"ATIR"	Kiadis' product candidates based on its Theralux platform that provide for "Allodepleted T-cell ImmunotheRapeutics", presently consisting of ATIR101, Kiadis' principal product, and ATIR201
"Bellicum"	Bellicum Pharmaceuticals, Inc.
"BLA"	a Biologic License Application
"Capital Restructuring"	the restructuring implemented on 12 June 2015 in which shares in Kiadis Pharma B.V. were contributed on shares in the Company, as a consequence whereof the Company became the holding company of the Kiadis corporate group and the direct holder of 97.52% of the shares of Kiadis Pharma B.V.
"CAT"	the EMA's Committee for Advanced Therapies
"Celmed"	Celmed BioSciences Inc.
"CEST"/or "CET"	Central European (Summer) Time
"CHMP"	the EMEA Committee for Medicinal Products for Human Use
"Company"	Kiadis Pharma N.V.

"Competent Authorities"	regulatory agencies and other national or supra-national regulatory authorities that lay down regulatory regulations
"Corporate Governance Code"	the Dutch Corporate Governance Code 2008
"EEA"	European Economic Area
"EU"	European Union
"Enterprise Chamber"	the Enterprise Chamber of the Amsterdam Court of Appeal (*Ondernemingskamer van het Gerechtshof te Amsterdam*)
"Euroclear Netherlands"	Nederlands Centraal Instituut voor Giraal Effectenverkeer B.V.
"Euronext"	Euronext Amsterdam and Euronext Brussels
"Euronext Amsterdam"	Euronext Amsterdam, a regulated market of Euronext Amsterdam N.V.
"Euronext Brussels"	Euronext Brussels, a regulated market of Euronext Brussels NV/SA
"Financial Reporting Supervision Act"	the Dutch Financial Reporting Supervision Act (*Wet toezicht financiële verslaggeving*)
"Financial Supervision Act"	the Dutch Financial Supervision Act (*Wet op het financieel toezicht*)
"Gamida Cell"	Gamida Cell Ltd.
"General Meeting"	any general meeting of the shareholders (*algemene vergadering van aandeelhouders*) of the Company duly held in accordance with the Articles of Association and applicable law
"Hospira Licence Agreement"	the December 2010 licence agreement that the Company (successor by merger of Kiadis Pharma B.V.) entered into with Hospira to develop and commercialise ATIR in certain territories

"Hospira Termination and Royalty Agreement"	the agreement that the Company (successor by merger of Kiadis Pharma B.V.) and Hospira entered into, by means of which Kiadis retrieved all its licensed and marketing rights related to products derived from the Theralux platform, and Hospira's obligations with respect to such products were terminated
"Hospira"	Hospira, Inc.
"IFRS"	international financial reporting standards as adopted by the European Union
"IPO"	initial public offering
"ITT"	Intent To Treat population
"Kiadis"	the Company and its consolidated subsidiaries
"KPMG"	KPMG Accountants N.V.
"Kreos Capital"	Kreos Capital V (UK) Limited
"Kreos Capital Facility Agreement"	the facility agreement entered into between the Company and Kreos Capital dated 17 August 2017
"Kreos Expert"	Kreos Capital V (Expert Fund) LP
"Management Board"	the Company's board of managing directors
"Management Board Rules"	internal rules regulating its decision-making process and working methods that the Management Board may adopt in addition to the relevant provisions of the Articles of Association
"Miltenyi"	Miltenyi Biotech GmbH
"MITT"	Modified Intent to Treat
"MolMed"	MolMed SpA
"PIP"	paediatric investigational plan

"Prospectus Directive"	Directive 2003/71/EC of the European Parliament and of the Council of the European Union as amended
"PUMA"	paediatric-use marketing authorisation
"Registration Document"	this registration document
"Registration Document Date"	12 March 2018, being the date of this Registration Document
"Relevant Member State"	each member state of the EEA that has implemented the Prospectus Directive
"RVO Nederland"	Netherlands Enterprise Agency (*Rijksdienst voor Ondernemend Nederland*), a division of the Dutch Ministry of Economic Affairs
"SARs"	stock appreciation right
"Securities Giro Act"	the Dutch securities giro Act (*Wet giraal effecten verkeer*)
"Senior Management"	Kiadis' senior management, that supports the Management Board in the day-to-day management of the operations
"Shareholder"	holder of at least one (1) of the Shares
"Shares"	all of the ordinary shares with a nominal value of €0,10 in the capital of the Company
"SME"	small or medium-size enterprises
"Supervisory Board"	the Company's board of supervisory directors
"Supervisory Board Rules"	internal rules regulating its decision-making process and working methods that the Supervisory Board may adopt in addition to the relevant provisions of the Articles of Association
"U.S. Securities Act"	the U.S. Securities Act of 1933, as amended

"United Kingdom" or "UK"	the United Kingdom of Great Britain and Northern Ireland
"United States" or "U.S."	the United States of America, its territories and possessions, any state of the United States of America and the District of Columbia
"2013 Exit Participation Plan"	the incentive plan that was created in 2013 in order to provide incentives to certain executives and key employees to pursue a distribution of proceeds to the shareholders, which plan was closed after the Company's IPO in 2015 and settled in June 2016

The following explanations are not intended to be exhaustive definitions, but to assist understanding of certain terms used in this Registration Document.

Advanced Therapy Medicinal Product (ATMP)	a medicinal product for human use which is a gene therapy medicinal product, a somatic cell therapy medicinal product, or a tissue engineered product
Acute lymphoblastic leukaemia (ALL)	an aggressive (fast-growing) type of leukaemia (blood cancer) in which too many lymphoblasts (immature white blood cells) are found in the blood and bone marrow. Also called acute lymphoblastic leukaemia and acute lymphocytic leukaemia
anaemia	the condition of having a lower-than-normal number of red blood cells or quantity of hemoglobin
allogeneic transplant	transplant using stem cells provided by a donor
alloreactive	pertaining to the immune response in reaction to a transplanted allograft
Acute myeloid leukaemia (AML)	a type of cancer in which the bone marrow makes abnormal myeloblasts (a type of white blood cell), red blood cells, or platelets
antibody	protein made by plasma cells (a type of white blood cell) in response to an antigen
antigen	a substance that when introduced into the body stimulates the production of an antibody
advertising preclearance agencies (APAs)	independent entities which review and pre-clear advertising material to help interested parties ensure compliance with the regulatory guidance developed by Health Canada
autologous transplant	transplant using cells provided by the patient
blind study	study in which neither the patient nor the treating physician is aware of the treatment being used
CDSA	the Controlled Drugs and Substances Act

Chimeric Antigen Receptor (CAR) T-cells	engineered, artificial T-cell receptors which graft an arbitrary specificity onto an immune effector cell
chronic lymphocytic leukaemia (CLL)	a type of slow growing leukaemia that affects developing B-cells, which are specialised white blood cells
chronic myeloid leukaemia (CML)	a slowly progressing blood and bone marrow disease in which the bone marrow makes too many white blood cells
CMO	contract manufacturing organisation
CRO	contract research organisation
cytotoxic	quality of being toxic to cells
day-120 questions	a consolidated list of questions posed by the EMA following the primary evaluation phase
DRI	Disease Risk Index
EMA	European Medicines Agency
engraftment	process by which transplanted or transfused cells begin to grow and reproduce within the recipient
ex vivo	pertaining to experimentation performed on living tissue in an artificial environment outside the organism
FDA	United States Food and Drug Administration
GCP	good clinical practices
GMP	good marketing practices, the practices required in order to confirm the guidelines recommended by competent authorisation agencies and regulatory authorities
Graft-versus-leukaemia (GVL)	T-cells having anti-malignancy (anti-leukaemia) effect
Graft-versus-host disease (GVHD)	complication during bone marrow transplantation in which transplanted cells attack the recipient
HAPLO	haploidentical
haploidentical stem cell transplantation	stem cell transplantation from family members who are only partially matched

Hematopoietic stem cell transplantation (HSCT)	transplantation of multipotent hematopoietic stem cells, usually derived from bone marrow, peripheral blood, or umbilical cord blood. It may be autologous (the patient's own stem cells are used) or allogeneic (the stem cells come from a donor). Except where the context requires differently, references in this Registration Document to HSCT are to allogeneic hematopoietic stem cell transplantation
Hematopoietic system	the blood-making organs, principally the bone marrow and lymph nodes
immune reactive cells	cells that defend a host organism against pathogens and tumour cells. An example of an immune reactive cell is a white blood cell
immunosuppressive	used to inhibit or prevent activity of the immune system
immunotherapy	treatment that uses the patients body's own immune system to help fight certain diseases, specifically cancer
incidence	the number of new occurrences of a certain disease or condition in a population over time
indication	a condition which makes a particular treatment or procedure advisable
interim clinical data	data that can be made available prior to the completion of a study
Investigational New Drug application (IND)	a filing made with the FDA after completion pre-clinical testing to begin clinical testing in humans
investigational medicinal product (IMP)	a pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial
lymphocyte	type of white blood cells that divide to form T-cells, which destroy antigens, or B-cells, which produce antibodies
MAA	Marketing Authorisation Application
MTD	maximum tolerated dose
mucopolysaccharidoses (MPS)	a group of inherited metabolic diseases in which a defective or missing enzyme causes large amounts of complex sugar molecules to accumulate in harmful amounts in the body's cells and tissues

multiple myeloma (MM)	cancer of plasma cells, a type of white blood cell normally responsible for producing antibodies
myelodysplastic syndromes (MDS)	a type of cancer in which the bone marrow does not make enough healthy blood cells (white blood cells, red blood cells, and platelets) and there are abnormal cells in the blood and/or bone marrow
new drug application (**NDA)**	following the completion of all three phases of clinical trial development, a company analyses all of the data and files an NDA with the FDA if the data successfully demonstrate both safety and effectiveness
new drug submission (NDS)	a new drug submission to the TPD of Health Canada
off-label use	prescribing legally available drugs or devices for an indication that has not been approved by the relevant regulatory authority
open-label study	study in which both the patient and the treating physician are aware of the treatment being used
OS	overall patient survival
PCT	Patent Cooperation Treaty
PDUFA	Prescription Drug User Fee Act
PFIC	a passive foreign investment company for U.S. federal income tax purposes
Phase I	an experimental drug or treatment in a small group of people for the first time. The purpose is to evaluate its safety and identify potential side effects
Phase II	the experimental drug or treatment is administered to a larger group of people to determine whether and how well it works (efficacy) and to further evaluate its safety
Phase III	the experimental drug or treatment is administered to large groups of people to confirm its efficacy, monitor side effects and compare it with standard or equivalent treatments

Phase IV	upon approval, the company sponsors ongoing "real-world" studies to monitor and report on the use of its drug or treatment
PMPRB	the Patented Medicine Prices Review Board, is an independent quasi-judicial administrative agency in Canada that is responsible for regulating the price charged by patentees for prescription and non-prescription patented drugs sold to wholesalers, hospitals or pharmacies for human and veterinary use to ensure that they are not excessive
prevalence	the number of cases of a certain disease or condition in a population at a given time
RMAT designation	Regenerative Medicine Advanced Therapy Designation
RRS	relapse related mortality
SAE	serious adverse events
SCID	severe combined immune deficiency
SIB	sibling donor
T-cells	cells belonging to a group of white blood cells known as lymphocytes. They can be distinguished from other lymphocyte types by the presence of a special receptor on their cell surface called the T-cell receptor
TH9402	the compound upon which the Theralux platform is based
Thalassaemia	a blood disorder passed down through families (inherited) in which the body makes an abnormal form of haemoglobin. Haemoglobin is the protein in red blood cells that carries oxygen. The disorder results in large numbers of red blood cells being destroyed, which leads to anaemia
TPD	Canadian Therapeutic Products Directorate
TRM	transplant related mortality
UCB	umbilical cord transplants

Unmet medical need	an unmet medical need is a condition whose treatment or diagnosis is not addressed adequately by available therapy

15 Index to Financial Statements

Unaudited special purpose consolidated interim financial statements and the notes thereto for the nine-month period ended 30 September 2017

Unaudited special purpose consolidated interim financial statements and the notes thereto for the nine-month period ended 30 September 2017

Special Purpose Consolidated Statement of Financial Position

(in € thousands)

	Note	September 30, 2017 Unaudited	December 31, 2016 Audited
Assets			
Property, plant and equipment	5	467	536
Intangible assets	6	13.134	13.540
Total non-current assets		**13.601**	**14.076**
Trade and other receivables	7	243	230
Deferred expenses	7	397	351
Cash and cash equivalents	8	13.215	14.559
Total current assets		**13.855**	**15.140**
Total assets		**27.456**	**29.216**
Equity			
Share capital		1.504	1.397
Share premium		108.405	103.200
Translation reserve		294	307
Warrant reserve		1.274	-
Accumulated deficit		(107.874)	(95.463)
Equity attributable to owners of the Company	9	**3.603**	**9.441**
Liabilities			
Loans and borrowings	10	18.081	15.605
Derivatives	11	1.546	-
Employee benefits	13	487	-
Total non-current liabilities		**20.114**	**15.605**
Loans and borrowings	10	1.280	1.555
Trade and other payables	12	2.459	2.615
Total current liabilities		**3.739**	**4.170**
Total liabilities		**23.853**	**19.775**
Total equity and liabilities		**27.456**	**29.216**

The notes on pages F-6 through F-17 are an integral part of these special purpose consolidated interim financial statements.

Special Purpose Consolidated Statement of Comprehensive Income

(in € thousands)

	Note	For the nine months ended September 30, 2017 Unaudited	For the nine months ended September 30, 2016 Unaudited
Revenue		**-**	**-**
Other income		**-**	**-**
Research and development expenses	13,14	(8.096)	(5.647)
General and administrative expenses	13,14	(3.607)	(2.172)
Total operating expenses		**(11.703)**	**(7.819)**
Operating loss		**(11.703)**	**(7.819)**
Interest income		-	29
Interest expenses		(1.439)	(1.167)
Other net finance income (expenses)		260	(936)
Net finance income (expenses)	15	**(1.179)**	**(2.074)**
Loss before tax		**(12.882)**	**(9.893)**
Income tax expense		-	-
Loss for the period		**(12.882)**	**(9.893)**
Other comprehensive income			
Items that are or may be reclassified subsequently to profit or loss			
Foreign currency translation difference for foreign operations		(13)	13
Related tax		-	-
Other comprehensive income for the period, net of tax		**(13)**	**13**
Total comprehensive income for the period		**(12.895)**	**(9.880)**
Loss attributable to:			
Owners of the Company		(12.882)	(9.893)
Non-controlling interests		-	-
		(12.882)	**(9.893)**
Total comprehensive income attributable to:			
Owners of the Company		(12.895)	(9.880)
Non-controlling interests		-	-
		(12.895)	**(9.880)**
Earnings per share			
Basic earnings per share (EUR)		(0,90)	(0,72)
Diluted earnings per share (EUR)		(0,90)	(0,72)

The notes on pages F-6 through F-17 are an integral part of these special purpose consolidated interim financial statements.

Special Purpose Consolidated Statement of Changes in Equity

(in € thousands)

	Note	Share Capital	Share Premium	Translation Reserve	Warrant Reserve	Accumulated deficit	Total Equity
Balance as at January 1, 2017		**1.397**	**103.200**	**307**	**-**	**(95.463)**	**9.441**
Total comprehensive income							
Loss for the period						(12.882)	(12.882)
Other comprehensive income				(13)			(13)
Total comprehensive income for the period		**-**	**-**	**(13)**	**-**	**(12.882)**	**(12.895)**
Transactions with owners, recorded directly in equity							
Issue of shares for cash	9	74	4.926				5.000
Transaction costs	9	-	(601)		155		(446)
Exercise of warrants	9	33	3.193		(854)		2.372
Equity-settled share-based payment	13				11	471	482
Issue of warrants	9		(2.313)		1.962		(351)
Balance as at September 30, 2017		**1.504**	**108.405**	**294**	**1.274**	**(107.874)**	**3.603**

	Note	Share Capital	Share Premium	Translation Reserve	Warrant Reserve	Accumulated deficit	Total Equity
Balance as at January 1, 2016		**1.347**	**98.137**	**271**	**-**	**(74.105)**	**25.650**
Total comprehensive income							
Loss for the period						(9.893)	(9.893)
Other comprehensive income				13			13
Total comprehensive income for the period		**-**	**-**	**13**	**-**	**(9.893)**	**(9.880)**
Transactions with owners, recorded directly in equity							
Issue of shares for cash		16	1.576				1.592
Issue of shares to EPP participants		34	3.487			(7.011)	(3.490)
Equity-settled share-based payment		-				163	163
Balance as at September 30, 2016		**1.397**	**103.200**	**284**	**-**	**(90.846)**	**14.035**

The notes on pages F-6 through F-17 are an integral part of these special purpose consolidated interim financial statements.

Special Purpose Consolidated Cash Flow Statement

(in € thousands)

	Note	For the nine months ended September 30, 2017 Unaudited	For the nine months ended September 30, 2016 Unaudited
Cash flows from operating activities			
Loss for the period		(12.882)	(9.893)
Adjustments for :			
Depreciation of property, plant & equipment (PP&E)	5	122	113
Net interest expenses	15	1.439	1.138
Share-based payment transactions	13	969	163
Net unrealized foreign exchange (gains) or losses		(890)	(553)
(Gain) or loss from change in fair value of derivatives	11	316	-
(Gain) or loss from restatements of loans	10	282	1.482
Income tax expense		-	-
Cash used in operating activities before changes in working capital and provisions:		**(10.644)**	**(7.550)**
Trade and other receivables		(21)	31
Deferred expenses		(46)	87
Trade and other payables		(208)	(3.613)
Other liabilities		88	91
Total change in working capital		**(187)**	**(3.404)**
Cash used in operating activities		**(10.831)**	**(10.954)**
Interest paid		(684)	(536)
Income taxes paid		(2)	(4)
Net cash used in operating activities		**(11.517)**	**(11.494)**
Cash flows from investing activities			
Interest received		8	51
Acquisition of PP&E	5	(53)	(185)
Net cash used in investing activities		**(45)**	**(134)**
Cash flows from financing activities			
Proceeds from issue of share capital	9	5.000	1.592
Proceeds from exercise of warrants	9	2.372	-
Proceeds from borrowings	10	10.000	-
Payment for share issue costs	9	(445)	-
Payment of transaction costs related to borrowings	10	(296)	-
Repayment of borrowings	10	(6.402)	(874)
Net cash from financing activities		**10.229**	**718**
Net decrease in cash and cash equivalents		**(1.333)**	**(10.910)**
Cash and cash equivalents as at January 1		14.559	28.666
Effect of exchange rate fluctuations on cash held		(11)	7
Cash and cash equivalents as at September 30	8	**13.215**	**17.763**

The notes on pages F-6 through F-17 are an integral part of these special purpose consolidated interim financial statements.

Notes to the Special Purpose Consolidated Interim Financial Statements

1 Company information

Kiadis Pharma N.V. (the "**Company**" or "**Kiadis Pharma**") and its subsidiaries (together the "**Group**") are engaged in the pharmaceutical development 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 Paasheuvelweg 25A, 1105 BP Amsterdam, the Netherlands.

2 Basis of preparation

The special purpose consolidated interim financial statements have been stated on a basis consistent with the audited Financial Statements, which are based on IFRS as adopted by the EU. They should be read in conjunction with the Company's Annual Report 2016.

The special purpose consolidated interim financial statements were authorised for issue by the Management Board and the Supervisory Board of the Company on 7 March 2018.

These interim financial statements have not been audited nor reviewed.

Going concern assessment

The interim financial statements have been prepared on a going concern basis, although based on the current operating plan, cash and cash equivalents are currently not sufficient to meet the Company's working capital requirements through the 12 months following 7 March 2018, the date on which these interim financial statements were authorised for issue by the Management Board and the Supervisory Board. The above circumstance indicates the existence of a material uncertainty which may cast significant doubt about the Company's ability to continue as a going concern. However, the Company believes that sufficient additional funds can be raised by means of equity financing, non-dilutive financing or strategic transactions, and is currently investigating funding options. The Management Board believes that the Company will be able to meet its financial obligations in the 12 months following 7 March 2018, the date on which these interim financial statements were authorised for issue by the Management Board and the Supervisory Board. Therefore, the Management Board is of the opinion that the going concern assumption is justified.

3 Significant accounting policies

There were no significant changes in accounting policies applied by the Group in these special purpose consolidated interim financial statements compared to those used in the Annual Report 2016.

Significant accounting estimates and judgments

The preparation of financial statements requires judgments and estimates that affect the reported amounts of assets and liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities at the date of the consolidated interim financial statements. The resulting accounting estimates will, by definition, seldom equal the actual results. The estimates and assumptions that have a significant risk of causing a material adjustment to the carrying amount of assets and liabilities within the next financial year are addressed

below.

Non-derivative financial liabilities

The Company presented non-current financial liabilities with a carrying value of EUR18.1 million as at September 30, 2017. An amount of EUR10.2 million relates to a loan from Hospira Inc. for which repayment is conditional (see Note 10). This loan has an effective interest rate (EIR) of 11% that was established at initial recognition. At each reporting date, the Company makes an assessment of the underlying future cash flows. In the event cash outflows related to repayment of the loan have changed during the period, the Company recalculates the net present value (NPV) of these re-estimated cash outflows using the original EIR. Any difference between the carrying amount and the recalculated NPV at the reporting date, will give rise to a gain or loss to be charged to the statement of income.

Derivative financial liabilities

The Company presented derivative financial liabilities with a carrying value of EUR1.5 million as at September 30, 2017. These liabilities represent the fair value of warrants issued and are based on models using assumptions with respect to, amongst others, the exercise of the warrants on or before maturity. The estimated fair value of derivatives that are level 2 financial liabilities in the fair value hierarchy (see Note 16) is based on a Hull & White model. Measurement inputs to calculate the fair value are the Company's share price, the exercise price of the warrants, share price volatility of peer companies, and a risk-free interest rate. Fair value changes of warrants that are not exercised between September 30, 2017 and subsequent reporting dates are charged to profit and loss.

4 Segment reporting

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision-makers. 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 September 30, 2017, 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.

5 Property, plant and equipment

	Laboratory Equipment	Furniture & Hardware	Leasehold Improvements	Total
Balance as at January 1, 2017				
Cost of acquisition	1.001	296	79	1.376
Depreciation / Impairment	(601)	(197)	(42)	(840)
Book value as at January 1, 2017	**400**	**99**	**37**	**536**
Changes in book value				
Additions	6	44	3	53
Depreciation	(91)	(25)	(6)	(122)
	(85)	**19**	**(3)**	**(69)**
Balance as at September 30, 2017				
Cost of acquisition	1.007	340	82	1.429
Depreciation / Impairment	(692)	(222)	(48)	(962)
Book value as at September 30, 2017	**315**	**118**	**34**	**467**

6 Intangible assets

	Goodwill	In-process Research & Development	Patents	Total
Balance as at January 1, 2017				
Cost	4.283	9.257	80	13.620
Amortization / Impairment	-	-	(80)	(80)
Book value as at January 1, 2017	**4.283**	**9.257**	**-**	**13.540**
Changes in book value				
Effect of changes in foreign exchange rates	(128)	(278)	-	(406)
	(128)	**(278)**	**-**	**(406)**
Balance as at September 30, 2017				
Cost	4.155	8.979	80	13.214
Amortization / Impairment	-	-	(80)	(80)
Book value as at September 30, 2017	**4.155**	**8.979**	**-**	**13.134**

The Company's intangible assets mainly relate to the business combination effected in 2006 in which Kiadis Pharma acquired Montreal, Canada, based Celmed BioSciences Inc. The carrying value of the Company's intangible assets decreased from EUR13.5 million at year end 2016 to EUR13.1 million at September 30, 2017. This decrease of EUR0.4 million is caused by a weakening of the Canadian dollar against the euro of approximately 4%.

7 Trade and other receivables

	September 30, 2017	December 31, 2016
VAT receivables	195	221
Deferred expenses	397	351
Interest receivable	-	8
Other amounts receivable	48	1
	640	**581**

8 Cash position and cash flows

	September 30, 2017	December 31, 2016
Cash as at bank and in hand	13.215	1.009
Short-term bank deposits	-	13.550
Cash and Cash Equivalents	**13.215**	**14.559**
Bank overdrafts used for cash management purposes	-	-
Net Cash as per Cash Flow Statement	**13.215**	**14.559**

All amounts reported as cash or cash equivalents are at the free disposal of the Company with the exception of an amount of €73 thousand that is pledged against certain bank guarantees provided as security for the lease of buildings.

The main cash flow items can be summarised as follows:

	For the nine months ended	
	September 30, 2017	September 30, 2016
Net cash used in operating activities	(11.517)	(11.494)
Net cash used in investing activities	(45)	(134)
Net cash from financing activities	10.229	718
Effect of exchange rate fluctuations on cash held	(11)	7
Net decrease for the period	**(1.344)**	**(10.903)**
Cash and cash equivalents, beginning of the period	14.559	28.666
Cash and cash equivalents, end of the period	**13.215**	**17.763**

9 Equity

In June 2017, the Company raised EUR5 million in gross proceeds by issuing a total of 746,269 units, each comprising 1 ordinary share and 1 warrant, in a private placement with existing and new shareholders.

The warrants issued in this private placement initially did not meet the fixed-for-fixed criteria

and were therefore classified as a liability. The fair value of these warrants at initial recognition was deducted from equity. On August 17, 2017, Kiadis Pharma entered into a loan agreement with Kreos Capital Ltd. As part of this loan agreement, Kiadis Pharma issued warrants towards Kreos Capital. As a consequence of the issuance of these warrants towards Kreos, the exercise price of the warrants previously issued in connection with the private placement became fixed and as a result, this change led to a reclassification from liabilities into equity. See also Note 11.

In connection with this private placement, the Company also issued 55,970 warrants to certain service providers. These warrants were classified as equity instruments and were recorded in warrant reserve.

In September 2017, the Company issued 324,627 shares upon the exercise of 324,627 warrants with an exercise price of EUR7.307 and received EUR2.4 million in cash.

As at September 30, 2017, a total number of 15,037,397 ordinary shares were outstanding. Ordinary shares have a nominal value of EUR0.10 and each share holds the right to one vote.

10 Loans and borrowings

	September 30, 2017	December 31, 2016
Non-current liabilities		
Government Loan I (RVO NL)	-	2.797
Government Loan II (RVO NL)	-	1.729
Loan from Kreos Capital	7.117	-
Loan from Hospira Inc.	10.162	10.206
Loan from University of Montreal	802	873
	18.081	**15.605**

	September 30, 2017	December 31, 2016
Current liabilities		
Government Loan I (RVO NL)	-	1.019
Government Loan II (RVO NL)	-	536
Loan from Kreos Capital	1.280	-
	1.280	**1.555**

In August 2017, the Company obtained a debt financing from Kreos Capital for up to EUR15 million (of which EUR5 million conditional) to refinance existing loans and fund the development of the Company's ATIR products. The first tranche of EUR10 million was immediately drawn down and partly used to repay the outstanding loans from Rijksdienst voor Ondernemend Nederland (RVO NL) of EUR5.3 million in total.

As part of the loan agreement, Kiadis Pharma issued warrants towards Kreos Capital. These warrants, to be classified as liabilities, had a total combined fair value of EUR0.9 million. Taking into account this fair value of the warrants and transaction costs of EUR0.3 million to be amortised, the loan with Kreos Capital had a carrying value of €8.8 million at initial

recognition.

In December 2011, the Company entered into an agreement with Hospira Inc. for which an amount of USD24.5 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:

1 a milestone payment of USD3 million upon the earlier of (i) the execution of a sub-licence on the Theralux platform, or (ii) the first commercial sale of a product derived from the Theralux platform; and

2 a 5% royalty on worldwide net sales of products derived from the Theralux product platform until the loan amount has been fully paid.

At September 30, 2017, the carrying amount of this loan has been adjusted to reflect changes in the (estimated) underlying future cash flows (EUR282 thousand increase) and a weakening of the U.S. dollar against the euro (EUR1.2 million decrease). These amounts have been charged to the income statement (see Note 15).

The changes in loans and borrowings in the first nine months of 2017 can be summarised as follows.

	RVO NL	Kreos Capital	Hospira Inc.	University of Montreal
Balance as at January 1, 2017	**6.081**	**-**	**10.206**	**873**
Interest accrued during the period	373	203	841	22
Interest payments	(372)	(312)	-	-
New loan agreements		8.826		
Repayments	(6.082)	(320)	-	-
Restatement of carrying amount	-	-	282	-
Effect of changes in foreign exchange rates	-	-	(1.167)	(93)
Balance as at September 30, 2017	**-**	**8.397**	**10.162**	**802**

11 Derivatives

	For the nine months ended	
	September 30, 2017	**September 30, 2016**
Balance as at January 1	**-**	**-**
Initial recognition upon issue	3.192	-
Loss included in 'finance expenses' :		
- Net change in fair value	667	-
Gain included in 'finance income' :		
- Net change in fair value	(351)	-
Reclassification to equity	(1.962)	-
Balance as at September 30	**1.546**	**-**

In June 2017, the Company issued 746,269 warrants to the investors who participated in a private placement of ordinary shares. See also Note 9. The warrants issued in this private placement initially did not meet the fixed-for-fixed criteria and were therefore classified as a liability. The fair value of these warrants at initial recognition of EUR2.3 million was deducted

from equity. On August 17, 2017, Kiadis Pharma entered into a loan agreement with Kreos Capital Ltd. As part of this loan agreement, Kiadis Pharma issued a new series of warrants towards Kreos Capital with a fair value of EUR0.9 million at initial recognition.

As a consequence of the issuance of these warrants towards Kreos, the exercise price of the warrants previously issued in connection with the private placement became fixed and as a result, this change led to a reclassification from liabilities into equity. Immediately prior to this reclassification the warrants were remeasured at EUR2.0 million and a gain of EUR0.4 million was recorded in finance income.

The warrants issued towards Kreos were remeasured at the reporting date at EUR1.5 million and the corresponding change in fair value of EUR0.7 million was recorded in finance expenses.

12 Trade and other payables

	September 30, 2017	December 31, 2016
Suppliers	1.050	1.268
Salaries, bonuses and vacation	358	339
Tax and social premium contributions	165	206
Accrued clinical costs	268	426
Accrued manufacturing costs	133	137
Accrued audit fees	90	95
Accrued legal fees	110	-
Other	285	144
	2.459	2.615

13 Employee Benefits

	For the nine months ended	
	September 30, 2017	September 30, 2016
Wages and salaries	3.362	2.007
Compulsory social security contributions	338	196
Contributions to defined contribution plans	145	85
Equity-settled share-based payment	471	163
Cash-settled share-based payment	487	-
Company cars	3	4
Other employee benefits	56	45
Total	**4.862**	**2.500**
Number of employees (headcount)		
Research & development positions	44	27
General & administrative positions	8	6
Number of employees (headcount),end of the period	**52**	**33**

Employee benefits excluding expenses related to share-based payment for the first nine

months of 2017 increased by EUR1.6 million compared to the same period in 2016. This was mainly due to increases in headcount across all R&D departments.

Equity-settled share-based payment expense relates to share options granted under the Kiadis Pharma 2016 share option plan. Under this plan an aggregate number of 86,200 share options were granted to employees on January 1, 2017. An additional number of 100,300 share options were granted on July 1, 2017 and 25,000 share options were granted on September 1, 2017.

On September 30, 2017, a total of 335,811 share options with an average exercise price of EUR8.79 were issued and outstanding. On this date, 56,505 of these share options were exercisable.

Cash-settled share-based payment expense relate to stock appreciations rights (SARs) granted under the Kiadis Pharma 2017 stock appreciation right plan. Under this plan 300,000 SARs were granted to Mr. Arthur Lahr, CEO of the Company, on April 4, 2017. On September 30, 2017, all 300,000 SARs were issued and outstanding. None of these SARs were exercisable on this date.

14 Expenses

	For the nine months ended	
	September 30, 2017	**September 30, 2016**
Employee benefits (see Note 13)	4.862	2.500
Depreciation expense	122	113
Facilities	308	257
Consultancy	1.822	1.176
Telecom & IT	148	62
Travel	298	329
Insurance	75	56
Clinical costs	1.546	539
Manufacturing	1.796	2.422
Other	726	365
Total	**11.703**	**7.819**

	For the nine months ended	
	September 30, 2017	**September 30, 2016**
Research and development expenses	8.096	5.647
General and administrative expenses	3.607	2.172
Total	**11.703**	**7.819**

Research and development expenses increased by EUR2.5 million mainly due to start-up costs for the Phase III trial with ATIR101, expansion of the workforce, and regulatory consultancy expenses related to the filing of the Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for lead product ATIR101.

General and administrative expenses increased by EUR1.3 million mainly due to consultancy expenses for business development and financing, share-based payment expenses and severance pay.

15 Finance income and expenses

	For the nine months ended	
	September 30, 2017	**September 30, 2016**
Finance income		
- Interest income	-	29
- Net foreign exchange gain	858	546
- Gain from change in fair value of derivatives	351	-
	1.209	**575**
Finance expenses		
- Bank borrowings, and other debt	(1.439)	(1.167)
- Loss from restatements of loans	(282)	(1.482)
- Loss from change in fair value of derivatives	(667)	-
	(2.388)	**(2.649)**

Net foreign exchange gain of EUR858 thousand in the first nine months of 2017 includes EUR387 thousand of unrealised (non-cash) Canadian dollar/euro exchange rate loss on intra-group loans and EUR1.2 million of unrealised (non-cash) U.S. dollar/euro exchange rate gain on the loan from Hospira Inc.

Finance income also includes a gain of EUR351 thousand from the remeasurement of derivatives at the reporting date. Finance expenses include a loss of EUR667 thousand from the remeasurement of derivatives at the reporting date. See also Note 11.

Due to an increase in the estimated future cash flows underlying the Hospira Inc. loan, the carrying amount of the loan was adjusted upward for EUR282 thousand (see also Note 10). This resulted in a charge included in finance expenses of the same amount.

16 Financial instruments

The following tables show the carrying amounts and fair values of financial assets and liabilities, including their levels in the fair value hierarchy. These tables do 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.

	Carrying amount				Fair value			
	Non-current assets	Current assets						
		Trade and other receivables	Cash and cash equivalents	Total	Level 1	Level 2	level 3	Total
September 30, 2017								
Financial assets not measured at fair value								
Trade and other receivables		243		243				
Cash and cash equivalents			13.215	13.215				
		243	**13.215**	**13.458**				
December 31, 2016								
Financial assets not measured at fair value								
Trade and other receivables		230		230				
Cash and cash equivalents			14.559	14.559				
		230	**14.559**	**14.789**				

	Carrying amount					Fair value			
	Non-current liabilities		Current liabilities						
	Derivatives	Loans and borrowings	Trade and other payables	Loans and borrowings	Total	Level 1	Level 2	level 3	Total
September 30, 2017									
Financial liabilities measured at fair value									
Derivatives	1.546				1.546		1.546		1.546
Financial liabilities not measured at fair value									
Government Loans (RVO NL)		-		-	-		-		-
Loan from Hospira Inc.		10.162			10.162		10.162		10.162
Loan from University of Montreal, Canada		802			802		802		802
Trade and other payables			2.413		2.413				
	1.546	**10.964**	**2.413**	**-**	**14.923**				
December 31, 2016									
Financial liabilities measured at fair value									
Derivatives	-				-		-		-
Financial liabilities not measured at fair value									
Government Loans (RVO NL)		4.526		1.555	6.081		6.081		6.081
Loan from Hospira Inc.		10.206			10.206		10.206		10.206
Loan from University of Montreal, Canada		873			873		873		873
Trade and other payables			2.615		2.615				
	-	**15.605**	**2.615**	**1.555**	**19.775**				

17 Contingencies and commitments

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

	September 30, 2017	December 31, 2016
Less than one year	180	177
Between one and five years	-	-
More than 5 years	-	-
	180	**177**

The operating lease contracts mainly relate to office and laboratory space in Amsterdam. In

December 2017, the Company signed a new lease contract for an existing commercial manufacturing facility in order to relocate its head offices and laboratories in Amsterdam. The lease term is 10 years starting 1 January 2018. Lease payments in the first twelve months amount to EUR923 thousand, lease payments between one and five years amount to EUR3.7 million, and lease payment after five years amount to EUR4.6 million. Payments for lease related services in the first twelve months amount to EUR512 thousand, payments for lease related services between one and five years amount to EUR2.0 million, and payments for lease related services after five years amount to EUR2.6 million

18 Transactions with related parties

The transactions with related parties that have a significant influence over the Company during the three months presented in this Interim Report are described below. Other than this, there were no transactions or business activities with related parties.

Management Board

The Management Board included in the table below relates to 2 members (Chief Executive Officer and Chief Financial Officer) who were in office during the first three months of 2017 and 2016.

	For the nine months ended	
	September 30, 2017	**September 30, 2016**
Salaries and other short-term employee benefits	679	498
Pensions	10	10
Share-based payments	753	163
Social securities	17	20
Other benefits	2	6
Total	**1.461**	**697**

Salaries and other short-term employee benefits include EUR315 thousand in severance pay for Dr. Rüdiger who left the Company effective April 1, 2017.

Supervisory Board

The remuneration of the Supervisory Board members included in the table below relates to the compensation for 5 members in the first nine months of 2017 (Q1 2016: 4; Q2 2016: 3; Q3 2016: 5). Only independent board members receive compensation for their services.

	For the nine months ended	
	September 30, 2017	**September 30, 2016**
Remuneration	60	24
Share-based payments	-	-
Total	**60**	**24**

19 Subsequent events

In October 2017, Kiadis Pharma raised EUR18.0 million as gross proceeds in a private placement of 2.25 million new shares.

Also in October 2017, Kiadis Pharma drew down EUR5 million as the second tranche of the debt facility of EUR15 million in total from Kreos Capital. In connection with this second tranche, the Company issued 42,269 warrants towards Kreos Capital.

In the period from 30 September 2017 up to the date of these interim financial statements 227,695 warrants resulting in proceeds of EUR1.66 million have been exercised.

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