Kiadis Pharma N.V.

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

Registration Document

This registration document (the "**Registration Document**") is published by Kiadis Pharma N.V. (the "**Company**", and together with its consolidated subsidiaries "**Kiadis**", "**we**", "**our**", "**ours**", "**us**" and similar terms).

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, "**Euronext**") 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 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 (including as per Directive 2010/73/EU) (the "**Prospectus Directive**"), 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 (collectively, a "**Summary and Securities Note**"), each of which is approved by the AFM (the "**Prospectus**").

The date of this Registration Document is May 31, 2019 (the "**Registration Document Date**").

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1. RISK FACTORS

You should carefully consider the risks and uncertainties described below and the other information in this Registration Document, as well as the risk factors and other information to be set out in the Summary and Securities Note that together with this Registration Document shall constitute a prospectus in accordance with the Prospectus Directive before making an investment in our Shares. Our business, financial condition or results of operations could be materially and adversely affected if any of these risks occurs, and as a result, the market price of our Shares could decline and you could lose all or part of your investment. This Registration Document also contains forward-looking statements that involve risks and uncertainties. See paragraph 2.8 below. Our actual results could differ materially and adversely from those anticipated in these forward-looking statements as a result of certain factors.

While we believe that the risks and uncertainties described below are the material risks and uncertainties concerning our business, they are not the only risks and uncertainties relating to us. In accordance with the Prospectus Directive, the risk factors included in this Registration Document are limited to risk factors relating to us and our business, whereas the risk factors relating to our Shares and other securities shall be included in a Summary and Securities Note. Furthermore, other risks, facts or circumstances not presently known to us, or that we currently deem to be immaterial could, individually or cumulatively, prove to be important and could have a material adverse effect on our business, results of operations, financial condition and prospects. The value of the Shares could decline as a result of the occurrence of any such risks, facts or circumstances or as a result of the events or circumstances described in these risk factors, and investors could lose part or all of their investment.

1.1 Risks related to our financial position

We have a history of operating losses and anticipate that we will continue to incur operating losses for the foreseeable future.

Developing pharmaceutical products is expensive, and there is typically a significant amount of time prior to realizing a return on an investment in product development, if a return is realized at all. For the years ended December 31, 2018 and December 31, 2017 our research and development expenses were €17.5 million and €11.2 million, respectively. We expect that the level of our research and development expenses will be even higher in 2019 as we ramp up our Phase III clinical trial for our lead product candidate ATIR101 and, in the event that the acquisition of CytoSen Therapeutics, Inc. ("**CytoSen**") is completed, progress development of CytoSen's lead programme CSTD002-NK (see paragraph 7.3).

To obtain regulatory approval for the sale of any product candidates, extensive clinical trials must demonstrate that our product candidates are safe and effective for use in humans. Clinical trials are included in our research and development expenses and may take years to complete. We cannot be sure that we or our collaboration partners, if we have such partners in the future, will complete clinical testing within the time we anticipate or that we or they will be able to do so without requiring significant resources or expertise in excess of what we anticipate. Completion of clinical trials depends on various factors, including the indication and size of the patient population and its proximity to clinical sites, the nature of the clinical protocol, the eligibility criteria for trial, competition for trial patients, availability of sufficient quantities of a product candidate, the assistance of third parties, regulatory compliance and adequate financial resources.

We have incurred losses in each year since inception. Our net losses for the fiscal years ended December 31, 2018 and 2017 were €29.8 million and €17.0 million, respectively, and our accumulated deficits for the fiscal years ended December 31, 2018 and 2017 were €139.5 million and €111.9 million, respectively. Currently, we do not have any products that have been approved for marketing, and we continue to incur costs for preclinical and clinical research and development, manufacturing and future commercialization, of product candidates, as well as general and administrative expenses.

We expect to continue to incur losses for the foreseeable future and expect these losses to increase significantly as we continue the development and manufacturing, and seek regulatory approval for, our product candidates and the commercialization thereof. In addition, as we seek to advance our product candidates through clinical trials, including our current and any future Phase III clinical trials, we will incur increased costs as we expand our development, manufacturing, regulatory and marketing capabilities by adding qualified personnel in these areas. Further, we are 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. Our losses, among other things, have caused and will continue to cause our working capital to decrease.

We have never generated any revenues from product sales, and our ability to generate future revenues from product sales and become profitable depends significantly on our success in commercializing our product candidates.

We have not generated any revenues from product sales. To achieve and maintain profitability, we will need to generate significant revenues from sales of our product candidates. However, none of our product candidates is approved for marketing at this stage. As a result, we do not expect to be able to generate revenues until the end of 2019 at the earliest, if at all. Should we fail to receive and maintain regulatory approval to market any or all of our product candidates, or if such product candidates fail to gain market acceptance, our business, financial condition, results of operations and prospects would be materially adversely affected. If we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

We are dependent on external funding in the near future.

As of December 31, 2018, we had cash and cash equivalents of €60.3 million and as of the Registration Document Date, we had cash and cash equivalents of approximately €42 million. Based on our operating plans, we believe that in the event that the Transaction (as defined below) completes and our operations will include those of CytoSen or in the event that the Transaction does not complete, existing cash and cash equivalents will allow us to continue operating the business in either case into the first quarter of 2020. The fact that our working capital requirements for the next twelve months following the Registration Document Date requires additional funds indicates the existence of a material uncertainty which may cast significant doubt about our ability to continue as a going concern. See also Note 2.1 of the consolidated financial statements for the financial year ended December 31, 2018 incorporated by reference in this Registration Document.

To address the working capital needs for our operations and those of CytoSen and the shortfall that would arise if the Transaction completes as set out above, on May 30, 2019 we launched an equity raising by means of a private placement of Shares that raised €25.4 million in net proceeds (€27.6 million in gross proceeds). For more information on this private placement which is expected to complete on or about June 4, 2019 and our working capital

position, we refer to the Summary and Securities Note that is made generally available in relation to the aforementioned private placement.

As our existing capital resources and the net proceeds from the Private Placement will fund us for the next twelve months following the Registration Document but may not be sufficient to fund us beyond such twelve months or to fund the completion of our clinical development programs, including ATIR101, and the development of the CytoSen programs in the event that the Transaction completes, we will need to raise additional funds through public or private equity offerings or by other means.

To further address our working capital needs, in addition to further equity raises in the private or public markets, we may also seek to enter into debt financing arrangements and/or delay, reduce the scope of, eliminate or divest clinical programs, partner with others or divest one or more of our activities, and consider other cost reduction initiatives, such as slowing down the planned organizational expansion, withholding expansion of additional clinical trials, slowing down the preparation and investments for the manufacturing facility and slowing down patient recruitment of clinical trials. In the event we are not be able to generate sufficient funds from these measures, we may be unable to continue as a going concern, our business, financial condition and/or results of operations could be materially and adversely affected and we may ultimately go into insolvency.

We require substantial funding to continue our operations.

We have used substantial funds to advance the development of our product candidates to date and will require substantial additional funds to complete our planned development programs through to commercialization, including to conduct further research and clinical development, to obtain, maintain, defend and enforce our patents and other intellectual property rights, to manufacture and market any products that may be approved for commercial sale, if any, and to meet our payment obligations under our loan arrangements and our royalty and milestone arrangements. As we do not generate sufficient cash from product revenues to meet our current working capital requirements, we are largely dependent on the issuance and sale of equity and debt securities, and other funding sources, to continue financing our operations and to proceed with our current plans for clinical development.

The failure to raise capital when needed would adversely affect our business, financial condition, results of operations or prospects and could reduce the price of our Shares. In addition, any perceived or actual inability by us to finance our clinical development program and other business activities, including as a result of required milestone and royalty payments to third parties, may cause the market price of our Shares to decline.

Our future funding requirements will depend on many factors, including:

- the progress and cost of our ongoing and future clinical trials and research and development activities;
- the outcome, timing and cost of regulatory approvals by the European Medicines Agency (the "**EMA**"), the U.S. Food and Drug Administration (the "**FDA**") and any other comparable regulatory authority;
- the growth in the number of our employees;

- the cost of establishing sales, marketing, manufacturing and distribution capabilities for any product candidates for which we aim to receive regulatory approval;

- the manufacturing cost of our product candidates, including the cost of establishing our own manufacturing facility in the Netherlands;

- the timing, receipt and amount of any required milestone, royalty and other payments from or to present and future licensors, collaborators or other third parties;

- the timing, receipt and amount of sales, if any, from our product candidates, if any, for which we receive regulatory approval;

- changes in regulatory policies or laws that affect our operations or clinical development;

- the effects of competing products and competing technologies; and

- the terms and timing of establishing potential collaborations, license agreements or other partnerships and private and government insurance reimbursement, including the U.S. federal health insurance program Medicare.

There can be no assurance that such funding will be available in a timely manner, on favorable terms, or at all, or that such funds, if raised, would be sufficient to enable us to continue to implement our long-term business strategy. If we are unable to obtain sufficient funding in a timely manner or on commercially acceptable terms, we may have to delay, scale back or stop some or all of our clinical development programs and commercialization efforts, or grant rights to third parties to develop and market product candidates that we would otherwise prefer to develop and market ourselves, thereby reducing our ultimate value. If we are unable to satisfy certain royalty payments - especially our royalty obligation to the University of Montreal (see paragraphs 6.1, 6.8 and 7.11 below) - we may furthermore lose rights to certain licenses or intellectual property rights for our product candidates, including to ATIR101, our lead product candidate. This may also result in us 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. The failure to raise capital when needed would materially adversely affect our business, financial condition, results of operations and prospects and could adversely affect the price of our Shares.

Raising additional capital may dilute the ownership interests of our Shareholders, and the terms of any additional funding may adversely affect a Shareholder's rights and diminish our future prospects.

To finance our operations, we may choose to issue equity or securities convertible into or exchangeable for equity, which would dilute your interest in us. Alternatively, it may be necessary for us to raise additional funds by incurring indebtedness. As a result, our interest expense, leverage and debt service requirements could increase significantly. Additional funds may not be available on terms that are favorable to us, if at all.

The terms of any securities that we 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 us to agree to covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends, thus limiting funds available for our business activities, or lenders could seek assignments or security rights over our assets

including patents. In order to obtain additional debt financing, we would need the approval of Kreos Capital V (UK) LP Kreos ("**Kreos Capital**").

If we raise additional funds through collaboration and licensing arrangements with third parties, we would need certain approvals from Hospira, Inc. ("**Hospira**") and we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us.

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

The terms of our secured debt facility place restrictions on our operating and financial flexibility.

We have a €15 million credit facility with Kreos Capital (the "**First Kreos Capital Facility Agreement**") and a €20 million credit facility with Kreos Capital (the "**Second Kreos Capital Facility Agreement**" and, together with the First Kreos Capital Facility Agreement, the "**Kreos Capital Facility Agreements**") that are secured by a lien on our assets, including our intellectual property. The full amount of €15 million available under the First Kreos Capital Facility Agreement has been drawn. Under the Second Kreos Capital Facility Agreement an amount of €5 million has been drawn. The remainder of €15 million is not available to us anymore. It had to be drawn down by March 31, 2019 and was conditional upon us having obtained a positive opinion of the Committee for Medicinal Products for Human Use ("**CHMP**") to the European Commission recommending we receive marketing authorization for ATIR101 by then.

The Kreos Capital Facility Agreements contain various affirmative and negative covenants and events of default, including the following:

- a negative pledge undertaking;
- a restriction on the disposals of assets outside of the ordinary course of business;
- a restriction on transferring or licensing our assets;
- a restriction on 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 and operational leases and financial leases up to a certain threshold amount);
- a restriction on entering into joint ventures, and on any amalgamations, demergers, mergers or corporate reconstructions;
- an undertaking to continue the business in the ordinary course of business;
- a restriction on the granting of guarantees in respect of the obligations of any person;
- a restriction on making a substantial change to the general nature or scope of our current business; and
- an undertaking to maintain adequate risk protection through insurances.

Further, as long as any of the loans under the Kreos Capital Facility Agreements remain outstanding, we are not entitled to make any dividend payment or other distributions to Shareholders without the prior written consent of Kreos Capital, which may not be unreasonably withheld or delayed. Additionally, none of our subsidiaries may issue any shares (other than to affiliates) without the prior written consent of Kreos Capital. See also paragraph 6.8 below.

Exchange rate fluctuations could negatively affect our financial condition.

Our consolidated financial statements are presented in euros. However, as we shall have increased our operations in the United States if the Transaction completes and CytoSen becomes our wholly owned subsidiary, and also since we have clinical trials in Canada and the United Kingdom and we intend to conduct clinical trials in the United States, Sweden, Croatia and Israel, we incur or will incur part of our expenses in U.S. dollars, Canadian dollars, British pounds, Swedish krona, Croatian kuna and Israeli shekel. As a result, our business and Share price will be affected by fluctuations in foreign exchange rates, primarily between the euro and the U.S. and Canadian dollar, which may have a significant impact on our reported results of operations and cash flows from period to period.

Our tax liability may be materially different from what is reflected in our income tax provisions and related balance sheet accounts.

We are subject to income taxes in the Netherlands and other jurisdictions. Our future effective income tax rate will be impacted by a number of factors, including the geographic composition of our worldwide taxable income and our ability to allocate debt and expenses effectively. If legislators, tax authorities or government agencies in the jurisdictions in which we operate were to change applicable tax laws and regulations (for example, as a 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 Organization for Economic Co-operation and Development and anti-tax avoidance measures proposed by the European Committee) or successfully challenge the manner in which our income taxes are currently recognized or calculated or the transfer pricing policies employed by us, our effective income tax rate could increase, which would adversely impact our 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 we believe our tax estimates are reasonable, the final determination of tax by means of an assessment or an audit could be materially different from our tax provisions and accruals and negatively impact our financial results.

Our ability to use our net operating losses in the Netherlands to offset future taxable income may be subject to certain limitations.

Our ability to use our net operating losses ("**NOLs**"), in the Netherlands is currently limited and may be further limited. As a result of Dutch income tax law, tax loss carry-forwards are subject to a time limitation of nine years from the year these tax losses were incurred. Legislation has been enacted that decreases the carry-forwards time limitation of tax losses incurred after 31 December 2018 from 9 years to 6 years. This means that the final year in which losses incurred in year-end December 31, 2019 can be set off against profits is the financial year 2025. As of December 31, 2018, we had a total of €93.7 million tax loss carry-forwards available for offset against future taxable profits in the Netherlands. The first amount of the tax loss carry-forward will expire in 2019. Our existing NOLs could expire earlier than currently accounted for. In addition, there is a risk that due to significant changes in ultimate ownership of the Company, the tax loss carry-forward can no longer be utilized.

For these reasons, we may not be able to use a material portion of the NOLs, even if we attain profitability.

1.2 Risks related to the development and clinical testing of our product candidates

Our future commercial potential depends on our lead product candidate, ATIR101. If we are unable to commercialize ATIR101 or any of our other product candidates that we may pursue, or experience significant delays in doing so, our business, financial condition, results of operations and prospects would be materially adversely affected.

ATIR101, our only product candidate in clinical testing, is in Phase III clinical development. Our ability to generate product revenues in the future will depend significantly, if not solely, on the successful clinical development and commercialization of ATIR101. If the ATIR101 or any other product candidate that we may pursue fails, we will have to develop, acquire or license new product candidates. ATIR101, as well as any other product candidates we may pursue, could be unsuccessful if they:

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

We do not expect ATIR101 to be commercially available in any market before at least the end of 2019, if at all. The results of the clinical trials to date cannot provide assurance that acceptable efficacy or safety will be shown upon completion of ongoing or planned clinical trials. Many products that show promise in Phase II trials fail in later clinical trials. If we are unable to make ATIR101 commercially available, or we experience significant delays in doing so, our business, financial condition, results of operations and prospects would be materially adversely affected.

We may experience setbacks in our clinical trials, including delays in commencing or completing, or inconclusive or negative results, all of which could harm our ability to market a product, generate revenues and could have a material adverse effect on our 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. We estimate that clinical trials of ATIR101 will continue for a significant period of time as we seek 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 our clinical 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, including later stages of clinical trials despite having progressed through preclinical and initial clinical

trials, for a variety of reasons, such as differences in patient populations, changes in trial and manufacturing protocols and complexities of larger, multi-center trials among others. For example, while we have recently observed positive results from our Phase II CR-AIR-007 in 36 patients (Intent To Treat (ITT) population), such results may not be replicated with statistical significance in future clinical trials that include larger numbers of patients with potentially different trial protocols and endpoints or in head-to-head clinical trials such as our Phase III CR-AIR-009. Furthermore, we significantly rely on contract research organizations ("**CROs**"), to supervise its clinical studies. Failure by these CROs to adequately conduct investigators could negatively affect the clinical studies, including the quality of the generated data. We may experience numerous events during, or as a result of, the clinical trial process that could delay or prevent commercialization of our current and any future product candidates. These events include, but are not limited to:

- delays in securing clinical investigators or trial sites for our clinical trials;
- delays in obtaining regulatory approval to commence or continue a clinical trial;
- slower than anticipated rates of patient recruitment and enrollment;
- patient dropout following enrollment;
- negative results from clinical trials;
- manufacturing issues;
- inconclusive results, which may stem from our clinical trials being open-label, inadequately powered for statistical significance, use of a novel primary endpoint, variability in patient populations and treatment approaches at clinical sites or from other factors;
- patient deaths, the development of side effects in patients or safety issues, such as Graft versus Host Disease ("**GVHD**") encephalopathy, or infections;
- variability of ATIR101 product composition, including types, specificities, quantity and viability of cells in final products;
- introduction of new therapies or changes in standards of practice or regulatory guidance that render our clinical trial endpoints or the targeting of our 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 our ongoing Phase II and Phase III trials or any future studies the safety and efficacy data obtained from a limited number of patients in our previous trials.

If we suffer any material delays, negative results or other setbacks in our clinical trials or if our clinical trials are put on clinical hold or terminated, we may be unable to continue development of our product candidates and our development costs could increase significantly, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our clinical trials for ATIR101 to date have not been conducted head-to-head with the PTCy protocol, and the comparison of our results to those published in literature about the PTCy protocol or to historical observational cohorts, and the conclusions we have drawn from such comparisons, may be inaccurate.

Our clinical trials for our product candidates to date have not been conducted head-to-head with the Post-Transplant Cyclophosphamide protocol ("**PTCy protocol**"), also commonly referred to as the Baltimore protocol, which is the protocol that the majority of sites use to perform haploidentical hematopoietic stem cell transplantation ("**HSCT**"). This means that none of the patient groups participating in these trials were treated with the PTCy protocol drugs alongside the groups treated with our product candidate. Instead, we have compared the results of our clinical trials of ATIR101 with historical data from third parties using the PTCy protocol, as reported in the scientific literature, as well as with data from a historical observational cohort trial in which data was collected on different HSCT protocols with different donor sources.

Direct comparison provides more reliable information about how two or more drugs compare, and reliance on indirect comparison for evaluating their relative efficacy or other qualities may be problematic due to lack of objective or validated methods to assess data comparability. For example, the various data were collected in different countries, different time periods, different treatment approaches in patients with different indications and demographic features, different baseline conditions and different disease risk indices among other relevant asymmetries. In addition, the data from the historical observational cohort trial and the scientific literature from the PTCy protocol were weighted averages of historical data, which may not represent the data that would have been obtained in a well-controlled clinical trial. Furthermore, HSCT protocol and the PTCy protocol may have been applied inconsistently in the relevant patient populations. Therefore, the conclusions we have drawn from comparing the results of our clinical trials with those published in the scientific literature for the PTCy protocol and with those from the observational cohort trial, including conclusions regarding the relative efficacy of ATIR101, may not be accurate. Further, the conclusions we have drawn regarding p-values from the results of pooled data from clinical trials were not randomized, controlled clinical trials. To compare the PTCy protocol with ATIR101, we screened available scientific literature for the PTCy protocol and selected publications ranging from after 2008 or 2013 in which at least half of the patients had acute myeloid leukemia ("**AML**") or acute lymphoblastic leukemia ("**ALL**") (in CR-AIR-007 all patients had AML or ALL) or in which the Disease Risk Index ("**DRI**"), information, which classifies blood cancers into low, intermediate, high or very high risk, was available for normalization. However, the FDA generally requires head-to-head studies to make labeling and advertising claims regarding superiority or comparability. We are currently conducting a Phase III trial of ATIR101 that will make a head-to-head comparison of haploidentical HSCT in combination with ATIR101 to haploidentical HSCT with the PTCy protocol. If patients in the PTCy arm of the study respond to the treatment more favorably than in the data reported in the literature we surveyed, then ATIR101 may not be able to demonstrate superiority, in which case the prospects for ATIR101 and our company may be harmed.

Our applications for regulatory approval could be delayed or denied due to problems with clinical trials conducted before we obtained our product candidates. Should this occur, our future results may be compromised and our ability to conduct clinical trials may be severely hampered.

We currently license some of the know-how and patents for ATIR101 from third parties, specifically under an exclusive license from the University of Montreal (see paragraphs 6.1, 6.8 and 7.11). Our present development involving ATIR101 relies upon previous research

conducted by third parties over whom we had no control. In order to receive regulatory approval for a product, we need to present all relevant data and information obtained during our research and development, including research conducted prior to us licensing the product. Any problems that emerge from preclinical research and testing conducted prior to our in-licensing may affect future results or our ability to document prior research and to conduct further clinical trials, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we fail to enroll patients in our clinical trials or if patients discontinue their participation, the clinical trials could be delayed and their results compromised, and we may suffer a meaningful delay or incur significantly higher costs in developing our product candidates.

We may encounter delays in the regulatory approval process if we, or physicians who may conduct clinical trials or evaluations of ATIR product candidates, are unable to enroll enough patients to complete clinical trials in a timely and cost-effective manner. Patient enrollment depends on many factors, including the size of the patient population, the nature of the protocol, competitive protocols, currently available treatments, 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. Our clinical trials will compete with other clinical trials for product candidates or HSCT protocols that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our clinical trials may instead opt to enroll in a trial being conducted by another party. In the past, we have faced difficulties in enrolling patients in our clinical trials. We have started our Phase III trial and plan to enroll 250 patients at 50 to 60 sites in the United States, Europe, Canada and certain additional countries. It may be difficult for us to enroll enough patients to complete the trial in a timely manner.

Moreover, when one product is evaluated in multiple clinical trials, patient enrollment 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 we fail to enroll patients in clinical trials or if patients discontinue their participation, this could have a material adverse effect on our business, financial condition, results of operations and prospects.

1.3 Risks related to regulatory approval of our product candidates

Our product candidates are subject to extensive regulation, which can be costly and time-consuming to comply with, and we may not obtain approvals for performing clinical trials or for the commercialization of any of our product candidates.

We are not permitted to perform clinical trials with or market any product until we receive approval from the appropriate regulatory authorities. We must obtain prior approval for performing clinical trials with any product candidates and for commercializing any product candidates from the appropriate regulatory authority of each jurisdiction in which we wish to perform clinical trials with or market our products. We have not received marketing approval from any regulatory authority for any of our product candidates. Even if we receive conditional marketing approval in the European Union, the results generated from our ongoing Phase II and Phase III trials or future studies after approval could result in loss of

marketing approval, changes in product labeling, and/or new or increased concerns about the side effects or efficacy of a product.

We invest substantial time and resources in preclinical studies, clinical trials, manufacturing and the preparation and submission of applications without any assurance that we will obtain regulatory approval or recoup our investment. The EMA, the FDA 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 candidate, the product's primary indication and the specific regulations and guidance documents applicable to any particular product candidate. The EMA, the FDA 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 candidate for many reasons, including but not limited to:

- concerns relating to the product candidate'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 our product candidates, or challenges to their accuracy or adequacy;
- the development or observation of adverse side effects;
- conditions in our or our third-party manufacturers' processes or facilities;
- regulatory changes requiring new or different evidence of safety and efficacy for the product candidate's primary indication;
- issues with adhering to industry good practice quality guidelines, regulations and requirements; or
- the inability to address questions and observations in the regulatory approval process.

In addition, GVHD-Free and Relapse-Free Survival ("**GRFS**"), is the primary endpoint in our ongoing Phase III trial. We believe GRFS is a clinically-accepted endpoint, which is reported in multiple publications and used in multiple clinical studies. However, there is no guarantee that the FDA or comparable regulatory authorities will approve ATIR101 on the basis of a positive efficacy result with respect to GRFS or that the EMA will consider the efficacy results sufficient to convert a conditional marketing authorization, if granted, into a standard marketing authorization. The FDA has informed us that because GRFS is a novel endpoint, the agency does not have sufficient experience to predict how it will behave in a clinical trial. Accordingly, the FDA suggested that it would likely not be able to conclude whether GRFS is

an acceptable endpoint until it reviews the marketing application. If the FDA concludes that GRFS is not an acceptable endpoint, additional clinical trials may be necessary to support approval.

Furthermore, we have received a second round of Day 180 questions from the EMA which we have answered with a submission date of May 22, 2019. In this response, we submitted analyses of the pooled results from CR-AIR-007 with those of patients who received a single dose of ATIR101 in CR-AIR-008 compared to pooled results from our initial control group, CR-AIR-006 with those of patients who received non-viable cells in the CR-AIR-004 study which the EMA agreed could be used in combination with CR-AIR-006 to provide a larger control group. Furthermore, we have also provided additional support for our submission by accessing an external database from the EBMT. We do not know whether the FDA will accept such analyses in support of a regulatory filing, and we may be required to submit additional efficacy data to the FDA.

Finally, additional clinical studies may be necessary to support U.S. marketing approval because the FDA generally requires safety and efficacy data from at least two adequate and well-controlled trials. We currently have only one ongoing Phase III trial and do not intend to initiate a second using ATIR101. Although the FDA could determine that safety and efficacy data resulting from the ongoing Phase III trial are sufficient to support approval, this ultimately depends on the FDA's opinion regarding the robustness and clinical meaningfulness of the generated results. Additionally, even if the FDA grants approval based on one Phase III trial, it could condition that approval on a post-approval commitment to conduct additional studies to verify the product's safety and efficacy.

Should any of these factors occur, regulatory approval of our clinical trials or product candidates 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 our business, financial condition, results of operations or prospects.

If we fail to obtain or maintain orphan drug status for ATIR product candidates in the indications that are important to our business, we would likely have limited or shortened protection or market exclusivity for ATIR product candidates.

To date, we have been granted five orphan drug designations in respect of ATIR101 in the European Union and the United States. In the European Union, we have been granted orphan drug designations for the treatment of AML, prevention of GVHD and for the treatment in HSCT. The latter two orphan drug designations are regardless of the underlying disease. In the United States, we have been granted two orphan drug designations for immune reconstitution and prevention of GVHD following HSCT and for prevention or reduction of transplant related mortality caused by GVHD or infections following haploidentical HSCT. There is no assurance that we will be able to obtain or maintain market exclusivity for our product candidates in indications that are important to our business. Our strategy is to apply our ATIR product candidates initially to indications for which we have orphan drug status, or for which we expect to qualify for orphan drug status in order to obtain market exclusivity for our product candidates, in particular ATIR101. While we have a license to patents relating to our proprietary photodynamic therapy device ("**PTD**"), these patents would likely afford only limited protection and we do not rely on them to provide us with market exclusivity for ATIR product candidates.

Orphan drug status confers market exclusivity upon the first product to receive marketing approval by the relevant regulatory authority for the jurisdiction and entails the right to exclusively market the product for the specified indication, during a maximum of 10 years for

the European Union and during a period of seven years in the United States and . 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.

Once granted, exceptions to market exclusivity through orphan drug status may be granted to other applicants of a similar product for the same indication if we are unable to supply sufficient quantities of the product, or if the product of a second applicant is safer, more effective or otherwise 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 we 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 our product candidates are directed, or from independently developing versions of our product candidates for different indications. Further, we may lose orphan drug exclusivity if the EMA or the FDA determines that the request for designation was materially defective or if we cannot assure sufficient quantity of the applicable drug to meet the needs of patients.

If we fail to obtain or maintain market exclusivity for our product candidates through orphan drug status, or if the commercial value of market exclusivity is diminished, our competitive position or financial and commercial prospects could be materially adversely affected.

The FDA's regulation of regenerative medicine products remains unpredictable and we are not certain what impact this will have on the potential approval of our products.

The FDA's regulation of therapies derived from stem cell products and technologies is evolving and may continue to evolve. In December 2016, the 21st Century Cures Act, (the "**Cures Act**"), was signed into law in the United States to advance access to medical innovations. Among other things, the Cures Act established a new FDA Regenerative Medicine Advanced Therapy ("**RMAT**") designation. ATIR101 has been awarded RMAT designation. This designation offers a variety of benefits to product candidates, including enhanced FDA support during clinical development, priority review on application filing, accelerated approval based on potential surrogate endpoints, and the potential use of patient registry data and other forms of real world evidence for post-approval confirmatory studies. While the FDA issued draft guidance on such designation in November 2017, this guidance has not been finalized to date. There is no certainty that the receipt of such designation for ATIR101 will provide an expedited pathway to FDA approval.

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

If any of our product candidates are approved by the EMA, the FDA, or another regulatory authority for clinical or commercial use, we would be subject to extensive regulatory requirements over product manufacturing, testing, labelling, packaging, storage, advertising, promotion, distribution, export, adverse event reporting and record keeping. We and our

suppliers, contract manufacturing organizations ("**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, facilities in the European Union that 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 our products, which could reduce the potential market for our products. We 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. We 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 we are not able to maintain regulatory compliance, we might not be permitted to market or continue to market our products and our business could suffer.

Failure to comply with the requirements of the EMA, the FDA and other applicable regulatory authorities may subject us 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 our 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 we are subject to any of these sanctions, our competitive position or financial and commercial prospects could be materially adversely affected.

We intend to seek a conditional marketing authorization in Europe for ATIR101 and we may also seek similar conditional marketing approvals for some or all of other product candidates that we may pursue, but we may not be able to obtain or maintain such designation.

As part of its marketing authorization process, the European Commission (following review by the EMA) may grant marketing authorizations for certain categories of medicinal products on the basis of less complete data than is normally required, when doing so may meet unmet medical needs of patients and serve the interest of public health. In such cases, it is possible for the CHMP, to recommend the granting of a marketing authorization, subject to certain specific obligations to be reviewed annually, which is referred to as a conditional marketing authorization. This may apply to medicinal products for human use that fall under the scope of the centralized procedure which the EMA and the European Commission administer, including those that aim at the treatment, the prevention, or the medical diagnosis of seriously debilitating or life-threatening diseases and those designated as orphan medicinal products.

A conditional marketing authorization may be granted when the CHMP recommends 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 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; and

- 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 is still required.

The granting of a conditional marketing authorization is restricted to situations in which only the clinical part of the application is not yet fully complete. Incomplete preclinical or quality data may only be accepted if duly justified and only in the case of a product intended to be used in emergency situations in response to public health threats. The holder will be required to complete ongoing trials or to conduct new trials within a specified period of time 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. Conditional marketing authorizations are valid for one year on a renewable basis until the required clinical research program has been completed and the CHMP has reviewed the resulting data and confirmed the approvability of the product on the basis of a standard marketing authorization.

Granting a conditional marketing authorization allows medicines to reach patients with unmet medical needs earlier than might otherwise be the case and will ensure that additional data on a product is generated, submitted, assessed and acted upon. The CHMP may ultimately not agree that the requirements for such conditional marketing authorization have been satisfied and hence delay the commercialization of our product candidates. Even if we receive conditional marketing approval, if we are unable to initiate or complete the necessary clinical trials within a specified period, for example because we cannot recruit the necessary patient numbers, the conditional marketing authorization might not be renewed. In addition, the results generated from our ongoing Phase II and Phase III trials or future studies after approval could result in loss of marketing approval, changes in product labeling, and/or new or increased concerns about the side effects or efficacy of the product.

Failure to obtain regulatory approval for our products in markets other than the European Union and the United States and to retain approvals already granted will prevent us from marketing or licensing our products in these markets.

Sales of our products outside the European Union and the United States and any of our product candidates that will be commercialized are subject to the regulatory requirements of each country in which the products are sold. Accordingly, the introduction of our products and product candidates in markets outside the European Union and the United States will be subject to regulatory clearances in those jurisdictions. Approval and other regulatory requirements vary by jurisdiction and may differ from EU or U.S. requirements. We may be required to perform additional preclinical or clinical studies even if EMA or FDA approval has been obtained. Many countries also impose product standards, packaging and labeling requirements and import restrictions on our products. The approval by government authorities outside of the European Union and the United States is unpredictable and uncertain and can be expensive. Our ability to market our approved products could be substantially limited due to delays in receipt of, or failure to receive, the necessary approvals or clearances.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

In the United States and some other jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of ATIR products, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

Among policy makers and payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. For example, in the United States there is significant interest in promoting health care reform, as evidenced by the enactment in the United States of the 2010 Patient Protection and Affordable Care Act (the "**Affordable Care Act**"), and the companion Health Care and Education Reconciliation Act in 2010 (the "**Health Care Reform Law**"). The Health Care Reform Law increased federal oversight of private health insurance plans and included a number of provisions designed to reduce Medicare expenditures and the cost of health care generally, to reduce fraud and abuse, and to provide access to increased health coverage.

Another provision of the Health Care Reform Law, generally referred to as the Physician Payment Sunshine Act or Open Payments Program, has imposed new reporting and disclosure requirements for pharmaceutical and medical device manufacturers and distributors with certain FDA-approved products, such as approved vaccines, with regard to payments or other transfers of value made to certain U.S. health care practitioners, such as physicians and academic medical centers, and with regard to certain ownership interests held by physicians in reporting entities. The Centers for Medicare and Medicaid Services (the "**CMS**"), publishes information from these reports on a publicly available website, including amounts transferred and the physician and teaching hospital identities.

Under the Physician Payment Sunshine Act, we are required to collect and report detailed information regarding certain financial relationships we have with physicians and teaching hospitals. Our compliance with these rules may also impose additional costs.

Since its enactment there have been judicial and Congressional challenges to certain aspects of the Health Care Reform Law. As a result, there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the Affordable Care Act. In January 2017, the federal government began directing federal agencies with authorities and responsibilities under the Affordable Care Act to waive, defer, grant exemptions from, or delay the implementation of any provision of the Affordable Care Act that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Further, in May 2017, the U.S. House of Representatives passed legislation known as the American Health Care Act (the "**AHCA**"), which, if enacted, would amend or repeal significant portions of the Affordable Care Act. Prospects for legislative action on this bill are uncertain. While Congress has not passed repeal legislation, the Tax Cuts and Jobs Act of 2017 (the "**TCJA**") includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Additionally, on January 22, 2018, a continuing resolution on appropriations for fiscal year 2018 was signed that delayed the implementation of certain ACA-mandated fees, including the so-called ''Cadillac'' tax on certain high cost employer-

sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Congress may consider other legislation to repeal or replace elements of the Affordable Care Act. Although we cannot predict the ultimate content, timing or effect of any changes to the Affordable Care Act or other federal and state reform efforts, we continue to evaluate the effect that the Affordable Care Act, as amended or replaced, will have on our business. In the coming years, additional legislative and regulatory changes could be made to governmental health programs that could significantly impact pharmaceutical companies and the success of our product candidates.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. These changes included aggregate reductions to Medicare payments to providers of 2% per financial year effective April 1, 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2025, unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Also, the Drug Supply Chain Security Act imposes new obligations on manufacturers of pharmaceutical products related to product tracking and tracing. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and, accordingly, our financial operations.

We expect that the Affordable Care Act, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenues, attain profitability, or commercialize our drugs.

In some countries outside the United States, the proposed pricing for a drug must be approved before it may be lawfully marketed. In addition, in some markets, the pricing of prescription drugs is subject to government control and reimbursement which may in some cases be unavailable. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product, may refuse to reimburse a product at the price set by the manufacturer or may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for biopharmaceutical products will allow favorable reimbursement and pricing arrangements for ATIR101 or any of our other product candidates that may be approved. Historically, biopharmaceutical products launched in the European Union do not follow price structures of the United States and generally tend to have significantly lower prices.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for drugs. In addition, there have been several recent Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer

patient programs, reduce the cost of drugs under Medicare and reform government program reimbursement methodologies for drugs. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of ATIR101, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent drug labeling and post-marketing testing and other requirements.

1.4 Risks related to our operations

Manufacturing and supply of ATIR101 is complex and subject to numerous risks, any of which may affect our ability to continue clinical development of and commercialize ATIR101. Manufacturing issues may also negatively impact the outcome of our clinical trials.

The manufacturing process for ATIR101 is complex, involving collection of donor and patient T-cells, shipment to our manufacturing facility, manufacture of the donor T-cells into ATIR101, freezing of the manufactured ATIR101 and shipment of the finished product to the treatment site, and thawing of ATIR101 at the treatment site. As a result of the complexities, the cost to manufacture our cell product candidates is generally higher than traditional small molecule chemical compounds or monoclonal antibodies, and the manufacturing process is less reliable and is more difficult to reproduce. Any lack of capabilities to manufacture, ship, store, freeze, thaw or infuse ATIR101 would adversely affect enrollment of our ongoing Phase III clinical trial and our ability to commercialize ATIR101, if approved, and consequently, our business and prospects.

The manufacturing process for ATIR101 is susceptible to product loss or failure due to logistical issues associated with the collection of white blood cells, (or 'starting material'), from the patient, shipping such material to the manufacturing site, shipping the final product back to the patient, and infusing the patient with the product, manufacturing issues associated with the differences in patient starting materials, inability to release product within specifications, interruptions in the manufacturing process, contamination, defects in or lack of manufacturing equipment, including the PTD we use in our manufacturing process, improper installation or operation of equipment, vendor or operator error, inability to secure or termination of contract manufacturing agreements, inability to set up our own manufacturing operations, inability to transfer manufacturing process to new facilities, variability in product characteristics, failure to comply with current Good Manufacturing Practices ("**cGMP**"), and other applicable regulations and quality assurance guidelines, prohibition by regulatory authorities, withdrawal from the market and import stops. Even minor deviations from normal manufacturing processes, including those for which we do not have in-process controls or release assays, could result in reduced production yields, product defects, inability to release product, adverse effects in the patient, and other disruptions. If for any reason we lose a patient's starting material or later-developed product at any point in the process, the manufacturing process for that patient will need to be restarted which may not be possible and the resulting delay may adversely affect that patient's outcome. If microbial, viral, or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which may lead to loss of revenues as no safety stock can be available because our product candidates are manufactured for each particular patient. Also, for our patient-specific products, we will be required to maintain a chain of identity with respect to materials as they move from the patient and donor to the manufacturing facility, through the manufacturing process, and back to the patient. Maintaining such a chain of

identity is difficult and complex, and failure to do so could result in adverse patient outcomes, loss of product, or regulatory action including withdrawal of our products from the market.

Further, as product candidates are developed through preclinical to late stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. For example, in our ongoing Phase III CR-AIR 009 trial, we made certain modifications to the manufacturing processes that were used in the CR-AIR-007 Phase II trial and for the CR-GVH-001 Phase I trial, and we do not yet know nor can we predict whether such changes will have an impact on patient outcomes. Such changes carry the risk that they will not achieve their intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials on other future clinical trials.

In addition, a failure of our manufacturing operations may adversely affect the results of, or even our ability to conduct, our clinical trials. For example, our Phase II CR-AIR-004 trial was terminated early in 2012 because a high number of manufactured batches of ATIR101 did not meet specifications, with the risk of serious adverse impact on patient outcomes. We believe this was due to improper storage of donor cells prior to manufacturing and lack of product release assays, which we believe we have adequately resolved. If we encounter similar or other manufacturing issues in our current Phase III trial or any future trial we may need to suspend enrollment while we improve our processes, which may delay the completion of the trial and delay or even adversely affect our ability to obtain marketing approval of ATIR101.

We currently rely on one contract manufacturing organization to provide supplies of ATIR101 for clinical trials. We expect to increase manufacturing capacity by using existing or other CMOs and developing our own manufacturing facilities for clinical trials and commercial production of ATIR101. We have no experience operating a manufacturing facility, and we may not be successful in developing our own manufacturing facilities or capacity. If we cannot manufacture ATIR101 or any future product candidate in sufficient amounts at acceptable costs and on a timely basis, we may be unable to have the necessary materials for clinical trials or commercialization.

ATIR101 is currently being manufactured by one third-party CMO, where we expect to expand capacity in a second facility. In addition, we may use one or more additional CMOs, as well as to establish our own manufacturing capabilities and infrastructure, including at least one manufacturing facility for future commercial supply. For our Phase III trial, and any future trials we may conduct, we need to produce sufficient amounts of ATIR101. If ATIR101 is approved for marketing, we will need to produce ATIR101 in order to commercialize it and generate revenue. Our current manufacturing plans may not be sufficient to manufacture enough of ATIR101 for our Phase III trial or commercial supply. If we cannot establish sufficient supply through third-party CMOs or in our own facilities, our ability to conduct the ongoing and future clinical trials and our plans for commercialization would be materially adversely affected. In addition, submission of products and new development programs for regulatory approval, as well as our plans for commercialization, could be delayed. Our competitive position and our prospects for achieving profitability could be materially and adversely affected. Additionally, it is likely that ATIR101 will need to be made within an appropriate geographic location for the area in which the product will be utilized. Accordingly, we may establish multiple manufacturing facilities, which may lead to regulatory delays or prove to be costly as we attempt to establish, qualify and perform technology transfer to additional manufacturing facilities.

We rely on a limited number of outside suppliers for equipment and disposables required to manufacture our products. For some of these supplies, we rely and may in the future rely on sole source vendors or a limited number of vendors. With part of these suppliers, we do not have supply contracts and may not be able to obtain key materials and equipment to support clinical or commercial manufacturing on acceptable terms, on a timely basis, or at all. If we are unable to source adequate supplies from our current suppliers, we will need to find alternatives. If we are unable to obtain regulatory approval for use with ATIR101 for an acceptable alternative, we may not be able to produce the necessary quantity or quality of our product for clinical trials or commercial sales.

Further, in our manufacturing process, we rely on our photodynamic therapy device to deplete activated T-cells using light. The current devices have been in use for many years, can no longer be manufactured, and we have a limited stock of components to replace parts breaking down routinely. We have an ongoing project to replace the existing light emitting component in the devices with a new one, and to replace the entire device. We cannot guarantee that the new components or devices will be available on time and perform the same as the old components and devices. If we are unable to adequately replace our components or device on time, we may not be able to produce the necessary quantity or quality of our product for clinical trials or commercial sales. Any differences between the new and old equipment carry the risk that our product candidates perform differently and may affect the timeline and results of planned or other future clinical trials, may lead to the need for additional clinical trials, and may delay or even adversely affect our ability to obtain marketing approval of ATIR101.

We expect that development of our own manufacturing facility will provide us with enhanced control of material supply for both clinical trials and the commercial market. However, we have no experience as a company in developing a manufacturing facility and may never be successful in developing our own manufacturing facility or capability. The establishment of a cell-based therapy manufacturing facility is a complex endeavor requiring knowledgeable individuals who have successful previous experience in, among others, cleanroom designs, construction and operations. Cell-based therapy facilities, like other biological agent manufacturing facilities, require appropriate commissioning and validation activities. Additionally, each manufacturing process must be validated through the performance of process validation runs to guarantee that the facility, personnel, equipment, and process work as designed. Finally, there is timing risk associated with in-house product manufacture. There can be no guarantee that the project can be completed within the time or budget allocated and that we will receive the necessary regulatory approvals, including the various license and environmental permits required. Even if we are successful, our manufacturing capabilities could be affected by unsuccessful technology transfer, cost-overruns, unexpected delays, equipment failures or shortages, labor shortages, natural disasters, power failures, regulatory issues and other factors that could prevent us from realizing the intended benefits of our manufacturing strategy and have a material adverse effect on our business. Furthermore, we will need to hire additional personnel with an appropriate background and training to staff and operate the facility on a daily basis. There are a small number of individuals with relevant experience, and we will have to hire these individuals internationally and motivate them to relocate, and the competition for such individuals is high.

In addition, the manufacturing process for any products that we may develop is subject to EMA and FDA approval processes for the jurisdictions in which we or our future collaborators will seek marketing approval. We will need to work with manufacturing facilities that can meet all applicable EMA, FDA and other regulatory authority requirements on an ongoing basis. If the manufacturing process is changed during the course of product

development, the EMA, the FDA or other regulatory authorities could require us to repeat some or all previously conducted trials or conduct additional trials to obtain bridging data, which could delay or impede our ability to obtain marketing approval. If we or our CMOs are unable to reliably produce and release product candidates or products to specifications acceptable to the EMA, the FDA or other regulatory authorities, such as the FDA's cGMP standards compliance, we may not obtain or maintain the approvals we need to further develop, conduct clinical trials for, and commercialize such products in the relevant territories. Similarly, the FDA approval of ATIR101 could be delayed or denied if the intended manufacturing site fails to pass the required preapproval inspection. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our CMOs will be able to manufacture the approved product to specifications acceptable to the EMA, the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require clinical trials to obtain bridging data or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and growth prospects.

We may in the future acquire businesses or engage in other transactions that could disrupt our operations.

We may selectively consider acquisitions or other transactions to obtain rights to other businesses or assets. Our valuation of any businesses or assets we obtain may prove incorrect and we cannot assure that we will realize the financial and strategic goals that were contemplated at the time of any transaction. Our 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 we may assume known and unknown contingencies related to product liability, intellectual property, financial disclosures, accounting practices, internal controls or other liabilities. We may also have tax exposures or lose anticipated tax benefits as a result of acquisitions or integration of merged entities.

Following an acquisition, our ongoing business may be disrupted and our management attention may be diverted by transition or integration issues. We may have higher than anticipated costs in continuing research and development of acquired products. If we are unable to successfully integrate acquisitions into our existing business, our 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 our business, results of operations, financial condition and prospects.

Our activities rely heavily on sensitive and personal materials and information, an area which is highly regulated by privacy laws. If we are unable to generate or maintain access to essential patient samples or data for our research and development, manufacturing and commercialization activities for our patient-specific and other potential products, our business could be materially adversely affected.

As a result of our clinical development, we will have access to very sensitive data regarding the patients enrolled in our 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 us. For example, the rules

promulgated by the U.S. Department of Health and Human Services under the U.S. 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 authorizations from patients prior to disclosing protected healthcare information of the patient to companies such as ours. If the patient fails to execute an authorization or the authorization fails to contain all required provisions, then we will not be allowed access to the patient's information and our research efforts can be substantially delayed. Furthermore, use of protected health information that is provided to us pursuant to a valid patient authorization is subject to the limits set forth in the authorization (i.e., for use in research and in submissions to regulatory authorities for product approvals). As such, we are required to implement policies, procedures and reasonable and appropriate security measures that protect individually identifiable health information we receive from covered entities and to ensure that such information is used only as authorized by the patient. Any violations of these rules by us could subject us to civil and criminal penalties and adverse publicity and could harm our ability to initiate and complete clinical trials required to support regulatory applications for our products. In addition, HIPAA does not replace federal, state, or other laws that may grant individuals even greater privacy protections.

In the European Union, the General Data Protection Regulation ("**GDPR**") imposes strict legal requirements and establish a series of standards regarding the storage of personally identifiable information on computers or recorded on other electronic media. This has been implemented by all European Union member states through national laws. The GDPR specifically requires all non-European Union countries doing business with European Union member states to provide adequate data privacy protection when receiving personal data from persons in any of the European Union member states. In addition, the use and disclosure of personal health and other private information is subject to regulation in other jurisdictions in which we do business or expect to do business in the future. Those jurisdictions may attempt to apply such laws extraterritorially or through treaties or other arrangements with European governmental entities.

Patient-specific products like ATIR rely on the use of patient materials and data, and are thus subject to certain privacy and security regulations. We have very limited experience with privacy and security policies, practices and regulations, and cannot assure you that our policies and practices will be sufficient to protect us from liability or adverse publicity relating to the privacy and security of personal information. We cannot assure you that current or future legislation will not prevent us from generating or maintaining personal data or that patients will consent to the use of their personal information; either of these circumstances may prevent us from undertaking or publishing essential research and development, manufacturing and commercialization, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

Our internal computer systems, or those used by our clinical investigators, contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or

inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

If our facilities become inoperable, or if we are unable to renew our existing (sub)lease agreements, we may be unable to perform our manufacturing, development or commercial activities and our business, financial condition, results of operations and prospects may be harmed.

We perform certain of our 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. Our sublease in Amsterdam for our manufacturing facility and office space has a 10-year term that is automatically extended thereafter for four years (until December 31, 2031) and thereafter for five years (until December 31, 2036), unless terminated at the end of a lease period with one year's notice, and our lease for additional office space has a 10-year term (until May 31, 2029) that is automatically extended for five year terms, unless terminated by us at the end of a lease period with one year's notice. Our lease in Amsterdam for our 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 we will be able to renew our current lease and sublease agreements in the existing locations on acceptable terms upon the lapse of the current terms or extended subsequent terms. If we are unable to perform or transfer our development and/or our manufacturing activities, we may suffer delays to our development programs and commercialization activities, and lead to significant loss if income, suspension or withdrawal of our products from the market, harm to our reputation. We could also incur significant costs to repair damage to or find new facilities and the equipment we use to perform our development and/or our manufacturing activities. Our insurance coverage for damage to our property and the disruption of our business may not be sufficient to cover all of our potential losses, including the loss of time as well as the costs of lost opportunities, and may not continue to be available to us on acceptable terms, or at all.

Regulations apply to, and claims could arise relating to, improper handling, storage or disposal of hazardous chemical or biological materials and gamma irradiation or other equipment. Complying with such regulations and/or defending against such claims could be time consuming and expensive.

Our research and development and manufacturing involves the controlled use of hazardous materials, including chemical and biological materials, and equipment, such as gamma irradiation and other equipment, chemical solvents and human cells. Our operations also generate hazardous waste products. We 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. We may be sued for any injury or contamination that results from our use or the use by third parties of these materials. Compliance with environmental laws and regulations may be expensive. Our facilities, the facilities of our CMOs and the other facilities that we source donor materials from may not comply with those regulations without significant investments, or at all. Current or future environmental regulations may impair our research, development and production efforts, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

Due to our limited resources and access to capital, we must prioritize development of certain product candidates and our decision to pursue these product candidates may

prove to be unsuccessful as they may never receive regulatory approval or achieve profitability.

Because we have limited resources and access to capital to fund our operations, our management must make significant prioritization decisions on which product candidates to pursue and the amount of resources to allocate to each product. Our current development activities are focused primarily on the development, manufacturing and commercialization of ATIR101. These, and future decisions concerning the allocation of capabilities, infrastructure, management and financial resources towards particular product candidates 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 us to miss valuable opportunities. If we make incorrect determinations regarding the market potential of our products or misreads trends in the biotechnology industry for cancer or noncancer therapies, our business, financial condition, results of operations and prospects could be materially adversely affected.

We are a party to certain agreements that contain liability or indemnification provisions under which we may claim damages from our counterparties and under which our counterparties may claim damages from us, including damages caused by product defects.

We are a party to certain agreements that contain liability or indemnification provisions under which we or the counterparty may claim damages. In the event we need to claim damages from a counterparty, we may not receive payments covering our 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 we try to limit our liability, such limitations may not be enforceable in certain jurisdictions or effective in the event that we need to pay damages and we nevertheless could become liable to make substantial payments. If we must make substantial liability payments under an agreement, this could have a material adverse effect on our business, results of operations, financial condition and prospects.

1.5 Risks related to the commercialization of our product candidates

We may fail to capitalize on other potential product candidates that may represent a greater commercial opportunity or for which there is a greater likelihood of success.

The success of our business depends upon our ability to develop and commercialize ATIR101 and our other product candidates that we may pursue. Because we have limited resources, we may forego or delay pursuit of opportunities with certain programs or product candidates or for indications that later prove to have greater commercial potential than ATIR101 or other product candidates that we may pursue. Our spending on current and future research and development programs may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaborations, licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Alternatively, we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement. If any of these events occur, we may be forced to abandon our development efforts with respect to a particular product candidate or fail to develop a

potentially successful product candidate. The market opportunities for our products may be smaller than currently anticipated, lowering our potential revenue.

We make projections of both the number of people who have the cancers and the other indications that we are targeting, as well as the number of individuals within our 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 we currently anticipate which would result in lower potential revenue for us.

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

We incur and will incur substantial research and development and manufacturing costs before we can confirm the scientific validity or commercial viability of a product. Even if the EMA, the FDA or any other regulatory authority approves the marketing of ATIR101, or any other products that we may develop, physicians, healthcare providers, patients, the medical community or payers 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 profiles of competing products and protocols;
- our ability to provide acceptable evidence of safety and efficacy;
- relative convenience and ease of collection, shipment and administration of materials, especially as required for patient-specific products;
- relative convenience and ease of our interactions with and service to physicians, healthcare providers and payers, especially as required for patient-specific products;
- cost-effectiveness;
- availability of coverage, reimbursement and adequate payment from health maintenance organizations and other insurers, both public and private;
- prevalence and severity of adverse side effects; and
- other potential advantages or disadvantages as compared to alternative treatment methods.

If ATIR101 or any other products that we may develop fails to achieve market acceptance, we may not be able to generate sufficient revenues.

In addition, we target specific indications with discrete patient populations. We will be allowed to market the product for only those indications that were approved by the EMA, the FDA and other regulatory authorities, because promoting the product for unapproved uses could subject us to substantial civil and criminal penalties. Furthermore, we may need to

ensure and demonstrate that ATIR101 or other products that we develop are suitable for approved indications to gain more widespread acceptance. We therefore may have to achieve significant market penetration in each target market for which the product is approved and obtain relatively high prices for our products to achieve profitability. We may make substantial investments in clinical development, manufacturing, supply chain and commercialization without any assurance that we will be able to attain significant market share at a price that would enable us to recover our investments. If we are unable to do so, our business, financial condition, results of operations and prospects would be materially adversely affected.

We operate in a highly competitive and rapidly changing industry. If we are unable to compete effectively, our business, financial condition, results of operations and prospects could be materially adversely affected.

We operate in the highly competitive pharmaceutical and biotechnology industries. We seek to develop and market products that, if approved, will compete with drugs, medical devices and other therapies that currently exist or are being developed. We 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. Our competitors or physicians have developed or may be developing alternative products or protocols for cancer and other indications into which we may expand, such as inborn diseases of the blood building system. Our competitors may have substantially greater financial, technological, manufacturing, marketing, managerial, regulatory and research and development resources and experience. Our competitors or physicians may also:

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

The pharmaceutical and biotechnology industries and clinical practice are characterized by rapid change and we expect competition to intensify as scientific, clinical or technical advances are made. These advances may render our products obsolete or noncompetitive. The emergence of a new standard of care in target markets may also result in our products becoming obsolete. Should any of these factors occur, our 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 our products and adversely affect our business, financial condition, results of operations and prospects.

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

We may encounter difficulties in managing our growth and expanding our operations successfully.

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

Governments and/or pricing authorities, especially in the European Union, often impose strict price and access controls, which may adversely affect our future profitability.

In some markets, especially in the European Union, prescription drug pricing is subject to governmental/pricing authority control which can vary by country and degree. In these countries, pricing negotiations with governmental/pricing authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct pharmacoeconomic studies/prepare economic models that compare the cost-effectiveness of our product to other available therapies and that may be best supported by ongoing Phase III clinical studies rather than the already available Phase II clinical data. For example, the Institute for Quality and Efficiency in Healthcare in Germany, the Commission Évaluation Économique et de Santé Publique in France and the National Institute for Health and Care Excellence in the United Kingdom evaluate the health economics data supporting new medicines and deliver reimbursement recommendations based on a product's clinical and cost effectiveness. In some jurisdictions, the application of pricing and reimbursement criteria used to assess traditional medicinal products may not be appropriate to evaluate our products. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels or the pricing negotiation is considerably delayed, we may be unable to achieve or sustain profitability.

Governments/pricing authorities in some of the member states of the European Union are developing strategies regarding joint negotiations in relation to pricing and reimbursement conditions.

We expect future pricing/access negotiations in the European Union to be based upon potential improvements with ATIR101 over the Baltimore protocol, for which we believe analysis of the Phase III data can provide the requisite input. Until the Phase III data is available, we will pursue pricing and reimbursement with select hospitals, payers and reimbursement agencies on the basis of more limited Phase II data, the outcome of which is uncertain.

If we fail to obtain adequate coverage and reimbursement from insurers, both public and private, commercially viable markets for our products may not develop or may be smaller than expected.

The commercial success of our 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 European Union and other markets, our 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 our products and pricing as attractive and/or cost-effective, reimbursement may not be available to patients or may be insufficient to allow our products to be marketed on a competitive basis. In the United States, Medicare, Medicaid, health maintenance organizations 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 our products. 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 our products. Any of these factors could impair the development of a commercial market for our products and our business, financial condition, results of operations and prospects could be materially adversely affected.

If any product liability lawsuits are successfully brought against us or any of our collaboration partners, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability lawsuits related to the testing of our product candidates in seriously ill patients and will face an even greater risk if our product candidates are approved by regulatory authorities and introduced commercially. Product liability claims may be brought against us or our partners by participants enrolled in our clinical trials, patients, health care providers or others using, administering or selling any of our future approved products. If we cannot successfully defend ourselves against any such claims, we may incur substantial liabilities.

If any of our product candidates are approved for commercial sale, we will be highly dependent upon consumer perceptions of us and the safety and quality of our products. We could be adversely affected if we are subject to negative publicity associated with illness or other adverse effects resulting from patients' use or misuse of our products or any similar products distributed by other companies.

Any product liability insurance coverage we obtain may not fully cover potential liabilities that we may incur. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. We will need to increase our insurance coverage if we commercialize any product that receives marketing approval. In addition, insurance coverage is becoming increasingly expensive. If we are unable to maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, it could prevent or inhibit the development and commercial production and

sale of our product candidates, which could harm our business, financial condition, results of operations and prospects.

If we are unable to establish commercial capabilities or enter into agreements with third parties to market, sell and distribute our product candidates, we may be unable to generate any revenues.

If ATIR101 receives marketing approval, we intend to market, sell and distribute it using our own commercial infrastructure. However, we have no experience marketing, selling and distributing pharmaceutical products or establishing a commercial organization. Marketing, selling and distributing patient-specific product candidates has not previously been done by many other pharmaceutical companies. In addition, there are few individuals with this experience available. We may enter into collaborations with other entities to utilize their mature sales, marketing and distribution capabilities, but we may be unable to enter into marketing agreements on favorable terms, if at all. If our future collaborative partners do not commit sufficient resources to commercialize our future products, if any, or if we are unable to develop the necessary commercialization capabilities on our own, we will be unable to generate sufficient product revenues to sustain our business. In building our commercial infrastructure or commercializing our products, we will be competing with other well-funded companies that currently have or are building extensive commercial operations. Without an internal team or the support of a third party to perform commercial functions, we may be unable to successfully commercialize our products and/or compete successfully against these companies.

We have limited information available regarding the ultimate cost of supplying our products, and cannot estimate what the cost of our products will be upon commercialization, should that occur.

We do not yet have sufficient information to reliably estimate the cost of the commercial manufacture and supply of our product candidates, and the actual cost to manufacture and supply our product candidates could materially and adversely affect the commercial viability of our product candidates. As a result, we may never be able to develop a commercially viable product. Because of the patient-specific nature of our manufacturing and supply process, it is not amenable to the economics of scale from traditional "scale up" to manufacture of larger lots as for traditional drugs and biological agents.

1.6 Risks related to the Transaction

The Transaction subjects us and investors in our Shares to potential significant risks

On April 17, 2019, we announced that Kiadis Pharma N.V., its wholly owned subsidiary CST Acquisition Corp. ("**CST**"), CytoSen and Philip R. McKee as representative of the CytoSen shareholders have entered into a binding agreement (the "**CytoSen Acquisition Agreement**") regarding the acquisition by us of the entire share capital of CytoSen, subject to the approval of Kiadis Pharma's general meeting of shareholders (the "**General Meeting**") - which approval has been granted on May 29, 2019 - and other customary closing conditions (the "**Transaction**"). See paragraph 7.3 for further information on CytoSen and the Transaction.

Shareholders should, among other risks, consider the following risk that could materialize after completion of the Transaction:

- CytoSen is an early stage biotech company, and is subject to the various and substantial risks that such companies are exposed to, such as dependency on external funding, a history of losses with no assurance on future profitability, uncertainty on whether regulatory approvals will be obtained, reliance on third parties, the risk of products not gaining market acceptance or being less effective or affordable than those of competitors and risks relating to intellectual property. Effectively, CytoSen has similar risks to the various risks that we face as set out in this Chapter 1 (Risk Factors). In addition, CSTD002 is at a much earlier stage of development than ATIR101. We will need to engage in substantially more early stage research and development and will need to find and fund the additional expertise required.

- Our due diligence reviews may have failed to identify risks or problems, such as issues with CytoSen's product quality, intellectual property position, unlicensed use of third-party intellectual property rights, chemistry/manufacturing/control (CMC), regulatory status of its cell therapy products, competitive position and collaboration agreements and relationships with key partners and collaborators such as the Blood and Marrow Transplant Clinical Trials Network, key opinion leaders and HSCT clinics.

- CytoSen is loss-making and does not generate any revenues, is not expected to generate revenues in the near to midterm future and may never do. Operating its business and progressing its lead product will require significant funds. Consequently, the Transaction will substantially increase our funding needs. Failure to raise capital when needed would adversely affect our business, financial condition, results of operations or prospects and could reduce the price of our Shares.

- Our valuation of CytoSen and its business or assets may prove incorrect, including as a result of not being able to successfully develop CytoSen's product candidates or utilize its technologies or otherwise. We cannot assure that we will realize the financial and strategic goals that were contemplated at the time of the Transaction.

- CytoSen's financial information is unaudited and may prove to contain errors and inaccuracies we did not detect and which may impact on the value of its assets and liabilities. The Unaudited Pro Forma Consolidated Financial Information set out in Chapter 5 was prepared using CytoSen's unaudited financial information and may not correctly reflect the combination of our businesses. In preparing the Unaudited Pro Forma Consolidated Financial Information, the only material difference between US GAAP and IFRS that we identified was in respect of accounting for CytoSen's option grants. We may not have identified other material differences.

- We may fail to realize some or all of the anticipated synergies, growth opportunities and other benefits of the Transaction, which could adversely affect the value of our Shares.

- We may fail to retain the services of CytoSen's management and key personnel, and to attract and retain skilled personnel, on which achieving our development and other business objectives in relation to CytoSen is dependent.

- The achievement of the anticipated benefits of the Transaction is subject to a number of uncertainties, including whether we are able to integrate the CytoSen businesses in an efficient and effective manner, and general competitive factors in the market place. It is possible that the process of integrating the operations of CytoSen in our

existing business takes longer or is more costly than anticipated or could result in the loss of key employees, the disruption of our businesses or inconsistencies in standards, controls, procedures and policies. Such adverse impacts could impair our ability to maintain relationships with universities, clinics, authorities, patients and employees, to achieve the anticipated benefits of the Transaction or to maintain quality standards.

- The acquisition of CytoSen may result in significant write-offs and we may assume known and unknown contingencies related to product liability, intellectual property, financial disclosures, accounting practices, internal controls or other liabilities

- We may have tax exposures or lose anticipated tax benefits as a result of the Transaction or the integration of CytoSen.

- Following the acquisition of CytoSen, our ongoing business may be disrupted and our management's attention may be diverted by transition or integration issues.

- We may have higher than anticipated costs in continuing research and development of acquired products.

- The market price of our Shares could decline because of the CytoSen shareholders disposing of the Shares that they shall acquire upon completion of the Transaction and future milestones being achieved, and upon the lapse of the lock-up restrictions that CytoSen shareholders are subjected to as per the CytoSen Acquisition Agreement.

1.7 Risks related to our reliance on third parties and key personnel

We rely on third parties who license intellectual property rights to us, including intellectual property relating to our proprietary device. If any such license is terminated, we may be unable to commercialize and market our product candidates, including the ATIR products.

We are reliant upon licenses to certain patent rights and proprietary technology from third parties that are important or necessary to the development of our technology and product candidates. Our current license agreements impose, and we expect that future license agreements will impose, various diligence, development, commercialization, payment and other obligations. For example, we have an exclusive license for the exploitation of intellectual property rights relating to our proprietary device granted by the University of Montreal and Maisonneuve-Rosemont Hospital (see paragraphs 6.1, 6.8 and 7.11). Under this license agreement, we are required to, among other things, develop, obtain regulatory approval of, seek intellectual property protection for and commercialize products based on our proprietary device technology. Our ability to comply with these requirements and requirements under our other current or future license agreements 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 our product candidates, including ATIR product candidates. In spite of our efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products and technology covered by these license agreements. If the licensors were to terminate the license, we would be prevented from continuing our use of the licensed technology and competitors and other third parties would have the freedom to seek regulatory approval of, and to market, products identical to ours. The loss of rights

under our license from University of Montreal and Maisonneuve-Rosemont Hospital could preclude us from further developing and commercializing ATIR101 and other product candidates that we may pursue, which would have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Moreover, disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including those relating to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on, misappropriate or otherwise violate intellectual property of the licensor that is not subject to the license agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- whether we are complying with our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates; and/or
- the allocation of ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and by us and our collaboration partners.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, including ATIR101. Any of the foregoing may have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be unable to enter into or maintain strategic alliances or collaborations which could affect our possibilities to commercialize our products.

We may seek strategic alliances or collaborations to further the clinical development and commercialization of certain of our product candidates, such as ATIR101, as they would likely require expensive and time consuming clinical trials. In seeking strategic partners, we face significant competition from other companies as well as public and private research institutions. There can be no assurance that we will be able to enter into strategic alliances on terms favorable to us, 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 adverse to us. Potential partners may fail to diligently fund, develop or commercialize our products.

Although we intend to establish our own manufacturing facility, we expect to rely on third-party support to manufacture certain of our products and technologies for the foreseeable future. Therefore, if we are unable to enter into or maintain our arrangements with third-party manufacturers under favorable terms, our ability to develop our products or generate sufficient product revenues could be harmed.

Historically, we have outsourced the manufacturing of ATIR and the photosensitizing reagent TH9402 compound to CMOs. Although we have recently entered into a lease agreement for commercial manufacturing space in the Netherlands for ATIR101, until that facility is fully functional, CMOs remain essential to our current manufacturing processes. We are currently establishing additional capacity for ATIR for purposes of the Phase III trial and commercialization with ATIR101. However, we do not yet have any long term supply agreements in place for TH9402 compounds or ATIR and there can be no assurance that we will enter into such arrangements on a timely basis, on satisfactory terms or at all. In addition, our reliance on a small number of suppliers, CMOs and contract testing laboratories limits our control over quality assurance, quality control, transport and delivery schedules and we cannot assure that any third parties will perform to our standards.

If we were to experience an unexpected loss of supply of, or if any CMO or supplier were unable to meet our demand for, any of our products, we could experience delays in our research and development activities, planned clinical studies or commercialization of approved products. We could be unable to find alternative CMOs or suppliers of acceptable quality who can deliver appropriate volumes at acceptable cost. Moreover, our 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 our clinical studies and the commercialization of our products. In addition, we may not be able to successfully transfer manufacturing from one CMO to another CMO or to in-house production.

We also need to work with CMOs and suppliers that are licensed by regulatory authorities of European Union Member States, the FDA and other authorities and must comply with regulations of such authorities, requiring us and/or our 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 we may also be subject to audits by the appropriate regulatory authorities. If any of our CMOs or suppliers fails to comply with applicable GMP or other applicable regulations, our ability to develop and commercialize our products or product candidates could suffer significant interruptions.

We face risks inherent in relying on a limited number of CMOs as any disruption, such as a contamination, infection, failure to comply with regulations, strikes, fire, natural hazards or vandalism at a CMO could significantly interrupt our manufacturing capability. Business interruption insurance may not adequately compensate us for any losses that may occur and we would have to bear the additional cost of any disruption.

If we achieve regulatory approval for any of our product candidates, we, our CMOs or suppliers may not be able to increase production to suitable commercial levels. Any failure to achieve and maintain high quality manufacturing standards and fulfill 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 our clinical trials may be deemed unreliable and the EMA, the FDA or

other comparable other regulatory authorities may require us to extend, repeat or perform additional clinical trials which would delay the regulatory approval process. We 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 our ability to manage production, cause delays in shipments and cancellation of orders and product availability to patients, which may adversely affect our relationships with future customers and potentially allow competitors or other protocols to take over our market. In addition, CMOs, suppliers and contract testing laboratories may prioritize capacity for others or increase prices charged to us, which could harm our ability to generate sufficient product revenues.

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

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

We rely on CROs clinical data management organizations, consultants and other service firms to design, conduct, supervise and monitor clinical studies. We and these third parties are required to comply with various regulations, including good clinical practices ("**GCP**"), which are enforced by the guidelines of the competent authorities of the member states of the European Economic Area ("**EEA**"), the FDA and comparable other 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. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. If we or any of these third parties fail to comply with applicable requirements, the clinical data generated in our clinical trials may be deemed unreliable and the EMA, the FDA or other comparable other regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with such requirements. In addition, our clinical trials must be conducted with products that are GMP produced. Failure to comply with these regulations may require us to repeat preclinical and clinical trials, which would delay the regulatory approval process.

Third-party staff are not our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and preclinical programs and meet their quality and other requirements. 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 product or clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our operations and the commercial prospects for our product candidates in development would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Because we have relied on third parties, our internal capacity to perform these functions is limited. Outsourcing these functions involves risk that third parties may not perform to our 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 us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third-party providers. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our business may be adversely affected. Though we carefully manage the relationships with third parties, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition, results of operation and prospects.

If we 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 preclinical studies or clinical trials or meet expected deadlines, our clinical development programs could be delayed and otherwise adversely affected. Any such event could have a material adverse effect on our business, financial condition, results of operations and prospects.

The failure to attract and retain senior management, members of our management board and skilled personnel could impair our development and commercialization efforts.

We are highly dependent on the members of the Company's management board (*raad van bestuur*) (the "**Management Board**"), consisting of Mr. Arthur Lahr and Mr. Scott Holmes, our senior management that supports the Management Board in the day-to-day management of Kiadis, Dr. Robert Friesen, Mr. James Joy, Mr. Dirk De Naeyer, Ms. Martine Nolan, Dr. Andrew Sandler, Mr. Mark Schaefer, Ms. Amy Sullivan, Mr. Jonathan Sweeting and Mr. Marcel Zwaal (the "**Management Team**"), and various key scientific and technical personnel, being our Vice President Science and Development, our Director Process Development & Technology, our Program Manager, our Director Analytics & Validation, our Director Pharmacovigilance & Safety, our Director of Regulatory Affairs and Clinical Science, our Director Immunology and our Senior Director Engineering and a number of key consultants. The loss of the services of any member of the Management Board, the Management Team or key scientific or technical staff or consultants may significantly delay or prevent us from achieving our development and other business objectives and could have a material adverse effect on our business, financial condition, results of operations and prospects. If we do not have sufficient numbers of skilled employees to support our research, development, manufacturing, commercialization, regulatory compliance or management functions, or if our employees lack the skills necessary for the development of our operations, we may be dependent on consultants and advisers, if available on terms acceptable to us, if at all, who may have conflicts of interest or other commitments, such as consulting or advisory contracts with other organizations that may affect their ability to contribute to us. If we are unable to attract and retain sufficient scientific, technical and managerial personnel, we will be unable to advance our clinical programs, commercialize any approved products or expand our business, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

1.8 Risks related to our intellectual property

If we are unable to obtain and maintain patent or trade secret protection for any products we develop and for our technology, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize any product candidates or technology we may develop may be adversely affected.

Our commercial success depends in part on obtaining and maintaining trade secrets or confidential know-how and current and future patent protection for our technology, product candidates, the methods used to manufacture those product candidates and the methods for treating patients using those product candidates. Failure to protect trade secrets or confidential know-how or to obtain, maintain or extend patent protection could materially adversely affect our ability to compete. In addition, certain of our issued patents relevant for ATIR or other aspects of our technology have already expired, and others will expire in the coming years. For example, certain of our U.S. and non-U.S. patents related to ATIR101 are projected to expire in 2020 and 2021. For further information on these patents, see paragraph 7.12 below. If we or our licensors are unable to obtain or maintain patent protection with respect to our proprietary products and technology, or if our trade secrets and any regulatory exclusivity we may obtain related to ATIR101 are not sufficient to prevent third parties from developing competing products, our business, financial condition, results of operations and prospects could be materially harmed.

The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patents and patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. In addition, we may not be aware of all third party intellectual property rights potentially relating to our product candidates and technology. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our owned or any licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly trade secrets and patents. Obtaining and enforcing patents in the pharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain.

We own or license pending patent applications. There is a risk that these and our future patent applications 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.* ("**Mayo**"). 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 U.S. Supreme 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.

In addition, even if our current or future patent applications are issued as patents, they may not be issued with the scope of claims sought by us, or the scope of claims we or our licensors are seeking may not be sufficiently broad to protect our product candidates or provide us with any competitive advantage. Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. If our patents expire or if a challenge to an existing patent is successful, there could be a material adverse effect on our business, financial condition, results of operations and prospects.

Our competitors and other third parties would be able to offer and sell products based on our compounds so long as they do not infringe any valid and enforceable patents or other proprietary rights that we or others, including our licensors, may have. The specific content of patents and patent applications that are necessary to support and interpret the scope of patent claims is highly uncertain due to the complex nature of the relevant legal, technical and factual issues. Such risks for us will increase if we or our licensors are not able to obtain additional patents protecting aspects of our ATIR product candidates and technology, 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 we have rights were to result in issued patents, they could also be subject to re-examination or opposition proceedings or judicial determination of invalidity.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our patents may be challenged in the courts or patent offices in the United States and elsewhere. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. In addition, given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

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

We consider proprietary trade secrets and confidential know-how and unpatented know-how to be important to our business. We rely on trade secrets and confidential know-how to protect our technology, especially where we do not believe that patent protection is appropriate or obtainable. However, trade secrets and confidential know-how are difficult to protect and some courts inside and outside the United States are less willing or unwilling to protect trade secrets. We seek to protect our proprietary trade secrets and confidential know-how, in part, by entering into confidentiality agreements with our current or former employees, consultants, contractors, outside scientific collaborators and other advisers. However, we cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or confidential know-how. Our current or former employees, consultants, contractors, outside scientific collaborators and other advisers may have access to and unintentionally or willfully disclose our confidential information, including to competitors. Our confidentiality agreements may be breached by such individuals and we may not have adequate remedies for any breach. Enforcing a claim that a third party obtained 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 our competitive business position. Moreover, our competitors and other third parties 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, our competitors could limit how we use our trade secrets and confidential know-how, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

The duration and scope of our patents may not be sufficient to effectively protect our 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. Similarly, if all maintenance fees are timely paid, a patent in the United States generally expires 20 years after its effective filing date.

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 authorization 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. 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.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop in the United States, our patents may qualify for a limited patent term extension 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) under the U.S. Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. Specifically, the Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request.

Even if additional patents covering our product candidates are obtained, the expiration of a patent may leave us more vulnerable to competition from biosimilar or generic alternatives. Certain of our issued patents relevant for ATIR or other aspects of our technology have already expired, and others will expire in the coming years. For example, certain of our U.S. and non-U.S. patents related to ATIR101 are projected to expire in 2020 and 2021. For further information on these patents, see paragraph 7.12 below. If we are unable to obtain patent term extension or if the term of any such extension is less than we request, or if our trade secrets and any regulatory exclusivity we may obtain related to ATIR101 are not sufficient to prevent third-party competition, third parties may obtain approval of competing

products, and our business, financial condition, results of operations and prospects could be materially harmed.

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

Our patent protection in respect of our product candidates and technology may be limited or lost if our issued patents were to be declared invalid, rendered unenforceable or narrowed in scope as a result of any re-examination, post grant review, *inter partes* review, interference proceedings, derivation proceedings, equivalent proceedings in other jurisdictions or judicial action. If one of our licensing partners or we initiate legal proceedings against a third party to enforce a patent covering one of our product candidates or technology, the defendant could counterclaim that the patent covering our product candidate is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, lack of patentable subject matter, lack of written description or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld information material to patentability from the European Patent Office or the U.S. Patent and Trademark Office ("**USPTO**"), or made a misleading statement, during prosecution. A challenge to our existing patents or future patents, if issued, could result in a ruling adverse to us that could invalidate or render unenforceable 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 European Patent Office, the USPTO, or another issuing body, the corresponding patent application did not meet the statutory requirements. If a competitor or other third parties were to successfully challenge our patents, and claims in these patents were consequently narrowed, rendered unenforceable or invalidated, our ability to protect the related product candidate or technology from competition could be compromised. Such proceedings could result in the revocation or cancellation of or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which the patent examiner and we or our licensing partners were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we could lose at least part, and perhaps all, of the patent protection on one or more of our product candidates. Such a loss of patent protection could have a material adverse impact on our business.

We may not be able to protect or enforce our intellectual property rights in all jurisdictions.

Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and the laws of other countries may not protect our rights to the same extent as the laws of the Netherlands or the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the Netherlands or the United States, or from selling or importing products made using our inventions in and into the Netherlands or the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may export otherwise infringing products to territories where we have patent protection but where enforcement is not as well developed as in the European Union or the United States. These products may compete with our products in jurisdictions where we do not have any issued patents.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. Patent laws vary by jurisdiction, and, accordingly, the degree of protection afforded to the same technology, if any, may differ depending on the jurisdiction. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and could provoke third parties to asset claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Our inability to protect or enforce our intellectual property rights throughout the world could have a material adverse effect on our business, prospects, financial condition, results of operations and prospects.

In addition, many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties and many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

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 our intellectual property or narrow the scope of our patent protection and could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents.

Recent patent reform legislation in the United States, including the Leahy-Smith America Invents Act (the "**America Invents Act**"), could increase those uncertainties and costs. The America Invents Act was signed into law on September 16, 2011, and many of the substantive changes became effective on March 16, 2013. The America Invents Act reforms United States patent law in part by changing the U.S. patent system from a "first to invent" system to a "first inventor to file" system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. In addition, the America Invents Act expands the definition of prior art and develops a post-grant review system. This legislation changed United States patent law in a way that may weaken our ability to obtain patent protection in the United States for those applications filed after March 16, 2013.

Further, the America Invents Act created new procedures to challenge the validity of issued patents in the United States, including post-grant review, *inter partes* review, and derivation proceedings, which some third parties have been using to cause the cancellation of selected or all claims of issued patents of competitors. For a patent with an effective filing date of

March 16, 2013 or later, a petition for post-grant review can be filed by a third party in a nine month window from issuance of the patent. A petition for *inter partes* review can be filed immediately following the issuance of a patent if the patent has an effective filing date prior to March 16, 2013. With respect to a patent with an effective filing date of March 16, 2013, a petition for *inter partes* review can be filed after the later of (i) nine months from the issuance of the patent and (ii) if a post-grant review is instituted, after the termination of such post-grant proceeding. Post-grant review proceedings can be brought on most grounds of invalidity, whereas *inter partes* review proceedings can only raise an invalidity challenge based on published prior art and patents. These adversarial actions at the USPTO review patent claims without the presumption of validity afforded to U.S. patents in lawsuits in U.S. federal courts, and use a lower burden of proof than used in litigation in U.S. federal courts. Therefore, it is generally considered easier for a competitor or third party to have a U.S. patent invalidated in a USPTO post-grant review or *inter partes* review proceeding than invalidated in a litigation in a U.S. federal court. If any of our patents are challenged by a third party in such a USPTO proceeding, there is no guarantee that we or our licensors or collaborators will be successful in defending the patent, which would result in a loss of the challenged patent right to us.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent court rulings in cases such as *Association for Molecular Pathology v. Myriad Genetics, Inc., BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litigation, Promega Corp. v. Life Technologies Corp. and Abbvie Deutschland GmbH v. Janssen Biotech, Inc.* have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on future actions by the U.S. Congress, the U.S. courts, and the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Any changes to patent law in the U.S. or other jurisdictions that impairs our ability to protect our ATIR technology and other product candidates that we may pursue could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

We consider proprietary trade secrets and confidential know-how and unpatented know-how to be important to our business. We rely on trade secrets and confidential know-how to protect our technology, especially where we do not believe that patent protection is appropriate or obtainable. However, trade secrets and confidential know-how are difficult to protect and some courts in the United States and elsewhere are less willing or unwilling to protect trade secrets. We seek to protect our proprietary trade secrets and confidential know-how, in part, by entering into confidentiality agreements with our current or former employees, consultants, contractors, outside scientific collaborators and other advisers. However, we cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or confidential know-how. Our current or former employees, consultants, contractors, outside scientific collaborators and other advisers may have access to and unintentionally or willfully disclose our confidential information, including to competitors. Our confidentiality agreements may be breached by such individuals and we may not have adequate remedies for any breach. 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 our competitive business position. Moreover, our competitors and other third parties 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, our competitors could limit how we use our trade secrets and confidential know-how, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

If we or our licensors infringe, misappropriate or otherwise violate intellectual property rights of third parties, we may face increased costs or we may be unable to commercialize our products.

Our commercial success depends upon our ability to develop, manufacture, market, sell and distribute our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the proprietary rights and intellectual property of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights. There is a risk that third parties may allege that we or the licensors 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 our research is conducted. Because patent applications take several years to complete, there may be currently pending applications, unknown to us, which may later result in issued patents that cover the production, manufacture, commercialization or use of our product candidates and technology. In addition, the production, manufacture, commercialization or use of our products may infringe existing patents of which we are not aware. Even if we believe such claims of infringement are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could materially and adversely affect our ability to commercialize our product candidates and technology. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

If we are found to infringe a third party's valid and enforceable intellectual property rights, we could be required to:

- cease developing, manufacturing selling or licensing the infringing product candidates or technology;

- obtain a license from such third party to continue developing, manufacturing and marketing our product candidates and technology, which may not available on commercially reasonable terms or at all and even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments or grant a cross license to our patents to another patent holder;

- pay substantial damages for past infringement, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right; 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.

Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies. Although we try to ensure that our employees, consultants, and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Intellectual property litigation or proceedings could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Competitors may infringe our patents or the patents of our licensing partners. However, we may not have the resources to reliably detect infringements of intellectual property rights, and even if we detect an infringement we may not be able to trace the source of the infringement, or uphold our rights. We may need to resort to litigation to enforce our intellectual property rights, including any patents issued to us or our licensors. If a competitor or other third party files a patent application claiming technology also invented by us, in order to protect our rights, we may have to participate in an expensive and time-consuming opposition proceeding before the European Patent Office, the USPTO or patent authorities or courts in other jurisdictions, with an uncertain outcome and which may have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, we may be required to defend against claims of infringement or challenges to our intellectual property. To counter infringement or unauthorized use claims or to defend against such claims and challenges can be expensive and time consuming. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will be due to be paid to the European Patent Office, the USPTO and various other government patent agencies over the lifetime of our licensed patents and/or applications and any patent rights we may own in the future. The European Patent Office, the USPTO and various other government patent agencies also require compliance with several procedural fee payments and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market and this circumstance could have a material adverse effect on our business.

We may not be successful in obtaining necessary rights to any product candidates we may develop through acquisitions and licenses.

We currently have rights to intellectual property, through licenses from third parties, to identify and develop product candidates. Many pharmaceutical companies, biotechnology companies, and academic institutions are competing with us and filing patent applications potentially relevant to our business. If patents issued to third parties contain valid claims that cover our compounds or their manufacture or uses or assays relevant to our development plans, in order to avoid infringing these patents, we may be required or find it prudent to obtain licenses to these patents or to develop or obtain alternative technology. However, we may be unable to secure such licenses or otherwise acquire or license any compositions, methods of use, processes, or other intellectual property rights from third parties that we identify as necessary for product candidates we may develop. The licensing or acquisition of third party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate.

In addition, if a patent is issued to a third party that covers our compounds or their manufacture or uses or assays related to our technology or product candidates and we cannot obtain a license to such patent, then we may not be in a position to commercialize such technology or product candidates unless we develop non-infringing alternative or successfully pursue 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. We cannot be certain that we would be able to enter into a licensing agreement with the patent holder on commercially reasonable terms, if at all. In either case, our business prospects could be materially adversely affected

Intellectual property rights do not necessarily address all potential risks to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to any product candidates we may develop or utilize similar technology but that are not covered by the claims of the patents that we license or may own in the future;
- we, or our license partners or current or future collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future;
- we, or our license partners or current or future collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that patent applications that we currently, or may in the future, own or license will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

1.9 Risks related to our business and industry

Our relationships with health care professionals, institutional providers, principal investigators, consultants, customers and third-party payers are, and will continue to be, subject, directly and indirectly, to federal and state health care fraud and abuse, false claims, marketing expenditure tracking and disclosure, government price reporting, and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face penalties, including, without limitation, civil, criminal, and administrative penalties, damages,

fines, exclusion from government-funded health care programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations.

Our business operations and activities may be directly or indirectly subject to various fraud and abuse laws, including, without limitation, the U.S. federal Anti-Kickback Statute and the U.S. federal False Claims Act. If we obtain EMA or FDA approval for any of our product candidates and begin commercializing those products in the European Union or the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research subjects, as well as proposed and future sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by the federal government and state governments in which we conduct our business. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal health care program such as Medicare and Medicaid;

- the federal false statements statute which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for health care benefits, items or services;

- the federal HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any health care benefit program or making false statements relating to health care matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and their respective implementing regulations, which impose requirements on certain covered health care providers, health plans, and health care clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization;

- the federal physician self-referral law, commonly known as the Stark Law, which prohibits a physician from making a referral to an entity for certain designated health services reimbursed by Medicare or Medicaid if the physician or a member of the physician's family has a financial relationship with the entity, and which also prohibits the submission of any claims for reimbursement for designated health services furnished pursuant to a prohibited referral;

- the federal transparency requirements under the Health Care Reform Law that will require manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to payments and other transfers of value to physicians and teaching hospitals and physician ownership and investment interests;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- federal government price reporting laws, changed by the Affordable Care Act to, among other things, increase the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program and offer such rebates to additional populations, that require us to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on our marketed drugs; participation in these programs and compliance with the applicable requirements may subject us to potentially significant discounts on our products, increased infrastructure costs, and potentially limit our ability to offer certain marketplace discounts;

- the Foreign Corrupt Practices Act, a U.S. law which regulates certain financial relationships with foreign government officials which could include, for example, certain medical professionals; and

- analogous laws and regulations at U.S. state level and of other countries and jurisdictions.

The Affordable Care Act, among other things, amended the intent standard of the federal Anti-Kickback Statute and criminal health care fraud statutes to a stricter standard such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the Affordable Care Act codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act.

Efforts to ensure that our business arrangements will comply with applicable health care laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other health care laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face penalties, including, without limitation, civil, criminal, and administrative penalties, damages, fines, exclusion from government funded health care programs, such as Medicare and Medicaid in the United States, and the curtailment or restructuring of our operations.

The regulatory approval and commercialization of any of our product candidates outside the European Union or the United States will also likely subject us to foreign equivalents of the health care laws mentioned above.

We may become exposed to costly and damaging liability claims, either when testing our product candidates in the clinic or at the commercial stage; and our product liability insurance may not cover all damages from such claims.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products. The current and future use of our product candidates in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients that use the product, health care providers, pharmaceutical companies or others selling such products. Any claims against us, regardless of their merit, could be difficult and costly to defend which may have a material adverse effect on our business, financial condition, results of operations and prospects.

Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit side effects. If any

of our product candidates were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities, including potential product liability claims. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates. We purchase liability insurance in connection with each of our clinical trials. It is possible that our liabilities could exceed our insurance coverage. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for any of our product candidates. However, we 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. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

Should any of the events described above occur, this could have a material adverse effect on our business, financial condition and results of operations, including, but not limited to:

- decreased demand for our current or future product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to clinical trial participants or patients;
- product recalls, withdrawals or labelling, marketing or promotional restrictions;
- loss of revenues;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize our products or product candidates; and
- a decline in the price of our Shares.

Rapid technological change could make our products, product candidates or technologies obsolete.

Pharmaceutical technologies and products are subject to rapid and significant technological change. We expect our competitors and physicians will develop new technologies, protocols and products that may render our products and drug formulation technologies uncompetitive or obsolete. The products, protocols and technologies of our competitors and physicians may be more effective than the products, product candidates and drug formulation technologies developed by us. As a result, our products and product candidates may become obsolete before we recover expenses incurred in connection with their development or realize revenues from any commercialized product. We are aware of other pharmaceutical companies that are developing competing technologies, which could render our lead product candidate, ATIR101, obsolete.

Our business may become subject to economic, political, regulatory and other risks associated with international operations.

As a company based in the Netherlands, our business is subject to risks associated with conducting business internationally. Many of our suppliers and collaborative and clinical trial relationships are located in different countries. Accordingly, our future results could be harmed by a variety of factors, including:

- economic weakness, including inflation, or political instability in particular economies and markets;
- differing regulatory requirements for drug approvals in different jurisdictions;
- differing jurisdictions could present different issues for securing, maintaining and/or obtaining freedom to operate in such jurisdictions;
- potentially reduced protection for intellectual property rights;
- difficulties in compliance with laws and regulations;
- changes in regulations and customs, tariffs and trade barriers;
- changes in currency exchange rates of the euro and currency controls;
- changes in a specific country's or region's political or economic environment;
- trade protection measures, import or export licensing requirements or other restrictive actions by various governments;
- differing reimbursement regimes and price controls in certain markets;
- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is more common than in the Netherlands or the United States;
- difficulties associated with staffing and managing international operations, including differing labor relations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

1.10 Risks related to legal compliance matters

Because we and our suppliers are subject to environmental, health and safety laws and regulations, we may become exposed to liability and substantial expenses in

connection with environmental compliance or remediation activities which may adversely affect our business and financial condition.

Our operations, including our research, development, testing and manufacturing activities, are subject to numerous environmental, health and safety laws and regulations. These laws and regulations govern, among other things, the controlled use, handling, release and disposal of, and the maintenance of a registry for, hazardous materials and biological materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds and compounds that have a toxic effect on reproduction, laboratory procedures and exposure to blood-borne pathogens. If we fail to comply with such laws and regulations, we could be subject to fines or other sanctions.

As with other companies engaged in activities similar to ours, we face a risk of environmental liability inherent in our current and historical activities, including liability relating to releases of or exposure to hazardous or biological materials. Environmental, health and safety laws and regulations are becoming more stringent. We may be required to incur substantial expenses in connection with future environmental compliance or remediation activities, in which case, our production and development efforts may be interrupted or delayed and our financial condition and results of operations may be materially adversely affected.

The third parties with whom we contract to manufacture our product candidates are also subject to these and other environmental, health and safety laws and regulations. Liabilities they incur pursuant to these laws and regulations could result in significant costs or in certain circumstances, an interruption in operations, any of which could adversely impact our business and financial condition if we are unable to find an alternate supplier in a timely manner.

Our employees, independent contractors, principal investigators, CROs, consultants, vendors and collaboration partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, consultants, vendors and collaboration partners may engage in fraudulent conduct or other illegal activities. Misconduct by these parties could include intentional, reckless and negligent conduct or unauthorized activities that violate, among other things: (i) the legal requirements or other requirements of the EMA, the FDA and other comparable authorities, including those laws that require the reporting of true, complete and accurate information to such authorities; (ii) manufacturing standards; (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and elsewhere; or (iv) laws that require the reporting of true, complete and accurate financial information and data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials or creating fraudulent data in our pre-clinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third-parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged

risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other U.S. federal healthcare programs, individual imprisonment, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, other sanctions, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We have identified material weaknesses in our internal control over financial reporting. If we are unable to successfully remediate these material weaknesses and to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud, and as a result, Shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our Shares.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. A material weakness is a deficiency or a combination of deficiencies in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. We identified material weaknesses in our internal controls related to deficiencies in segregation of duties and approval of manual journal entries. While we have taken, and are continuing to take, steps to remediate these material weaknesses, we cannot assure you that we will be able to successfully remediate the material weaknesses or that other material weakness will not be discovered in the future. If we do not remediate these issues or if we fail to design and operate effective internal controls in the future, it could result in material misstatements in our financial statements.

2. IMPORTANT INFORMATION

2.1 General

You should rely only on the information contained in, or incorporated by reference into, this Registration Document, any supplement to this Registration Document within the meaning of article 5:23 of the Financial Supervision Act should such supplement be published, and the Summary and Securities Note that together with this Registration Document shall constitute a prospectus in accordance with the Prospectus Directive. No person is or has been authorized 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 authorized by us or any of our affiliates or agents. The delivery of this Registration Document shall not under any circumstances, create any implication that there has been no change in our 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 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 our 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) and the Summary and Securities Note that together with this Registration Document shall constitute a prospectus in accordance with the Prospectus Directive.

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. Kiadis Pharma N.V. does not accept any legal responsibility for any violation by any person, of any such restrictions.

2.3 Presentation of financial and other information

Financial information

Kiadis Pharma N.V.'s consolidated financial statements for the financial years ended December 31, 2018, 2017 and 2016 have been incorporated by reference in this Registration Document (see paragraph 2.4 below).

The consolidated financial statements for the financial years ended December 31, 2018, 2017 and 2016 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.

Although the opinions of the independent auditor KPMG Accountants N.V. are not modified in relation to this matter, it is noted that the 2018 audit opinion issued on April 30, 2019 and the 2016 audit opinion issued on March 30, 2017 include an emphasis of matter paragraph which indicated that at the time of the opinions we had insufficient cash and cash equivalents to meet our working capital requirements through the subsequent twelve months. Bearing in mind the aforementioned, there are no qualifications in the auditor's report on the audited consolidated financial statements for the financial years ended December 31, 2018, 2017 and 2016.

The emphasis of matter paragraph included in the 2016 audit opinion issued on March 30, 2017 is copied below.

"*Material uncertainty related to going concern*

We draw attention to the going concern paragraph in note 2.1 of the financial statements 2016 which indicates that the company has insufficient cash and cash equivalents to meet their working capital requirements through the next twelve months and therefore depends on an equity financing, a nondilutive financing or strategic transactions. These conditions indicate the existence of a material uncertainty which may cast significant doubt about the company's ability to continue as a going concern. Our opinion is not modified in respect of this matter.

We evaluated and challenged the company's future business plans and related cash flow forecasts and the process in which these were prepared. We tested the underlying key assumptions, such as expected cash outflow for R&D and tested related expenses and other operating expenses. In order to corroborate management's future business plans and to identify potential contradictory information we, amongst others, read the board minutes and supervisory board minutes, read analyst reports and read the test results of the Phase II testing performed by the Company.

Management is currently investigating funding options. We evaluated the progress of management's plans and assessed the accessibility to potential sources of funding."

The emphasis of matter paragraph included the 2018 audit opinion issued on April 30, 2019 is copied below.

"*Material uncertainty related to going concern*

We draw attention to the going concern paragraph in note 2.1 of the consolidated financial statements which indicates that the company has insufficient cash and cash equivalents to meet their working capital requirements through the next twelve months and therefore depends on an equity financing, a non-dilutive financing or strategic transactions. These conditions indicate the existence of a material uncertainty which may cast significant doubt about the company's ability to continue as a going concern. Our opinion is not modified in respect of this matter."

Financial and other information in connection with the Transaction and CytoSen

The Transaction is expected to be completed in June 2019 and, accordingly, the results of operations of CytoSen are not reflected in our financial and operational information as at and for the years ended December 31, 2018, 2017 and 2016. See paragraph 7.3 for more information on the Transaction and CytoSen. Following completion of the Transaction, CytoSen will become our wholly owned subsidiary. The financial and other information pertaining to CytoSen in this Registration Document has been received from CytoSen.

Pro forma financial information

In this Registration Document, any reference to “pro forma” financial information is to information which has been extracted without material adjustment from the unaudited financial information contained in Chapter 5 (Unaudited Pro Forma Consolidated Financial Information). The Unaudited Pro Forma Consolidated Financial Information (as defined in Chapter 5) is for illustrative purposes only. Because of its nature, the pro forma financial information addresses a hypothetical situation and, therefore, does not represent the actual financial position or results of Kiadis or CytoSen. Future results of operations may differ materially from those presented in the Unaudited Pro Forma Consolidated Financial Information due to various factors.

Rounding

We have made rounding adjustments to some of the figures included in this Registration Document. Accordingly, numerical figures shown as totals in some tables may not be an arithmetic aggregation of the figures that preceded them.

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.

Exchange rate information

The following table sets forth, for each period indicated, the low and high exchange rates of U.S. dollars per euro, the exchange rate at the end of such period and the average of such exchange rates on the last day of each month during such period, based on the noon buying rate of the Federal Reserve Bank of New York for the euro. As used in this document, the term "noon buying rate" refers to the rate of exchange for the euro, expressed in U.S. dollars per euro, as certified by the Federal Reserve Bank of New York for customs purposes. The exchange rates set forth below demonstrate trends in exchange rates, but the actual exchange rates used throughout this Registration Document may vary.

	2014	**2015**	**2016**	**2017**	**2018**
High	1.3927	1.2015	1.1516	1.2041	1.1594
Low	1.2101	1.0524	1.0375	1.0416	1.1281
Rate at end of period	1.2101	1.0859	1.0552	1.2022	1.1456
Average rate per period	1.3210	1.1032	1.1029	1.1396	1.1418

The following table sets forth, for each of the last six months, the low and high exchange rates for euro expressed in U.S. dollars and the exchange rate at the end of the month based on the noon buying rate as described above.

	November 2019	December 2018	January 2019	February 2019	March 2019	April 2019
High	1.1459	1.1456	1.1524	1.1268	1.1376	1.1304
Low	1.1281	1.1300	1.1322	1.1474	1.1214	1.1214
Rate at end of period	1.1323	1.1456	1.1454	1.1379	1.1228	1.1201

On May 17, 2019, the noon buying rate of the Federal Reserve Bank of New York for the euro was 1.00 = US$1.1166. Unless otherwise indicated, currency translations in this Registration Document reflect the May 17, 2019 exchange rate for euros.

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

Kiadis Pharma N.V.'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 (hyperlinked)) are incorporated by reference in the Registration Document. In addition, our audited consolidated financial statements for the financial years ended December 31, 2018, 2017 and 2016, i.e. Kiadis Pharma N.V.'s consolidated financial statements for the financial year ended December 31, 2018, Kiadis Pharma N.V.'s consolidated financial statements for the financial year ended December 31, 2017 and Kiadis Pharma N.V.'s consolidated financial statements for the financial year ended December 31, 2016 (hyperlinked) are incorporated by reference in this Registration Document.

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 our website at http://www.kiadis.com. No documents or information other than the information incorporated by reference, including the content of our 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. Except for documents incorporated by reference in this Registration Document referenced to by hyperlinks,

information referred to by hyperlinks is not part of this Registration Document on the basis of article 6(1)-(2) Delegated Regulation (EU) 2016/301.

2.5 Available information

Copies of this Registration Document, our consolidated financial statements for the financial years ended December 31, 2018, 2017 and 2016, 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 us 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 us may be limited under Dutch law. We are a public limited liability company (*naamloze vennootschap*) incorporated under the laws of the Netherlands and have our statutory seat (*statutaire zetel*) in Amsterdam, the Netherlands.

All but one of the members of the Management Board and 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. Our 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 us 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. Consequently, a final judgment for payment given by a court in the United States, whether or not predicated solely upon U.S. securities laws, would not automatically be recognized or enforceable in the Netherlands. In order to obtain a judgment which is enforceable in the Netherlands, the party in whose favor a final and conclusive judgment of the U.S. court has been rendered will be required to file its claim with a court of competent jurisdiction in the Netherlands. Such party may submit to the Dutch court the final judgment rendered by the U.S. court. This court will have discretion to attach such weight to the judgment rendered by the relevant U.S. court as it deems appropriate. The Dutch courts can be expected to give conclusive effect to a final and enforceable judgment of such court in respect of the contractual obligations thereunder without re-examination or re-litigation of the substantive matters adjudicated upon, provided that: (i) the U.S. court involved accepted jurisdiction on the basis of internationally recognized grounds to accept jurisdiction, (ii) the proceedings before such court being in compliance with principles of proper procedure (*behoorlijke rechtspleging*), (iii) such judgment not being contrary to the public policy of the Netherlands and (iv) such judgment not being incompatible with a judgment given between the same parties by a Netherlands court or with a prior judgment given between the same parties by a foreign court in a dispute concerning the same subject matter and based on the same cause of action, provided such prior judgment fulfills the conditions necessary for it to be given binding effect in the Netherlands. Dutch courts may deny the recognition and enforcement of punitive damages or other awards. Moreover, a Dutch court may reduce the amount of damages granted by a U.S. court and recognize damages only to the extent that they are necessary to compensate actual losses or damages. Enforcement and recognition of judgments of U.S. courts in the Netherlands are solely governed by the provisions of the Dutch Civil Procedure Code.

Dutch civil procedure differs substantially from U.S. civil procedure in a number of respects. Insofar as the production of evidence is concerned, U.S. law and the laws of several other jurisdictions based on common law provide for pre-trial discovery, a process by which parties to the proceedings may prior to trial compel the production of documents by adverse or third parties and the deposition of witnesses. Evidence obtained in this manner may be decisive in the outcome of any proceeding. No such pre-trial discovery process exists under Dutch law.

Subject to the foregoing and service of process in accordance with applicable treaties, investors may be able to enforce in the Netherlands judgments in civil and commercial matters obtained from U.S. federal or state courts. However, no assurance can be given that those judgments will be enforceable. In addition, it is doubtful whether a Dutch court would accept jurisdiction and impose civil liability in an original action commenced in the Netherlands and predicated solely upon U.S. federal securities laws.

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 we are 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 we believe these sources to be reliable, as we do not have access to the information, methodology and other bases for such information, we have not independently verified the information. We are not aware of any exhaustive industry or market reports that cover or address our specific markets.

In this Registration Document, we make certain statements regarding the markets and the competitive position in the sectors and geographies in which we compete. We believe these statements to be true based on market data and industry statistics which are in the public domain, but have not independently verified the information.

2.8 Forward-looking statements

This Registration Document contains certain statements that are or may be forward-looking statements with respect to our 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 our 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 in Chapter 1 (Risk Factors).

You should refer to Chapter 1 (Risk Factors) for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Registration Document will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we

will achieve our objectives and plans in any specified time frame or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

You should read this Registration Document and the documents 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, as well as the Summary and Securities Note that together with this Registration Document shall constitute a prospectus in accordance with the Prospectus Directive completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

2.9 References to defined terms and incorporation of terms

Certain terms used in this Registration Document, including capitalized terms and certain technical and other terms are explained in Chapter 13 (Definitions and Glossary).

3. DIVIDEND POLICY

3.1 Dividend history

We have never declared or paid any dividends on our Shares

3.2 Dividend policy

We expect to retain all earnings, if any, generated by our operations for the development and growth of our business and do not anticipate paying any dividends to our Shareholders in the near future. Under Dutch law, we may only pay dividends if our shareholders' equity (*eigen vermogen*) exceeds the sum of the paid-up and called-up share capital *plus* the reserves required to be maintained by Dutch law or by our Articles of Association. Also, pursuant to the facility agreements that we entered into with Kreos Capital on August 17, 2017 and on July 31, 2018, as long as any of the loans provided by Kreos Capital remains outstanding, we are not permitted to make any dividend payment or other distributions to Shareholders without the prior written consent of Kreos Capital.

Our 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 our earnings, cash flow, financial condition, capital investment requirements and other factors considered important by the Management Board.

4. SELECTED CONSOLIDATED HISTORICAL FINANCIAL INFORMATION

You should read the following selected financial and operating data in conjunction with the consolidated financial statements and related notes incorporated by reference in this Registration Document and in Chapter 6 (Operating and Financial Review). Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

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 International Financial Reporting Standards ("**IFRS**") as adopted by the European Union.

4.1 Selected consolidated income statement data

	For the year ended December 31		
	2018	**2017**	**2016**
	Audited		
	(€ in thousands, except per share data)		
Revenues	-	-	-
Other income	-	-	-
Research and development expenses	(17,468)	(11,215)	(8,206)
General and administrative expenses	(7,733)	(4,905)	(3,202)
Total operating expenses	**(25,201)**	**(16,120)**	**(11,408)**
Operating loss	**(25,201)**	**(16,120)**	**(11,408)**
Interest income	-	-	13
Interest expenses	(4,302)	(2,285)	(1,571)
Other net finance (expenses) income	(288)	1,372	(1,827)
Net finance (expenses)	**(4,590)**	**(913)**	**(3,385)**
Loss before tax	**(29,791)**	**(17,033)**	**(14,793)**
Income tax expenses	(10)	(5)	(1)
Loss for the period	**(29,801)**	**(17,038)**	**(14,794)**
Basic and diluted loss per share	(1.46)	(1.14)	(1.08)
Weighted average number of ordinary shares[1]	20,450,398	14,950,701	13,754,725

1. The basic loss per share is based on the weighted average number of ordinary shares of the Company outstanding during the periods presented. The calculation of diluted loss per share has been based on a weighted-average number of ordinary shares outstanding after adjustment for the effects of all dilutive potential ordinary shares. Both stock options and warrants were excluded from the diluted weighted-average of ordinary shares calculation because their effect would have been anti-dilutive. As a result, diluted loss per share equals basic loss per share

4.2 Selected consolidated statement of financial position statement data

	As of December 31		
	2018	**2017**	**2016**
	Audited		
	(€ in thousands)		
Assets			
Property, plant and equipment	7,720	602	536
Intangible assets	12,368	12,830	13,540
Total non-current assets	**20,088**	**13,432**	**14,076**
Trade and other receivables	729	582	230

	As of December 31		
	2018	2017	2016
	Audited		
Deferred expenses	1,413	767	351
Cash and cash equivalents	60,314	29,906	14,559
Total current assets	**62,456**	**31,255**	**15,140**
Total assets	**82,544**	**44,687**	**29,216**
Equity			
Share capital	2,434	1,729	1,397
Share premium	180,553	124,413	103,200
Translation reserve	298	295	307
Warrant reserve	392	1,275	-
Accumulated deficit	(139,533)	(111,853)	(95,463)
Equity attributable to equity holders	**44,144**	**15,859**	**9,441**
Liabilities			
Loans and borrowings	21,836	21,599	15,605
Lease liabilities	5,255	-	-
Derivatives	-	1,445	-
Employee benefits	-	540	-
Total noncurrent liabilities	**27,091**	**23,584**	**15,605**
Loans and borrowings	5,308	1,789	1,555
Lease liabilities	1,033	-	-
Trade and other payables	4,968	3,455	2,615
Total current liabilities	**11,309**	**5,244**	**4,170**
Total liabilities	**38,400**	**28,828**	**19,775**
Total equity and liabilities	**82,544**	**44,687**	**29,216**

5. UNAUDITED PRO FORMA CONSOLIDATED FINANCIAL INFORMATION

5.1 Unaudited pro forma consolidated financial information

We have entered into a definitive agreement to acquire CytoSen, subject to approval of the General Meeting - which approval has been granted on May 29, 2019 - and customary closing conditions. See also paragraph 7.3.

*The following unaudited pro forma consolidated financial information has been prepared to illustrate the impact of the Transaction (the "**Unaudited Pro Forma Consolidated Financial Information**") as if it had occurred on January 1, 2018 for the purposes of the income statement and on December 31, 2018 for the purposes of the statement of financial position.*

The Unaudited Pro Forma Consolidated Financial Information has been prepared in accordance with Commission Regulation (EC) No 809/2004. The Unaudited Pro Forma Financial Information have not been prepared in accordance with the rules or regulations of the United States Securities and Exchange Commission (SEC), and is not compliant therewith or any other comprehensive basis of preparation. Any use of this information should take this fully into consideration.

The Unaudited Pro Forma Consolidated Financial Information includes the historical results of Kiadis and CytoSen, each of which are presented in accordance with IFRS as adopted by the European Union, and adjusted as described below.

In the case of the US GAAP historical results of CytoSen, this information and other information in connection with the Transaction and CytoSen has been received from CytoSen. Under IFRS, as reflected in the Unaudited Pro Forma Consolidated Financial Information (see second column headed "CytoSen" of the unaudited pro forma consolidated income statement for the year ended December 31, 2018), each instalment of an option grant (or "share based payment award") is separately measured and attributed to expense over the related vesting period, which accelerates the expense recognition compared to US GAAP. We assume there are no other differences between US GAAP and IFRS that would have a material impact on the Unaudited Pro Forma Consolidated Financial Information.

We expect to complete the Transaction in June 2019. As it regards a payment in Shares, the consideration will be based on the closing price on Euronext Amsterdam of our Share on the completion date of the Transaction. For the purposes of the Unaudited Pro Forma Consolidated Financial Information, we have assumed a preliminary estimated fair value of the total acquisition consideration of €38.0 million which is primarily based on the closing price on Euronext Amsterdam of our Share on May 24, 2019, being €9.38.

The CytoSen balance sheet positions initially expressed in U.S. dollars have been translated in euro by using the closing EUR/USD exchange rate as at December 31, 2018 (1EUR = 1.1439USD); whereas the CytoSen Statement of Income positions initially expressed in U.S. dollars have been translated into euro by using the average EUR/USD exchange rate over the year 2018 (1EUR = 1.1810USD).

The Unaudited Pro Forma Consolidated Financial Information has been prepared for illustrative purposes only, and because of its nature addresses a hypothetical situation and therefore does not represent the actual financial position or results of operations as of December 31, 2018. Accordingly, you should not place undue reliance on the Unaudited Pro Forma Consolidated Financial Information.

The Transaction will be accounted for in accordance with IFRS 3 using the acquisition method of accounting under which the Transaction consideration is allocated to assets acquired and liabilities assumed based on their estimated fair values as of the date of completion of the Transaction. We will acquire CytoSen for its intellectual property and research and development portfolio. In-process research and development (IPR&D) estimated at €30.1 million has been provisionally recorded in the unaudited pro forma consolidated balance sheet. The actual calculation and allocation of the consideration outlined above will be based on the assets purchased and liabilities assumed at the effective date of the Transaction and other information available at that date. Accordingly, the actual amounts for each of these assets and liabilities will vary from the pro forma amounts disclosed above and the variations may be material.

Unaudited pro forma consolidated income statement for the year ended December 31, 2018

(€ in thousands)	Kiadis[1]	CytoSen[2]	Pro forma Transaction adjustment	Pro forma combined group
	Audited	**Unaudited**	**Unaudited**	**Unaudited**
Revenues	-	-	-	-
Other income	-	-	-	-
Research and development expenses	(17,468)	(3,670)	-	(21,138)
General and administrative expenses	(7,733)	(1,554)	-	(9,287)
Total operating expenses	**(25,201)**	**(5,224)**	**-**	**(30,425)**
Operating loss	**(25,201)**	**(5,224)**	**-**	**(30,425)**
Interest income	-	74	-	74
Interest expenses	(4,302)	-	-	(4,302)
Other net finance (expenses) income	(288)	-	-	(288)
Net finance (expenses) income	**(4,590)**	**74**	**-**	**(4,517)**
Loss before tax	**(29,791)**	**(5,150)**	**-**	**(34,941)**
Income tax expenses	(10)	-	-	(10)
Loss for the period	**(29,801)**	**(5,150)**	**-**	**(34,951)**
Other comprehensive income	**-**	**-**	**-**	**-**
Foreign currency translation difference for foreign operations	3	(167)	-	(164)
Related tax	-	-	-	-
Other comprehensive income for the period, net of tax	**3**	**(167)**	**-**	**(164)**
Total comprehensive income for the period	**(29,798)**	**(5,317)**	**-**	**(35,115)**
Loss attributable to owners of the company	**(29,801)**	**(5,150)**	**-**	**(34,951)**
Total comprehensive income attributable to owners of the company	**(29,798)**	**(5,317)**	**-**	**(35,115)**

Unaudited pro forma consolidated statement of financial position as at December 31, 2018

(€ in thousands)	Kiadis[1]	CytoSen[2], [3]	Pro forma Transaction adjustment[3], [4]	Pro forma combined group
	Audited	**Unaudited**	**Unaudited**	**Unaudited**
Assets				
Property, plant and equipment	7,720	83	-	7,803
Goodwill	-	-	6,322	6,322
Intangible assets (IPR&D)	12,368	-	30,106	42,474
Total non-current assets	**20,088**	**83**	**36,428**	**56,599**

Trade and other receivables	729	27	-	756
Deferred expenses	1,413	-	-	1,413
Cash and cash equivalents	60,314	8,697	-	69,011
Total current assets	**62,456**	**8,724**	**-**	**71,180**
Total assets	**82,544**	**8,807**	**36,428**	**127,779**
Equity				
Share capital	2,434	841	(669)	2,606
Share premium	180,553	13,553	3,345	197,451
Translation reserve	298	(167)	167	298
Warrant reserve	392	-	-	392
Accumulated deficit	(139,533)	(6,339)	6,339	(139,533)
Equity attributable to equity holders	**44,144**	**7,888**	**9,182**	**61,214**
Liabilities				
Loans and borrowings	21,836	-	-	21,836
Lease liabilities	5,255	-	-	5,255
Derivatives	-	-	-	-
Contingent Acquisition Consideration	-	-	20,924	20,924
Deferred Tax Liability	-	-	6,322	6,322
Total noncurrent liabilities	**27,091**	**-**	**27,246**	**54,337**
Loans and borrowings	5,308	-	-	5,308
Lease liabilities	1,033	-	-	1,033
Trade and other payables	4,968	919	-	5,887
Total current liabilities	**11,309**	**919**	**-**	**12,228**
Total liabilities	**38,400**	**919**	**27,246**	**66,565**
Total equity and liabilities	**82,544**	**8,807**	**36,428**	**127,779**

(1) Kiadis' financial information included in the Unaudited Pro Forma Consolidated Financial Information is based on Kiadis Pharma N.V.'s audited consolidated financial statements for the financial year ended December 31, 2018 as incorporated by reference in this Registration Document.

(2) The unaudited historical financial information of CytoSen is presented in accordance with IFRS and is based on management information in accordance with US GAAP received from CytoSen. Under IFRS, and as reflected in the Unaudited Pro Forma Consolidated Financial Information, each installment of an option grant is separately measured and attributed to expense over the related vesting period, which accelerates the expense recognition compared to US GAAP. The expenses for share based payments have a corresponding increase in equity resulting in a zero net equity impact. We assume there are no other differences between US GAAP and IFRS that would have a material impact on the Unaudited Pro Forma Consolidated Financial Information. Foreign currency differences are recognized in Other Comprehensive Income (OCI) and accumulated in the translation reserve.

The CytoSen balance sheet positions initially expressed in U.S. dollars have been translated into euro by using the closing EUR/USD exchange rate as at December 31, 2018 (1EUR = 1.1439USD); whereas the CytoSen Statement of Income positions initially expressed in U.S. dollars have been translated into euro by using the average EUR/USD exchange rate over the year 2018 (1EUR = 1.1810USD).

(3) The estimated fair value of the Acquisition Consideration (as defined below) minus the asset value of CytoSen has been allocated to intangibles. In the column "Pro forma combined group", the equity accounts of CytoSen for the total amount of €7,888

thousand has been reversed against the net asset value of CytoSen as reflected in the column "Pro forma Transaction adjustment".

(4) In the column "Pro forma Transaction adjustment", the movement in equity for the amount of €9,182 thousand is as follows:

(€ in thousands)	**Unaudited**
Initial Acquisition Consideration	17,070
- Shares	172
- Share premium	16,898
Reversal equity accounts CytoSen	(7,888)

Basis of preparation

The Unaudited Pro Forma Financial Information has been prepared in accordance with IFRS as adopted by the European Union.

In accordance with IFRS 3 the Unaudited Pro Forma Financial Information has been prepared using the acquisition method of accounting under which the Acquisition Consideration is allocated to assets acquired and liabilities assumed based on their estimated fair values as of the date of completion of the Transaction.

Pro forma transaction adjustments

Preliminary calculation of Acquisition Consideration and allocation to assets and liabilities

The total upfront consideration to be paid to the holders of CytoSen shares and options for the acquisition of CytoSen in exchange for all outstanding CytoSen shares on a fully diluted basis consists of the Upfront Payment Shares (as defined in paragraph 7.3), of which 15% constitute Holdback Shares (as defined in paragraph 7.3), and the Upfront Payment Options (as defined in paragraph 7.3) (collectively, the **Initial Acquisition Consideration**). Based on the number of CytoSen shares and options outstanding on the Registration Document Date, it is assumed for the purposes of the Unaudited Pro Forma Consolidated Financial Information that the number of Upfront Payment Shares is 1,724,899, of which 258,732 are Holdback Shares, and that the number of Upfront Payment Options is 214,941.

In addition, CytoSen's shareholders are eligible for potential future consideration of up to 5,174,670 additional Shares and its option holders for a potential future consideration of up to 644,790 Shares upon the achievement of six clinical development and regulatory milestones (the **Contingent Acquisition Consideration** and together with the Initial Acquisition Consideration, the **Acquisition Consideration**). See also in paragraph 7.3.

The options to acquire Shares included in the Initial Acquisition Consideration regard outstanding CytoSen options that shall be assumed by us and converted at substantially the same terms and conditions into the Upfront Payment Options at exercise prices ranging from €9.52 to €11.20. The entitlement of CytoSen's option holders to receive up to 644,790 Shares upon the achievement of milestones shall be subject to the terms and conditions of a Milestone Bonus Plan which is being developed.

The following table summarizes the preliminary estimated fair value of the Acquisition Consideration:

(€ in thousands)	**Unaudited**
Initial Acquisition Consideration – Shares (including Hold back Shares)	16,180
Initial Acquisition Consideration – Options to acquire Shares[(1)]	890
Contingent Acquisition Consideration – CytoSen shareholders	18,606
Contingent Acquisition Consideration – CytoSen option holders	2,318
Acquisition Consideration	**37,994**

(1) Fair value estimated on average at €4.14 per option.

The estimated fair value of the part of the Initial Acquisition Consideration that consists of Shares (including Holdback Shares) and the Contingent Acquisition Consideration presented in the above table is based on the closing price on Euronext Amsterdam of our Share on May 24, 2019, being €9.38.

The calculation of the final value of the part of the Initial Acquisition Consideration that consists of Shares (including Holdback Shares) is expected to be based on the closing price on Euronext Amsterdam of our Share on the completion date of the Transaction.

For calculating the fair value of the part of the initial Acquisition Consideration that consists of options to acquire Shares, the Hull and White option valuation model is applied. The parameters used in the model are

Exercise price (in Euro), between	€9.52 - €11.20
Expected volatilities	57.5% -57.7%
Risk-free interest rates	(0.157)% - (0.067)%
Exercise multiple	2
Dividend yield	0%
Estimated fair value options	€4.06 - €4.20

The estimated fair value of the Contingent Acquisition Consideration of €20.9 million relates to the achievement of certain clinical development and regulatory milestones and is based on the contractual terms defined in the CytoSen Acquisition Agreement.

The estimated fair value of the Contingent Acquisition Consideration that CytoSen's shareholders are entitled to is determined using the assumed probability rates of success (PoS) of the different milestones and the closing price on Euronext Amsterdam of our Share on May 24, 2019. This part of the Contingent Acquisition Consideration is classified as a liability as the contingent payments are not independent of each other and are therefore accounted for as one contract. This contract is settled in a variable number of Shares.

The estimated fair value of the Contingent Acquisition Consideration that CytoSen's option holders are entitled to is also determined using the assumed probability rates of success (PoS) of the different milestones and the closing price on Euronext Amsterdam of our Share on May 24, 2019 and is also classified as a liability as the different payments are not independent of each other and are therefore accounted for as one contract. This contract is settled in a variable number of Shares.

The fair values assigned to the intangible assets acquired from CytoSen are based on our estimates and assumptions. We acquired CytoSen mainly for its intellectual property and research and development portfolio. We allocated the full consideration minus acquired net

assets (for an amount of €7,888 thousand) to in-process research and development (IPR&D) for an estimated amount of €30,106 thousand. Based on a 21% US income tax rate, a deferred tax liability related to the IPR&D is included for the amount of €6,322 thousand. We recorded a goodwill balance for the same amount.

The estimated fair values of these assets acquired are considered preliminary. We believe that the information provides a reasonable basis for estimating the fair values of assets acquired; however, the provisional measurements of fair value are subject to change. We expect to finalize the valuation of the intangible assets as soon as practicable, but not later than one year from the completion date of the Transaction.

If the value of the acquired net assets would be lower than €7,888 thousand, the value of the estimated IPR&D is expected to increase with a similar amount. If the Acquisition Consideration minus acquired net assets would surpass a reasonable value to allocate to IPR&D, which we currently do not expect to occur, goodwill would increase with a similar amount. The value of acquired net assets and the estimated IPR&D are not expected to exceed the Acquisition Consideration. Therefore, we consider the risk of a negative Goodwill balance minimal.

IPR&D is amortized on a straight-line basis over the term of its expected benefit from the moment this asset is available for use, being the commencement of the commercial introduction of the product which did not occur in 2018. Therefore, any change in IPR&D value is not expected to have an impact on the income statement for the year end December 31, 2018.

We may make changes in the final calculation of the Acquisition Consideration and its allocation to assets and liabilities, for instance by using a different fair value method to determine the Acquisition Consideration.

Under the acquisition method, acquisition-related transaction costs (e.g. advisory, legal, valuation and other professional fees) are not included as consideration transferred but are accounted for as expenses in the periods in which the costs are incurred. These costs are not presented in the unaudited pro forma consolidated income statement, because they will not have a continuing impact on the combined results. Total acquisition-related transaction costs of the combined company were immaterial.

We do not expect to materially benefit from any cost savings in connection with the acquisition of CytoSen (e.g. general & administrative expenses of CytoSen). We therefore have not included any potential cost savings in the unaudited pro forma consolidated income statement, nor do we expect such potential cost savings to have a significant cash flow impact.

5.2 Assurance report of the independent auditor

To: the Supervisory Board of Kiadis Pharma N.V.

Our opinion

We have examined the compilation of the pro forma financial information of Kiadis Pharma N.V. ('the Company') based in Amsterdam, included in Chapter 5 (Unaudited Pro Forma Consolidated Financial Information) of the registration document dated May 31, 2019 of the Company (the 'Registration Document').

In our opinion:

- the pro forma financial information has been properly compiled based on the basis stated; and

- such basis is consistent with the accounting policies of the Company as described in the notes to the financial statements of the Company for the period ended December 31, 2018.

The pro forma financial information comprises the Company's pro forma consolidated income statement for the year ended December 31, 2018, pro forma consolidated statement of financial position as at December 31, 2018, and related notes to the pro forma consolidated financial information as set out in Chapter 5 (Unaudited Pro Forma Consolidated Financial Information) of the Registration Document issued by the Company.

Basis for our opinion

We conducted our examination in accordance with Dutch law, including the Dutch Standard 3420, 'Assurance-opdrachten om te rapporteren over het opstellen van pro forma financiële informatie die in een prospectus is opgenomen' (Assurance Engagements to Report on the Compilation of Pro Forma Financial Information Included in a Prospectus). This engagement is aimed to obtain reasonable assurance about whether management compiled the pro forma financial information, in all material aspects, based on the applicable criteria. Our responsibilities under this standard are further described in the section 'Our responsibilities for the examination of the compilation of the pro forma financial information'.

We are independent of Kiadis Pharma N.V. in accordance with the 'Verordening inzake de onafhankelijkheid van accountants bij assurance-opdrachten' (ViO, Code of Ethics for Professional Accountants, a regulation with respect to independence) and other relevant independence requirements in The Netherlands. Furthermore we have complied with the 'Verordening gedrags- en beroepsregels accountants' (VGBA, Dutch Code of Ethics).

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

Applicable criteria

For this engagement, the following criteria apply:

- the Commission Regulation (EC) No 809/2004 to the proper compilation of the pro forma financial information and the consistency of accounting policies; and

- the assumptions made and disclosed by management in the basis of preparation of the pro forma financial information, as set out in the notes to the pro forma financial information.

Relevant matters relating to the scope of our examination

The unadjusted historical financial information has been derived from the audited consolidated financial statements of the Company for the year ended December 31, 2018. For purposes of this engagement, we are not responsible for updating or reissuing any reports or opinions on any historical financial information used in compiling the pro forma financial information, nor have we, in the course of this engagement, performed an audit or review of the financial information used in compiling the pro forma financial information.

The purpose of pro forma financial information included in a prospectus is solely to illustrate the impact of a significant event or transaction on unadjusted financial information of the Company as if the event had occurred or the transaction had been undertaken at an earlier date selected for purposes of the illustration. Accordingly, we do not provide any assurance that the actual outcome of the event or transaction at January 1, 2018 would have been as presented.

Our opinion is not modified in respect of these matters.

Restriction on use

The pro forma financial information is prepared for the purpose of inclusion in the Registration Document. As a result, the pro forma financial information may not be suitable for another purpose. This report is required by the Commission Regulation (EC) No 809/2004 and is given for the purpose of complying with that Regulation and inclusion in the Registration Document and for no other purpose.

Responsibilities of the Management Board and the Supervisory Board for the pro forma financial information

The Management Board is responsible for preparing the pro forma financial information in accordance with the applicable criteria. Furthermore management is responsible for such internal control as it determines is necessary to enable the compilation of the pro forma financial information that is free from material misstatement, whether due to fraud or error.

The Supervisory Board is responsible for overseeing the Management Board's reporting process of the pro forma financial information.

Our responsibilities for the examination of the compilation of the pro forma financial information

Our responsibility is to plan and perform our examination in a manner that allows us to obtain sufficient and appropriate assurance evidence for our opinion.

Our examination has been performed with a high, but not absolute, level of assurance, which means we may not have detected all material errors and fraud.

We apply the 'Nadere voorschriften kwaliteitssystemen' (NVKS, regulations for quality management systems) and accordingly maintain a comprehensive system of quality control including documented policies and procedures regarding compliance with ethical requirements, professional standards and applicable legal and regulatory requirements.

Our examination included among others:

- identifying and assessing the risks of material misstatement in the compilation of the pro forma financial information, whether due to errors or fraud, designing and performing assurance procedures responsive to those risks, and obtaining assurance-evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from errors, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control;

- obtaining an understanding of internal controls relevant to the examination in order to design assurance procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal controls;

- assessing whether the criteria applied by management in the compilation of the pro forma financial information provide a reasonable basis for presenting the significant effects directly attributable to the event or transaction, and to obtain sufficient and appropriate assurance-evidence about whether:

    - the related pro forma adjustments give appropriate effect to those criteria; and

    - the pro forma financial information reflects the proper application of those adjustments to the unadjusted financial information;

- evaluating the procedures undertaken by the Company in compiling the pro forma financial information and evaluating the consistency of the pro forma financial information with the accounting policies of the Company as described in the notes to the financial statements of the Company for the period ended December 31, 2018; and

- evaluating the overall presentation of the pro forma financial information.

Amstelveen, May 31, 2019

KPMG Accountants N.V.

H.A.P.M. van Meel RA

6. OPERATING AND FINANCIAL REVIEW

You should read the following discussion of our financial condition and results of operations in conjunction with the financial statements and notes thereto incorporated by reference in this Registration Document. The following discussion contains forward-looking statements that involve certain risks and uncertainties. Our actual results could differ materially from those discussed in these statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this Registration Document, particularly in Chapter 1 (Risk Factors) and in paragraph 2.8.

Our audited consolidated financial statements and unaudited interim financial statements are included elsewhere in this Registration Document. These financial statements are prepared pursuant to IFRS as adopted by the European Union.

This Chapter does not include a discussion and analysis of the results of operations and financial condition of CytoSen, the acquisition of which is expected to be completed in June 2019. Pro forma financial information relating to the combination of Kiadis and CytoSen is set forth in Chapter 5 (Unaudited Pro Forma Consolidated Financial Information).

6.1 Overview

We are building a fully integrated biopharmaceutical company to maximize the potential of ATIR, our proprietary cell-based immunotherapy platform. Our lead program, ATIR101, is focused on helping improve outcomes for patients with blood cancers who are in urgent need of stem cell transplants. ATIR101 is a patient-specific T-cell therapy designed to be delivered following a haploidentical hematopoietic stem cell transplant (HSCT), in order to support the patient's newly transplanted immune system before it becomes fully functional. We manufacture ATIR101 ex vivo from donor T-cells by selectively depleting harmful donor T-cells that can attack patient tissue and cause Graft versus Host Disease (GVHD), while retaining those T-cells that fight relapse and infections. We believe that ATIR can improve haploidentical HSCT outcomes and treatment options, thereby enabling the use of haploidentical HSCT in a broader range of patient groups and a broader range of diseases of the blood or immune system. We believe that as therapies, like ATIR101, are approved, the number of patients receiving haploidentical HSCTs will increase significantly, as physicians move away from matched unrelated donor transplants due to the time and consequences of waiting to find a donor. We estimate that, over time, a substantial target population could potentially benefit from ATIR as an adjunctive therapy to haploidentical HSCT. This reflects the continued growth of allogeneic transplantations from the current >30,000 a year in the EU and the US, and a continuation of the current rapid growth of haploidentical HSCTs, from the estimated 3,800 haploidentical HSCT performed in 2016.

Since inception, we have not generated any revenues or net cash flows from sales of our product candidates. ATIR101, has not yet been approved for marketing. To date, we have relied principally on the issuance and sale of equity and debt securities to finance our operations, internal growth and selective acquisitions of businesses, technologies and other assets.

We have incurred significant losses in each year of operations, as we have devoted a significant amount of our resources to clinical development and research. Our net losses were €14.8 million, €17.0 million and €29.8 million for the years ended December 31, 2016, 2017 and 2018, respectively. As of December 31, 2018, we had an accumulated deficit of €139.5 million. Our research and development expenses were €8.2 million, €11.2 million and €17.5 million for the years ended December 31, 2016, 2017 and 2018, respectively. In 2017,

we expanded the work force in our research and development departments and started a Phase III clinical trial for ATIR101. In 2018 we continued to expand our workforce and increased our clinical expenses and facility costs due to the move to a larger building, which includes a commercial manufacturing facility, laboratories and office space. General and administrative expenses increased from €3.2 million for the year ended December 31, 2016 to €4.9 million for the year ended December 31, 2017 and to €7.7 million for the year ended December 31, 2018, mainly due to increased headcount across all departments to support the continued growth of the company and consultancy expenses for business development, market access and strategic projects.

We expect to continue to incur substantial operating losses in the future as we continue to develop and seek regulatory approval for our product candidates. We will not receive any revenues or net cash flows from sales of our product candidates unless they have been approved by the EMA, the FDA or similar regulatory authorities in other countries and commercialized successfully, which we do not expect to be before the end of 2019, if at all.

License Agreements

Since the 1990s, we and our predecessors have collaborated with the University of Montreal, Canada and with a group of researchers led by Prof. Denis Claude Roy at the Hospital Maisonneuve-Rosemont and researchers at the Hotel-Dieu de Montreal in Montreal, Canada, each of which are hospitals affiliated with the University of Montreal, for research and clinical development projects relating to our ATIR technology. Professor Roy's research includes research relating to the mechanism of action of the ATIR technology, applications of the ATIR technology in various disease indications and development work to establish certain assays for the characterization of cellular products related to the ATIR technology. We intend to continue our collaboration with these institutions going forward.

Under a research and licensing agreement between us and the University of Montreal dated December 1, 1997 (the "**Montreal Agreement**"), we are obligated to pay royalties of a mid-single digit percentage of (i) net sales of certain cell-based products, including products based on the ATIR platform, and (ii) payments we receive in connection with any sublicenses we grant to third parties, for the term of our or their commercialization of such products.

We also entered into an exclusive license agreement with Hospira on December 21, 2010 (the "**Hospira Exclusive License Agreement**") which was terminated by a termination and royalty agreement that we entered into with Hospira on January 31, 2012 (the "**Hospira Termination and Royalty Agreement**"). Under the Hospira Termination and Royalty Agreement, we must make certain payments to Hospira including a $3 million milestone payment and a mid-single digit percentage royalty on worldwide net sales of certain cell-based products, including products based on the ATIR platform, until we repay the $24.5 million received from Hospira under the Hospira Exclusive License Agreement plus a low-single digit percentage interest amount compounded annually (the "**Reimbursement Amount**"). After that, a low-single digit percentage royalty on net sales in all countries (except for those in North America and South America, China, Mongolia and Antarctica) applies. As of December 31, 2018, the repayment amount owed to Hospira is $27.2 million. We have determined that our repayment obligations with regard to the Reimbursement Amount should be characterized as a loan. Once we have paid the Reimbursement Amount in full, we will continue to pay royalties to Hospira, which will be reflected in selling and distribution expenses. See paragraph 7.11 below for more information.

Moreover, under a letter agreement with the University of Montreal and the Hospital Maisonneuve-Rosemont dated September 19, 2012, we agreed to pay the University of Montreal an amount of $750,000, subject to a low-single digit percentage interest per annum as of January 1, 2011, as a royalty fee in relation to the Hospira Exclusive License Agreement with Hospira. For further information regarding these agreements and amounts that could become payable in the future under these agreements, see paragraph 7.11 below.

We intend to continue our collaboration with these institutions going forward. We currently license some of the components used in our ATIR platform from the University of Montreal and are subject to certain payment obligations in connection with the commercialization of certain cell-based products, including products based on the ATIR platform.

6.2 Financial operations overview

We believe that the following factors have had and will continue to have a material effect on our results of operations and financial condition.

Revenues

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

Research and development expenses

We are focused on the clinical development of our lead product candidate ATIR101. To date, we have devoted substantially all of our resources to research and development efforts relating to our product candidates. We expect research and development expenses to continue to increase as we seek to complete the development of, and achieve regulatory approval for, our lead product candidate, ATIR101, and potentially add new programs.

Research and development expenses consist of the following:

- the costs of conducting and managing our sponsored clinical trials, including clinical investigator cost, payments of patient expenses and costs, and payments to CROs, assisting with our 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 and rental expenses;
- 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 our clinical trials and research and development activities;
- costs associated with manufacturing clinical products at our CMO and building our own manufacturing capabilities;
- license costs; and

- costs of preclinical studies, including toxicology studies.

We are currently focused on advancing ATIR101 through a Phase III clinical trial in the United States, Canada, the European Union and certain additional countries. We anticipate making decisions on the further development and funding of our other existing clinical programs and any additional programs we may pursue in response to the scientific and clinical success of ATIR101, as well as our ongoing assessment of market opportunities. To the extent we further advance our other existing clinical programs or pursue additional programs, we anticipate that research and development expenses will continue to increase.

There is a risk that any clinical development or product discovery program may not result in marketing approval. To the extent that we fail to obtain approval to market any of our product candidates in a timely manner, we would need to continue to conduct clinical trials over a longer period of time, and we anticipate that our research and development expenses may further increase.

Clinical development timelines and associated costs may vary significantly and the successful development of our lead product candidate or any other product candidate we may seek to develop is highly uncertain. At this time, we cannot reasonably estimate the nature, timing and estimated costs of the efforts that will be necessary to complete the development of, or the period, if any, in which material net cash inflows may commence from, any of our product candidates. Moreover, we cannot assure that we will be able to successfully develop or commercialize any of our product candidates, if approved for marketing. This is due to numerous risks and uncertainties associated with developing drugs. See Chapter 1 (Risk Factors).

Selling and distribution expenses

Historically, we have not incurred any selling and distribution expenses. If any of our product candidates were to be approved for marketing, we anticipate incurring substantial selling and distribution expenses in future periods in order to establish an infrastructure for independent marketing, direct sales and distribution to specialized transplantation centers, obtain supplies of active pharmaceutical ingredients including patient and donor materials, and manufacture commercial quantities of our product candidates. We would also be subject to royalty payments under the terms of the Montreal Agreement and certain milestone and royalty payment obligations pursuant to the terms of the Hospira Termination and Royalty Agreement if our product candidates were to be approved for marketing and successfully commercialized. See paragraph 7.11 below.

General and administrative expenses

We anticipate that our general and administrative expenses will increase as we advance our lead product candidate, ATIR101, prepare for the commercialization of ATIR101, and potentially further advance other programs based on ATIR or add new programs. General and administrative expenses consist of the following:

- employee benefits, including salaries, pensions, profit-sharing plans, share-based compensation expenses, bonus plans and other related costs for employees in executive and operational functions;

- advisors' fees, including accounting, legal, intellectual property and consulting services; and

- rental expenses, facilities expenses and other general expenses relating to our operations.

We have adopted an employee share option and stock appreciation rights plan under which key management personnel and employees may be granted share options and/or stock appreciation rights ("**SARs**"). Previously, options and SARs were granted under separate plans, but these two plans have been combined to a single plan as of April 20, 2018. The fair value of these instruments will be recognized as an employee expense. These employee compensation expenses may contribute to the increase in our general and administrative expenses.

We also anticipate that the continuing development of our business, the expansion of our 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.

6.3 Results of operations

The historical financial information for the three years ended December 31, 2018, 2017 and 2016 has been extracted from our historical financial information incorporated by reference in this Registration Document.

The following table summarizes our loss for the periods indicated:

	For the year ended December 31		
	2018	**2017**	**2016**
	Audited		
	(€ in thousands, except per share data)		
Revenues	-	-	-
Other income	-	-	-
Research and development expenses	(17,468)	(11,215)	(8,206)
General and administrative expenses	(7,733)	(4,905)	(3,202)
Total operating expenses	**(25,201)**	**(16,120)**	**(11,408)**
Operating loss	**(25,201)**	**(16,120)**	**(11,408)**
Interest income	-	-	13
Interest expenses	(4,302)	(2,285)	(1,571)
Other net finance (expenses) income	(288)	1,372	(1,827)
Net finance (expenses)	**(4,590)**	**(913)**	**(3,385)**
Loss before tax	**(29,791)**	**(17,033)**	**(14,793)**
Income tax expenses	(10)	(5)	(1)
Loss for the period	**(29,801)**	**(17,038)**	**(14,794)**
Basic and diluted loss per share	(1.46)	(1.14)	(1.08)
Weighted average number of ordinary shares[1]	20,450,398	14,950,701	13,754,725

1. The basic loss per share is based on the weighted average number of ordinary shares of the Company outstanding during the periods presented. The calculation of diluted loss per share has been based on a weighted-average number of ordinary shares outstanding after adjustment for the effects of all dilutive potential ordinary shares. Both stock options and warrants were excluded from the diluted weighted-average of ordinary shares calculation because their effect would have been anti-dilutive. As a result, diluted loss per share equals basic loss per share

Revenues

We have not generated any revenues for the years ended December 31, 2018, December 31, 2017 or December 31, 2016.

Other income

We have not generated any other income for the years ended December 31, 2018, December 31, 2017 or December 31, 2016.

Research and development expense

Research and development expenses increased from €11.2 million for the year ended December 31, 2017 to €17.5 million for the year ended December 31, 2018, an increase of 56%. This increase is mainly due to a further expansion of the workforce, clinical expenses, and the move to a larger building, which includes a commercial manufacturing facility, laboratories and office space.

Research and development expenses increased from €8.2 million for the year ended December 31, 2016 to €11.2 million for the year ended December 31, 2017, an increase of 37%. This increase is mainly due to the expansion of the work force in our research and development departments and, start-up costs for the Phase III clinical trial for ATIR101, and higher consultancy expenses mainly for our submission of a Marketing Authorization Application ("**MAA**") with the EMA for ATIR101.

General and administrative expense

General and administrative expenses increased from €4.9 million for the year ended December 31, 2017 to €7.7 million for the year ended December 31, 2018, an increase of 57%. This increase was mainly due to increased headcount across all departments to support the continued growth of the company, increased share-based payments as a result of share options and consultancy expenses for business development, market access and strategic projects.

General and administrative expenses increased from €3.2 million for the year ended December 31, 2016 to €4.9 million for the year ended December 31, 2017, an increase of 53%. This increase was primarily due to higher consultancy expenses related to funding activities, severance pay to our former CEO and increased share-based payments as a result of share options and SARs granted to employees and management in 2017.

Operating loss

Operating loss increased from €16.1 million for the year ended December 31, 2017 to €25.2 million for the year ended December 31, 2018, an increase of 56%. This increase was due to a higher level of expenses for research and development and higher general and administrative expenses.

Operating loss increased from €11.4 million for the year ended December 31, 2016 to €16.1 million for the year ended December 31, 2017, an increase of 41%. This increase was due to a higher level of expenses for research and development and higher general and administrative expenses.

Net finance expenses

Net finance expenses increased from €0.9 million for the year ended December 31, 2017 to €4.6 million for the year ended December 31, 2018, an increase of 405%. This was primarily due to increased interest expenses on loans of €2.0 million, interest expenses on lease liabilities of €0.5 million, and a net foreign exchange loss of €1.0 million for the year ended

December 31, 2018, compared to a net foreign exchange gain of €0.7 million for the year ended December 31, 2017. The major driver of foreign exchange results are unrealized exchange differences on intragroup positions as well as the obligations under the Hospira Termination and Royalty Agreement, which are characterized as a loan. The adjustment of the carrying value of our obligations under the Hospira Termination and Royalty Agreement that are characterized as a loan resulted in a gain of €1.3 million for the year ended December 31, 2018, compared to a gain of €0.6 million for the year ended December 31, 2017. Loss in fair value of derivatives for the year ended December 31, 2018 was €0.6 million compared to a minor gain for the year ended December 31, 2017.

Net finance expenses decreased from €3.4 million for the year ended December 31, 2016 to €0.9 million for the year ended December 31, 2017, a decrease of 73%. This was primarily due to a loss of €2.2 million in the year 2016 from adjusting the carrying value of our obligations under the Hospira Termination and Royalty Agreement, which are characterized as a loan, compared to a gain of €0.6 million from adjusting the carrying value of this loan for the year ended December 31, 2017. Deterioration of the carrying value of this loan involves significant judgments and estimates by management with respect to future cash flows under the Hospira Termination and Royalty Agreement.

Income tax expense

We have a history of losses. We expect to continue incurring losses in the near future as we continue to invest in development of our lead product candidate, ATIR101, and potentially further advance our other existing programs or add new programs. Consequently, we do not have any deferred tax asset on our statement of financial position. However, in 2016, 2017 and 2018, we recognized income tax expenses as a result of certain intercompany transactions.

Profit (loss) for the period

Loss for the period increased from €17.0 million for the year ended December 31, 2017 to €29.8 million for the year ended December 31, 2018, an increase of 75%. This increase was a result of higher operating expenses and higher net finance expenses.

Loss for the period increased from €14.8 million for the year ended December 31, 2016 to €17.0 million for the year ended December 31, 2017, an increase of 15%. This increase was a result of higher operating expenses and lower net finance expenses.

6.4 Significant change to our financial or trading position since December 31, 2018

On April 17, 2019, we announced that Kiadis Pharma N.V., its wholly owned subsidiary CST, CytoSen and Philip R. McKee as representative of the CytoSen shareholders have entered into a binding agreement – the CytoSen Acquisition Agreement - regarding the acquisition by us of the entire share capital of CytoSen, subject to the approval of the General Meeting - which approval has been granted on May 29, 2019 - and customary closing conditions. See paragraph 7.3 for further information on CytoSen and the Transaction.

On May 30, 2019 we launched an equity raising by means of a private placement of Shares that raised €25.4 million in net proceeds (€27.6 million in gross proceeds). For more information on this private placement which is expected to complete on or about June 4, 2019, we refer to the Summary and Securities Note that is made generally available in relation to the aforementioned private placement.

6.5 Liquidity and capital resources

We incurred losses of €14.8 million during the year ended December 31, 2016, €17.0 million during the year ended December 31, 2017 and €29.8 million during the year ended December 31, 2018. We will not receive any revenues or net cash flows from sales of our product candidates until they have been approved by regulatory authorities and commercialized successfully. We do not anticipate commercializing any of our product candidates before the end of 2019, if at all.

Since inception, we have not generated any revenues or net cash flows from sales of our product candidates. ATIR101, has not yet been approved for marketing. To date, we have relied principally on the issuance and sale of equity and debt securities to finance our operations, internal growth and selective acquisitions of businesses, technologies and other assets. For the periods presented, we raised the following capital:

- In 2016, we raised an additional €1.6 million in equity.
- In June 2017, we raised a further €4.6 million in net proceeds (€5.0 million in gross proceeds) in equity.
- In September 2017, we issued Shares upon the exercise of warrants and received €2.4 million in cash.
- In October 2017 we raised another €16.2 million in net proceeds (€18.0 million in gross proceeds) in equity.
- In January and February 2018, we issued Shares upon the exercise of warrants and received €1.7 million of cash in total.
- In March 2018, we raised €21.6 million in net proceeds (€23.4 million in gross proceeds) in equity, and
- in October 2018, we raised another €29.1 million in net proceeds (€31.2 million in gross proceeds) in equity.

In August 2017, we obtained a debt facility of up to €15 million from Kreos Capital – the First Kreos Capital Facility Agreement. The first tranche of €10 million of this facility was drawn down in August 2017, and the second tranche of €5 million was drawn down in October 2017. In July 2018, we obtained a second debt facility of up to €20 million from Kreos Capital – the Second Kreos Capital Facility Agreement. The first tranche of €5 million of this facility was drawn down in July 2018. The remainder of €15 million is not available to us anymore. It had to be drawn down by March 31, 2019 and was conditional upon us having obtained a positive opinion of the CHMP to the European Commission recommending we receive marketing authorization for ATIR101 by then.

As of December 31, 2018, we had cash and cash equivalents of €60.3 million and as of the Registration Document Date, we had cash and cash equivalents of approximately €42 million. We expect that the level of our expenses, in particular our research and development expenses and sales and marketing expenses, will be higher in 2019 than in 2018 as we ramp up our Phase III clinical trial for ATIR101, progress development of CSTD002-NK in the event that the acquisition of CytoSen is completed, and build up our capabilities in advance of the anticipated regulatory approval and commercial launch of ATIR101. Based on our operating plans, we believe that in the event that the Transaction completes and our

operations will include those of CytoSen, or in the event that the Transaction does not complete, existing cash and cash equivalents will allow us to continue operating the business in either case into the first quarter of 2020. We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. For example, we may require additional capital resources due to significant uncertainty associated with and time required to complete the clinical trials. We may also need to raise additional funds more quickly if we choose to expand our development activities or if we consider acquisitions. Factors that could influence our future capital requirements and the timing thereof include:

- the progress and cost of our clinical trials, including payments of patient cost, clinical investigator cost and payments to CROs that are assisting with our 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 any future 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 supplies used in our manufacturing process;
- the cost and timing of establishing our own and contracted production capacities and obtaining sufficient quantities of our products for clinical trials;
- the costs associated with process optimizations;
- the repayment obligations under the Kreos Capital Facility Agreements and the loan provided by the University of Montreal;
- the royalty and milestone obligations to Hospira and the University of Montreal;
- the terms and timing of any collaborative, licensing and other arrangements that we 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 commercialization of our product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings, convertible loans, warrants, collaborations or other means. We may consider raising additional capital to take advantage of favorable market conditions or other strategic considerations even if we have sufficient funds for planned operations.

To the extent that we raise additional funds by issuance and sale of equity or equity-linked securities, Shareholders will experience dilution. Debt financings, if available, may subject us to financial and other restrictive covenants that limit our ability to engage in activities that we may believe to be in our 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 our control. If we are unable to raise additional funds when needed, we may be required to delay, reduce, or terminate some or all of our development programs and clinical trials. We may also be required to sell or license to others technologies or clinical product candidates or programs that we would prefer to develop and commercialize ourselves.

6.6 Capital expenditures and principal investments

The following table sets forth our capital expenditures for the years ended December 31, 2018, 2017 and 2016.

	Year ended December 31		
	2018	**2017**	**2016**
	Audited		
	(in € thousands)		
Laboratory equipment	716	152	250
Other tangible assets	595	91	103
Capital expenditure	1,311	**243**	**353**

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 and have been financed out of our available cash. Other tangible assets are IT equipment and furniture & fittings and leasehold improvements. For the period from December 31, 2018 up to the Registration Document Date investments amount to €0.9 million.

Based on our current operations, we expect that our 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.

6.7 Cash Flows

Comparison for the three years ended December 31, 2018, 2017 and 2016.

The following table sets forth our primary sources and uses of our liquid assets for each of the periods set forth below:

	For the year ended December 31		
	2018	**2017**	**2016**
	Audited		
	(in € thousands)		
Net cash used in operating activities	(24,167)	(15,873)	(14,311)
Net cash used in investing activities	(1,122)	(75)	(242)
Net cash from financing activities	55,694	31,304	426
Net increase (decrease) in cash and cash equivalents	**30,405**	**15,356**	**(14,127)**
Cash and cash equivalents at beginning of period	**29,906**	**14,559**	**28,666**
Effect of exchange rate fluctuations on cash held	3	(9)	20
Cash and cash equivalents at end of period	**60,314**	**29,906**	**14,559**

Net cash used in operating activities

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

Net cash used in operating activities was €24.2 million for the year ended December 31, 2018, an increase of €8.3 million compared to €15.9 million for the year ended December 31, 2017, and €14.3 million for the year ended December 31, 2016, primarily reflecting the increase in operating losses and higher interest payments offset by a positive working capital movements.

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 year ended December 31, 2018 was €1.1 million compared to €0.1 million for the year ended December 31, 2017 and €0.2 million for the year ended December 31, 2016, mainly due to higher capital expenditures related to laboratory equipment and lease hold improvements.

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 year ended December 31, 2018, cash from financing activities amounted to €55.7 million compared to cash from financing activities of €31.3 million for the year ended December 31, 2017 and €0.4 million for the year ended December 31, 2016. In January and February 2018, we issued new Shares upon the exercise of warrants and received €1.7 million in cash. In March 2018, we issued new Shares for cash and raised €23.4 million in gross proceeds, and in October 2018, we issued new Shares for cash and raised €31.2 million in gross proceeds.

On July 31, 2018, we entered into a second debt facility of up to €20 million with Kreos Capital - the Second Kreos Capital Facility Agreement. The first tranche of €5 million – Tranche A – was drawn down immediately after execution of the Second Kreos Capital Facility Agreement. The remainder of €15 million is not available to us anymore. It had to be drawn down by March 31, 2019 and was conditional upon us having obtained a positive CHMP opinion to the European Commission recommending we receive marketing authorization for ATIR101 by then.

During the year ended December 31, 2018 we received proceeds from the exercise of warrants for the amount of €2.9 million.

For the year ended December 31, 2017, cash from financing activities amounted to €31.3 million compared to cash from financing activities of €0.4 million for the year ended December 31, 2016. In the year ended December 31, 2016, we issued new Shares for cash and raised €1.6 million in gross proceeds, and in the year ended December 31, 2017, we issued new Shares for cash and raised €23.0 million in gross proceeds. In the third quarter of 2017, we issued new Shares for cash upon the exercise of warrants and raised €2.4 million. In addition, in August 2017, we restructured our debt and entered into the First Kreos Capital Facility Agreement with Kreos Capital, which is a loan consisting of two tranches.

The first tranche of €10 million – Tranche A – was drawn down immediately after execution of the First Kreos Capital Facility Agreement. Of this €10 million drawn, we used €5.3 million to fully repay the loans from the Netherlands Enterprise Agency ("**RVO Nederland**"). The second tranche of €5 million – Tranche B – was drawn down in October 2017.

6.8 Contractual obligations and commitments

The following table sets forth information relating to our contractual obligations and commitments as of December 31, 2018:

	Payments due by Period				
	Total	**< 1 year**	**1 to 3 years**	**3 to 5 years**	**> 5 years**
	(in € thousands)				
Lease commitments	13,187	1,630	2,947	2,870	5,740
First Kreos Capital Facility Agreement, Tranche A	9,460	3,840	5,620	-	-
First Kreos Capital Facility Agreement, Tranche B	5,530	1,920	3,610	-	-
Second Kreos Capital Facility Agreement, Tranche A	5,924	1,413	3,788	723	-
Total	**34,101**	**8,803**	**15,965**	**3,593**	**5,740**

The table above does not include potential milestone fees, sublicense fees, royalty fees, contingent loans and loans for which the repayment schedule has not been fixed, licensing maintenance fees, and reimbursement of patent maintenance costs that we may be required to pay under agreements we have entered into with certain institutions to license intellectual property. We have not included such potential obligations in the table above because they are contingent upon the occurrence of future events and the timing and likelihood of such potential obligations are not known with certainty. For further information regarding these agreements and amounts that could become payable in the future under these agreements, see paragraph 7.11 below.

On April 17, 2019, we announced that Kiadis Pharma N.V., its wholly owned subsidiary CST, CytoSen and Philip R. McKee as representative of the CytoSen shareholders have entered into a binding agreement – the CytoSen Acquisition Agreement - regarding the acquisition by us of the entire share capital of CytoSen, subject to the approval of the General Meeting - which approval has been granted on May 29, 2019 - and customary closing conditions. See paragraph 7.3 for further information on CytoSen and the Transaction.

RVO Nederland

In the period 2009 through 2011, we obtained investment loans for the development of ATIR granted by RVO Nederland. A total amount of €5.3 million was recorded as a loan from RVO Nederland, outstanding at the end of June 2017, including accrued interest, which consisted of two parts: (i) a €3.3 million loan, bearing interest of 11.4% per annum, and (ii) a €2.0 million loan, bearing interest of 10.0% per annum. We repaid these two loans in full in August 2017 using €5.3 million of the €10 million loan received from Kreos Capital pursuant to Tranche A of the First Kreos Capital Facility Agreement.

Kreos Capital Facility Agreements

On August 17, 2017, we entered into a debt facility of up to €15 million with Kreos Capital - the Kreos Capital Facility Agreement.

The First Kreos Capital Facility Agreement is a loan consisting of two tranches. The first tranche of €10 million – Tranche A – was drawn down immediately after execution of the First Kreos Capital Facility Agreement. Of the €10 million received, we 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 us raising at least €20 million of additional funds before July 1, 2018. It was drawn down in October 2017, following the October 2017 equity raise.

On July 31, 2018, we entered into a second debt facility of up to €20 million with Kreos Capital - the Second Kreos Capital Facility Agreement.

The Second Kreos Capital Facility Agreement is a loan consisting of two tranches. The first tranche of €5 million – Tranche A – was drawn down immediately after execution of the Second Kreos Capital Facility Agreement. The remainder of €15 million is not available to us anymore. It had to be drawn down by March 31, 2019 and was conditional upon us having obtained a positive CHMP opinion to the European Commission recommending we receive marketing authorization for ATIR101 by then.

Tranche A of each of the Kreos Capital Facility Agreements has a 45-month term from drawdown. Tranche A of the First Kreos Capital Facility Agreement has an implied 10% annual fixed interest rate and Tranche A of the Second Kreos Capital Facility Agreement has an implied 9% annual fixed interest rate. Interest payments are to be made during the first 9 months, with the remaining 36 months amortizing in equal monthly instalments comprising principal and interest. Tranche B of the First Kreos Capital Facility Agreement has a 48-month term from drawdown and an implied 10% annual fixed interest rate. Interest payments are to be made during the first 12 months, with the remaining 36 months amortizing in equal monthly instalments comprising principal and interest. In relation to each of the Kreos Capital Facility Agreements, an end of loan payment equal to 5% of the amount drawn down is due at maturity and in the event of early repayment of all or any part of either facility a prepayment fee is payable by us.

Our obligations under the Kreos Capital Facility Agreements are secured for the benefit of Kreos Capital by means of security rights over our assets, including our 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 Agreements also include customary undertakings and restrictions. These include a restriction on granting liens, 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, and on any amalgamations, demergers, mergers or corporate reconstructions, 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 our 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 Agreements remain outstanding, we are not entitled to make any dividend payment or other distributions to our Shareholders.

The loans provided under the Kreos Capital Facility Agreements 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 us by (i) obtaining the power to (a) to cast or control the casting of more than half the votes that can be cast at a general meeting of shareholders, (b) appoint or remove all or the majority of the directors or (c) give binding directions with respect to our operating and financial policies or (ii) beneficially holding more than 50% of our issued share capital.

In connection with the First Kreos Capital Facility Agreement, 253,617 warrants were 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. In connection with the Second Kreos Capital Agreement, 41,212 warrants were issued to Kreos Expert at closing of the debt facility in July 2018.

Hospira

On January 31, 2012, we and Hospira entered into the Hospira Termination and Royalty Agreement which terminated the Hospira Exclusive License Agreement between Hospira and us. Pursuant to the terms of the Hospira Termination and Royalty Agreement, we have agreed to use, and cause our affiliates and licensees to use, commercially reasonable efforts to commercialize certain cell-based products, including products based on the ATIR platform, worldwide until we repay the $24.5 million we received from Hospira in connection with the Hospira Exclusive License Agreement plus the Reimbursement Amount. As of December 31, 2018, the repayment amount owed to Hospira is $27.2 million. As part of the repayment, there is a potential milestone payment of $3 million upon the earlier of (i) the execution of the first license agreement with a third party under which we grant such third party a license under certain intellectual property to commercialize certain cell-based products, including products based on the ATIR platform, or (ii) the first commercial sale of such products by us, our affiliates or our licensees. In addition, we must pay Hospira a mid-single digit percentage royalty on worldwide net sales of such products until we have paid the Reimbursement Amount, after which we must pay Hospira a low-single digit percentage royalty on net sales of such products in all countries (except for those in North America and South America, China, Mongolia, and Antarctica).

We have determined that our repayment obligations under the Hospira Termination and Royalty Agreement with regard to the Reimbursement Amount should be characterized as a loan. After initial recognition at fair value, the carrying amount of the loan is restated at each reporting date if there has been a change in the estimated underlying cash flows. In the statement of financial position as of December 31, 2018, the carrying amount of the loan is €9.6 million. The low-single digit percentage royalty obligations mentioned above are not presented in the statement of financial position.

University of Montreal

Under the Montreal Agreement, we committed to pay the University of Montreal royalties of a mid-single digit percentage of revenues of (i) net sales of certain cell-based products, including products based on the ATIR platform, and (ii) payments we receive in connection with any sublicenses we grant to third parties, for the term of our or their commercialization of such products. In addition, under a letter agreement with the University of Montreal and the Hospital Maisonneuve-Rosemont dated September 19, 2012, we agreed to pay the University of Montreal an amount of $750,000, subject to a low-single digit percentage interest amount per annum as of January 1, 2011, as a royalty fee in relation to the sublicense granted to Hospira. The royalty fee will be paid by temporarily increasing the

royalty rate under the Montreal Agreement on net sales of licensed products from a mid-single digit percentage to a high-single digit percentage until the royalty fee is paid off, after which the royalty rate will return to the original royalty rate. In addition, 50% of the royalty fee must be paid if we grant a sublicense to any of the licensed products under the Montreal Agreement so long as the sublicense includes an upfront fee and 100% of the royalty fee must be paid upon our undergoing a change of control. As of December 31, 2018, an amount of €0.9 million related to this royalty fee is recorded as loan, including accrued interest.

Main lease commitments

In December 2017, we signed a new sublease contract for an existing office, laboratory, warehousing and commercial manufacturing facility in Amsterdam in order to relocate our head offices and laboratories, establish our own manufacturing facilities, and expand our activities. The sublease term is 10 years starting January 1, 2018. Sublease payments over this 10-year period total €9.2 million, to be increased with the yearly indexation and VAT and advance payments for lease related services amount to €5.1 million. We make rental payments in advance, and there is a balancing payment or credit at year end to reflect final variable amounts for the year.

In April 2019, we signed a lease contract for approximately 1,250 m^2 additional office space in our Amsterdam head offices. The lease term is 10 years starting June 1, 2019. Lease payments over this 10-year period total €2.0 million, to be increased with the yearly indexation and VAT and advance payments for lease related services amount to €0.4 million. We make rental payments in advance, and there is a balancing payment or credit at year end to reflect final variable amounts for the year.

Off-Balance Sheet Arrangements

In the year ended December 31, 2018, we entered into various contracts with services and products still to be delivered for a total amount of approximately €4.5 million.

6.9 Quantitative and qualitative disclosures about market risk

We are exposed to several financial risks caused by, for example, the following factors: (i) changes to market prices in debt and capital markets and (ii) fluctuation of exchange rates and interest rates. Our risk management principles focus on the unpredictability of the financial markets and aim at minimizing any undesired impacts on our financial result. Our members of the Management Board define our general risk management principles and provides operational guidelines concerning specific areas including but not limited to foreign exchange risk, interest rate risk, credit risk, use of derivatives and investment of our liquid assets.

Foreign exchange risk

Our functional currency is the euro. We operate via our Dutch entities, but we also conduct business in North America. We therefore have expenses denominated in Canadian dollars and U.S. dollars in connection with, among other things, our sponsored clinical trials, process development, loans and the maintenance of our intellectual property portfolio. We also have intercompany financing between companies within our corporate group and have U.S. dollar-denominated loans.

Upon preparing consolidated financial statements, our 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 we will be able to effectively manage our currency risk to minimize our impact on our business. Our exposure to foreign currency translation gains and losses may change over time if we expand our operations and could have a material adverse effect on our business, results of operations or financial condition. We do not currently engage in any hedging activities to limit our exposure to exchange rate fluctuations.

Liquidity risk

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

Credit risk

Credit risk is the risk of financial loss if a customer or counterparty to a financial instrument fails to meet our contractual obligations. We attempt to limit our exposure to credit risk by maintaining our bank accounts and short-term deposits with well-established banks.

6.10 Critical accounting estimates and judgments

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

We review 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 our 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 recognized if the carrying amount of an asset exceeds our recoverable amount. Impairment losses are recognized in profit or loss. The recoverable amount of an asset is the greater of our value in use and our 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 amortized 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.

Income tax expense

We exercise judgment in determining the extent of realization 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 utilize these net operating losses, these net operating losses have not been recognized 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 our financial position and results of operations.

As of December 31, 2018, we had deferred tax assets in respect of gross cumulative tax losses of €93.7 million in the Netherlands and €23.5 million in Canada. We have concluded that our deferred tax assets exceed our deferred tax liabilities. The deferred tax assets have been recognized only to the extent they are used to offset the deferred tax liabilities. We have not recognized a deferred tax asset for the remaining part of the unused tax losses.

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 recognized 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 recognized as an expense will be adjusted to reflect the latest estimate of the number of options that will vest. At each reporting date, we will revise our estimates of the number of options which are expected to vest. We recognize the impact of the revision of original estimates, if any, in the income statement and make 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 remeasured at each reporting date. The amount recognized as an expense for cash-settled share-based payments reflects the estimated change in fair value of the corresponding liability at the reporting date. We have adopted an employee share option and stock appreciation rights plan under which key management personnel and employees may be granted share options and/or SARs.

Derivatives

We exercise judgment in determining the estimated value of derivatives. For derivatives that are level 3 financial liabilities or inputs not based on observable market data, management has to make assumptions about significant unobservable inputs used to calculate fair values, using the Black, Scholes and Merton option pricing model.

Loans and borrowings

We exercise judgment in determining which financial liabilities qualify as loans and subsequently exercise 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.

Lease liabilities

We have early adopted IFRS 16 'Leases' as of January 1, 2018. The adoption of IFRS 16 'Leases' has a material impact on the interim financial statements. We have implemented

IFRS 16 by applying the modified retrospective method, meaning that the comparative numbers in the financial statements have not been restated to reflect the impact of IFRS 16.

We have elected the following practical expedients and applied these consistently to all of its leases:

- we did not reassess whether any expired or existing contracts are or contain leases;
- we excluded initial direct costs for any existing leases; and
- we did not apply the recognition requirements to short-term leases.

On adoption of IFRS 16, we recognized lease liabilities in relation to leases which had previously been classified as 'operating leases' under the principles of IAS 17 Leases. These liabilities were measured at the present value of the remaining lease payments, discounted using our incremental borrowing rate (IBR). Our IBR was determined using the following input parameters: the lease term, our credit rating, a risk-free interest rate corresponding to the lease term, and a lease specific adjustment considering the 'secured borrowing' element of the leases. The weighted average IBR applied to the lease liabilities on January 1, 2019 was 7.38 percent.

On January 1, 2018, the date of initial application, we recognized our lease liabilities in our statement of financial position and recognized corresponding Right-of-Use assets presented under Property, plant and equipment for the same amount of €6.9 million.

7. BUSINESS

7.1 Summary

We are building a fully integrated biopharmaceutical company to maximize the potential of ATIR, our proprietary cell-based immunotherapy platform. Our lead program, ATIR101, is focused on helping improve outcomes for patients with blood cancers who are in urgent need of stem cell transplants. ATIR101 is a patient-specific T-cell therapy designed to be delivered following a haploidentical hematopoietic stem cell transplant (HSCT), in order to support the patient's newly transplanted immune system before it becomes fully functional. We manufacture ATIR101 ex vivo from donor T-cells by selectively depleting harmful donor T-cells that can attack patient tissue and cause Graft versus Host Disease (GVHD), while retaining those T-cells that fight relapse and infections. We believe that ATIR can improve haploidentical HSCT outcomes and treatment options, thereby enabling the use of haploidentical HSCT in a broader range of patient groups and a broader range of diseases of the blood or immune system. We believe that as therapies, like ATIR101, are approved, the number of patients receiving haploidentical HSCTs will increase significantly, as physicians move away from matched unrelated donor transplants due to the time and consequences of waiting to find a donor. We estimate that, over time, a substantial target population could potentially benefit from ATIR as an adjunctive therapy to haploidentical HSCT. This reflects the continued growth of allogeneic transplantations from the current >30,000 a year in the EU and the US, and a continuation of the current rapid growth of haploidentical HSCTs, from the estimated 3,800 haploidentical HSCT performed in 2016.

We are initially developing our lead product candidate, ATIR101, for use in conjunction with haploidentical HSCT for adult blood cancers to address key limitations of haploidentical HSCT, without prophylactic immunosuppression and its associated morbidity and mortality. Based on the positive results from our single dose Phase II CR-AIR-007 study, we submitted a Marketing Authorization Application (MAA), to the EMA, in April 2017 for approval of ATIR101 as an adjunctive treatment in haploidentical HSCT for high risk adult hematological malignancies. We submitted responses to the EMA's Day 180 List of Issues in August 2018. In October 2018, we received a second Day 180 List of Issues which we have answered with a submission date of May 22, 2019. The second Day 180 List of Issues is a common step in the EMA review process. Addressing the second Day 180 List of Issues did not require new experimental or new clinical data to be generated, and was focused on one remaining major observation. We have thoroughly analyzed this observation and as part of our answers have created multiple analyses of existing clinical data to address this observation, including analyses of various (pooled) ATIR and historical control data. We aim to receive a CHMP opinion in 2019 – in June 2019 at the earliest - which, if positive, would enable us to receive a conditional marketing approval from the European Commission, followed by commercial use of ATIR101 in a first patient in a European country at the end of 2019. Conditional marketing approval is a regulatory pathway in the EU that permits commercialization subject to completing specified obligations, such as the performance of a confirmatory clinical trial and annual renewals.

The status of ATIR101 for adult blood cancers is as set forth in the table below.

Region	Phase I	Phase II	Phase III	Filing	Catalysts	Commercial Rights	Comments
EU	Orphan Drug Designation				• EU Approval '19 • EU Launch: one patient, late '19	Kiadis pharma	Received EMA Day 180 2nd List of Issues (9/2018)
US	Orphan Drug & RMAT Designations				• Phase 3 interim read out ('21; 105 events)	Kiadis pharma	RMAT 'breakthrough' designation (9/2017; FDA access, priority review, support)

*Filing completed in the European Union based on Phase II clinical data for conditional marketing approval.

In December 2017, we commenced an international, multicenter, randomized and controlled Phase III clinical trial of ATIR101 against the PTCy protocol (post-transplant cyclophosphamide (PTCy) or 'Baltimore' protocol), the main protocol used to perform a haploidentical HSCT. The trial will be performed in 250 patients with acute leukemia and myelodysplastic syndrome ("**MDS**"), at approximately 50 sites in the United States, Canada, Europe and certain additional countries. The trial's primary endpoint is GVHD-Free and Relapse-Free Survival (GRFS), which is defined as survival without acute GVHD grade III/IV, without chronic GVHD requiring systemic immunosuppression, and without relapse, and is a composite endpoint widely used in HSCT trials that captures survival, quality of life and future prognosis. The first patient was enrolled in December 2017. An interim analysis of the composite primary endpoint is planned when at least 105 events of either graft-versus-host disease, relapse or death, and Kiadis estimates this interim analysis to occur in 2021 after completion of enrollment in the study.

If successful, we intend to use data from this Phase III trial as a basis for the filing of a Biologics License Application ("**BLA**") with the FDA. The FDA has informed us that because GRFS is a novel endpoint, it would review acceptability of GRFS in connection with our marketing application. We also plan to use data from the Phase III trial to support the conversion of the anticipated conditional marketing approval of ATIR101 in Europe into a standard marketing approval. ATIR101 received regenerative medicine advanced therapy (RMAT) designation from the FDA in September 2017, which provides benefits that are materially equivalent to a breakthrough designation from the FDA. In addition, ATIR101 has been granted multiple orphan drug designations both in the European Union and the United States.

7.2 Overview

HSCT is an established treatment for blood cancers and inherited blood diseases in which the diseased bone marrow, the underlying root cause of the disease, is first ablated, or destroyed, with chemotherapy alone and, in some cases, radiation therapy with or without chemotherapy and then replaced with a graft of donor hematopoietic stem cells, from which the new immune and blood system of the patient will be reconstituted, and mature donor leukocytes, or white blood cells. Approximately 84% of all HSCT is performed in adults. While approximately 55% and 52% of allogeneic HSCT is performed in patients with acute leukemia in Europe and the United States, respectively, approximately 85% and 84% of allogeneic HSCT is performed in patients with blood cancers and related conditions more broadly in Europe and the United States, respectively. Despite being potentially curative, use of HSCT is constrained by lack of donors, low effectiveness and the inherent risk of causing GVHD in patients. GVHD occurs when certain T-cells from the donor (i.e., the graft) recognize the patient's tissues as foreign and attack the patient (i.e., the host). GVHD can

cause rash and severe skin disease, ulceration, severe GI tract disease, liver cirrhosis, immunodeficiency, infections, muscle constriction, lung disease, thyroid dysfunction and eye disease. In its acute form, GVHD can be life threatening, and as a chronic disease it can be severely debilitating.

In order to mitigate the risk of GVHD, HSCT has been historically preferentially performed with a graft from a genetically matched donor. According to an article published in the New England Journal of Medicine in 2014, however, depending on genetic background, between approximately 25% (*e.g.* White European) and 80% (*e.g.* African American) of patients who are eligible for HSCT will not find an adequately matched donor in time. In 2012, it was estimated that 13,500 eligible patients in the United States failed to receive a stem cell transplant. Use of genetically half-matched, or haploidentical, donors (such as parents, children and, in many cases, other relatives of the patient) can address donor availability limitations. However, mature donor T-cells of a half-matched donor in a haploidentical HSCT may carry the risk of severe and potentially lethal GVHD.

To mitigate risk of GVHD in haploidentical HSCT caused by mature T-cells, clinicians originally developed a protocol in which mature T-cells are removed ex vivo and only stem cells are infused (T-cell depleted haploidentical HSCT); however, while T-cell depleted haploidentical HSCT has resulted in significantly lower rates of GVHD, this approach was hampered by high infections and nonrelapse mortality (NRM).

In order to address these outcomes, the PTCy protocol, originating at Johns Hopkins University in Baltimore, MD, United States, and thus also commonly referred to as the Baltimore protocol, was developed for haploidentical HSCT. Under the PTCy protocol, a transplant is performed with a graft that includes both stem cells and mature T-cells being infused into the patient, causing patient-specific T-cells to become activated. Activated donor T-cells are then depleted with cyclophosphamide, a chemotherapy agent, immediately after the transplant in the patient and subsequently suppressed with prophylactic immunosuppression. A recent retrospective literature review published in Advances in Hematology shows that the PTCy protocol resulted in a lower rate of GVHD and a higher relapse rate than genetically matched unrelated donors ("**MUD**") HSCT, with similar survival. Moreover, with haploidentical HSCT, patients do not have to wait for a matched donor, which many may not find at all. As a result of these benefits, the number of haploidentical transplants has grown threefold in four years.

Although the use of the PTCy protocol has expanded the use of HSCT, the PTCy protocol's use of cyclophosphamide and immunosuppression is associated with secondary malignancies, severe toxicities and compromises the Graft-versus-Leukemia ("**GVL**") effect of transplanted donor cells. At the one year follow-up point, we estimate, based on a review of available literature, that almost 30% of PTCy protocol patients relapse and approximately a quarter of patients suffer from chronic GVHD. High rates of relapse and GVHD are also reflected in the long term GRFS outcomes of approximately a third for PTCy patients, as reported in publications by Solh 2016 (Northside, Atlanta) and McCurdy 2017 (Johns Hopkins, Baltimore). We believe new haploidentical HSCT approaches that provide clinically meaningful benefits over the PTCy protocol would further contribute to the growth of haploidentical HSCT procedures.

Our lead product candidate, ATIR101, is an adjunctive treatment to a haploidentical T-cell depleted HSCT. We are initially developing ATIR101 for use in conjunction with haploidentical HSCT for adult blood cancers to address key limitations of haploidentical HSCT. With ATIR101 as adjunctive treatment to a haploidentical T-cell depleted HSCT, we believe we can improve overall survival ("**OS**") and NRM of a haploidentical T-cell depleted

HSCT without ATIR101, while retaining lower relapse and GVHD rates, without prophylactic immunosuppression and its associated mortality or morbidity. Furthermore, we have commenced a Phase III trial that is designed to show superiority in GRFS of ATIR101 compared to the PTCy protocol.

In our international Phase II CR-AIR-007 trial, a single dose of ATIR101 given in 23 patients after a T-cell depleted haploidentical HSCT led to a reduction in the primary endpoint, transplant related mortality ("**TRM**") (which is referred to interchangeably with NRM), at six months (reduced from 37% to 13%, modified intent to treat ("**MITT**"), the primary endpoint of the trial), and a clinically meaningful increase in overall survival (OS), at 12 months (increased from 20% to 61%, MITT) when compared with data from our non-interventional CR-AIR-006 trial, which observed a cohort of patients who received only a T-cell depleted haploidentical HSCT. These results, if observed in a randomized, controlled clinical trial, would represent a p-value of 0.0035. P-value is a conventional statistical method for measuring the statistical significance of clinical trial results. A p-value of less than 0.05 is generally considered to represent statistical significance, meaning that there is a less than five percent likelihood that the observed results occurred by chance. Even though patients did not receive prophylactic immunosuppressants, the single dose of ATIR101 in CR-AIR-007 did not cause severe acute GVHD, and only one patient developed chronic GVHD. In our subsequent CR-AIR-008 trial, a single dose of ATIR101 after a T-cell depleted haploidentical HSCT demonstrated higher survival than in CR-AIR-007, while only two patients developed acute GVHD grade III/IV after infusion of a single dose of ATIR101. GRFS at 12 months in CR-AIR-007 was 54% and in CR-AIR-008 was 55% (ITT, single dose), and GRFS at 12 months in CR-AIR-007 pooled with CR-AIR-008 was 53% (ITT, single dose).

In response to 120 Day List of Questions from the EMA, we have also performed and submitted to the EMA additional analyses, pooling results from CR-AIR-007 with those from patients in CR-AIR-008 who received a single dose of ATIR101. We have compared these results to those for patients that received a T-cell depleted haploidentical HSCT without ATIR from CR-AIR-006 pooled with CR-AIR-004. We believe that pooling of the studies is appropriate because the design of the studies is aligned, with similar in/exclusion criteria and overlapping centers participating. Comparison of the demographics and baseline disease characteristics confirms that the patient populations of the studies were similar. In the pooled results from CR-AIR-007 trial with those from patients in CR-AIR-008 who received a single dose of ATIR101, a single dose of ATIR101 given in 37 patients after a T-cell depleted haploidentical HSCT led to a clinically meaningful reduction in the primary endpoint, TRM, at six months (reduced from 36% to 13%, MITT), and a clinically meaningful increase in OS at 12 months (increased from 23% to 58%, ITT) when compared with pooled data from our non-interventional CR-AIR-006 trial and CR-AIR-004. These results, if observed in a randomized, controlled clinical trial, would represent a p-value of 0.005 (OS 0-12 months) and 0.02 (NRM 0-6 months). In the pooled results, the average rate of different grades of GVHD in the T-cell depleted haploidentical HSCT with ATIR101 and without ATIR101 were similar. The analyses demonstrate that adding ATIR101 to a T-cell depleted HSCT provides clinically meaningful benefits to OS and NRM, without increasing GVHD. Further details on the analysis are set out in the below table.

Phase 2 Studies in AML/ALL/MDS

CR-AIR-007: Single dose ATIR

- Open label single arm; 2013-2018
- 23/26 patients (MITT/ITT*)
- 2 year follow up
- Sites in BE, CA, GE, UK

CR-AIR-008: Single dose ATIR and two doses ATIR**

- Open label single arm; 2015-2018 (ongoing)
- 9/11 single dose; 6/6 patients two doses (MITT/ITT)
- 3 patients still at risk
- 1 year follow up
- Sites in CA, BE, GE, UK

CR-AIR-004: Historical Control, No ATIR

- Open label single arm; 2009-2012
- 40 patients (29 matched to CR-AIR-007)
- Sites in BE, CA, GE, NL, UK, US

CR-AIR-006: Historical Control, No ATIR

- Observational cohort, EBMT registry; 2006-2013
- 35 patients (all matched to CR-AIR-007)
- 1 year follow up

* MITT: Modified Intent to Treat (transplanted and ATIR); ITT: Intent to Treat (transplanted); ** CR-AIR-008 was designed to test safety of second dose, but due to higher then expected GVHD it was decided to stop infusing second dose (in accordance with protocol)

ATIR Phase 2 Data	T-cell depleted (CD34+) *with* single dose ATIR (n=37)*			T-cell depleted (CD34+) *without* ATIR (n=64)*		
	CR-AIR-007	CR-AIR-008	007-008	CR-AIR-006	CR-AIR-004	004-006
1 year post HSCT	**(ITT n=26)**	**(ITT n=11)**	**(ITT n=37)**	**(n=35)**	**(n=29)**	**(n=64)**
Overall Survival	58% (42-80)	64% (41-100)	58% (44-77)	20% (10-39)	27% (13-54)	23% (14-37)
Non-relapse mortality	35%	27%	33%	66%	59%	63%
Relapse-related mortality	8%	9%	8%	15%	14%	14%
Relapse	8%	9%	8%	NA	NA	NA
Acute GVHD grade II-IV	19%	27%	21%	20%	18%	19%
Acute GVHD grade III-IV	0%	18%	5%	6%	7%	6%
Chronic GVHD	4%	0%	3%	11%	5%	8%
Chronic GVHD severe	0%	0%	0%	9%	5%	7%
6mths post HSCT	**(MITT n=23)**	**(MITT n=9)**	**(MITT n=32)**	**(n=35)**	**(n=29)**	**(n=64)**
Non-relapse mortality	13% (0-27)	11% (0-29)	13% (0-24)	37% (19-51)	35% (15-51)	36% (23-47)

*Notes: NRM at 6 months primary endpoint of CR-AIR-007; Kaplan-Meier estimates for OS and NRM at 6 months; all other estimates cumulative incidence analyses; ITT: patients receiving HSCT; MITT: patients receiving HSCT and ATIR; OS: overall survival; CR-AIR-008 status 1 June 2018 (3 patients at risk);
All trials: Conditioning: Myeloablative; Graft source: Haplo PBMCs; HSCT: T-cell depleted; ATIR: ~30 days after HSCT; No prophylactic immunosuppression

We are conducting an international, multi-center, randomized and controlled Phase III clinical trial with a head-to-head comparison of a haploidentical HSCT with ATIR101 against the PTCy protocol in 250 patients with acute leukemia and myelodysplastic syndrome, or MDS, at approximately 50 sites in the United States, Canada and Europe. Following our interactions with the FDA and regulators in the European Union, we designed this trial to support marketing approval of ATIR101 in the United States, as well as to support the conversion of the conditional marketing approval of ATIR101 in Europe into a standard marketing approval. The trial's primary endpoint is GRFS. The FDA has informed us that it considers GRFS to be a novel endpoint and it will review the acceptability of which in connection with our marketing application. The first patient for this study was enrolled in December 2017.

We have retained worldwide development and commercialization rights for ATIR101. If approved, we believe we are well positioned to and intend to independently commercialize ATIR101 in the European Union and North America through our own commercial organization and may seek partners in other regions such as in China. We believe we can market ATIR101 with a relatively small infrastructure, as the stem cell transplant community has a small number of key opinion leaders ("**KOLs**") and is concentrated among relatively few stem cell transplant centers. For example, there are only approximately 63 stem cell transplant centers in France, Germany, Italy, and the United Kingdom. In 2016 in the United States, approximately 27 stem cell transplant centers performed 50% of the allogeneic HSCTs. In addition, the ongoing Phase III study is allowing us to continue to build strong relationships within the international stem cell transplant community. We have started building our own patient-specific cell therapy commercial, market access, medical affairs, manufacturing and supply chain infrastructure, including our own manufacturing facility in the

Netherlands to support our early requirements in Europe. We believe our proprietary manufacturing platform has the potential for an attractive cost of goods profile and lower capital expenditures relative to other personalized cell or gene therapy approaches, such as chimeric antigen receptor T-cell therapy ("**CAR-T**"), which involves removing T-cells from patients, genetically modifying them and transplanting them back into the patient.

In the future, we intend to develop ATIR101 for pediatric blood cancer patients, and as an adjunctive therapy to haploidentical HSCT performed with other protocols, such as the PTCy protocol and α/β T-cell depleted HSCT. In addition, HSCT is at times currently performed to address inherited blood disorders (e.g., thalassemia or sickle cell anemia), inherited immune disorders (*e.g.*, severe combined immunodeficiency) and autoimmune disease (*e.g.*, multiple sclerosis or lupus), and we believe ATIR could be developed as an adjunctive therapy to haploidentical HSCT for these indications. Also, we aim to expand to other regions, such as China, where haploidentical HSCT is often the only available treatment due to small family sizes and lack of donor registries.

7.3 The Transaction, acquisition of CytoSen

On April 17, 2019, we announced that Kiadis Pharma N.V., its wholly owned subsidiary CST, CytoSen and Philip R. McKee as representative of the CytoSen shareholders have entered into a binding agreement – the CytoSen Acquisition Agreement – regarding the acquisition by us of the entire share capital of CytoSen, subject to the approval of the General Meeting - which approval has been granted on May 29, 2019 - and customary closing conditions.

We believe that the Transaction will enable us to create a leading cell-based cancer immunotherapy company by adding CytoSen's complementary natural killer (NK)-cell therapy platform to our T-cell therapy platform. We believe that this unique combination has the potential to revolutionize hematopoietic stem cell transplants (HSCT) and enables us to create a pipeline of innovative treatments for cancer patients.

Rationale for the transaction

We believe that the acquisition of US-based CytoSen will transform us into a unique company with two synergistic proprietary cell-based immunotherapy platforms with an excellent strategic fit:

Creates a leader in cell-based cancer immunotherapy

- Two synergistic cellular immunotherapy platforms: NK-cells and T-cells

Optimal treatment opportunities by combining the innate and adaptive arms of the immune system

- Uniquely positioned in HSCT with complementary programs
- ATIR101 under review by the EMA; enrolling global Phase III study
- CSDT002-NK to advance in US clinical development in 2020 building on successful clinical proof-of-concept in 25 patients at the MD Anderson Cancer Center (MDACC)
- Combination strategies of ATIR101 and CSDT002-NK cell therapies with potential to revolutionize HSCT

Broadens product pipeline

- Builds a diverse pipeline of innovative cell therapy cancer treatments, e.g. treatment of relapse/refractory AML

Expands our presence in the US

- Leverage CytoSen's existing relationships with leading key opinion leaders (KOLs) and transplant centers for both ATIR and CSDT002-NK
- CSDT002-NK clinical trial to be conducted by the Blood and Marrow Transplant Clinical Trials Network (BMT CTN)

Leverage our cell therapy capabilities and infrastructure

- Accelerate the delivery of CytoSen's NK-cell therapies to patients

Our product pipeline after the completion of the acquisition of CytoSen is shown below.

	Indication / Region	Development	Phase 3	Filing	Catalysts	Commercial Rights	Status / Remarks
ATIR101	Adjunct to HSCT (EU)	*Orphan Drug Designation*			• EU Approval (2019) • EU Launch (first patient, late 2019)	Kiadis pharma	• Responding to EMA Day 180 questions end May 2019
	Adjunct to HSCT (US)	*Orphan Drug & RMAT Designations*			• Phase 3 full enrollment and interim read out (2021)	Kiadis pharma	• RMAT 'breakthrough' designation (9/2017)
CSDT002-NK	Adjunct to HSCT				• Start clinical trial with BMT-CTN (2020)	Kiadis pharma	• Proof-of-concept at MD Anderson Cancer Center (25 patients)
	Other cancer treatments				• Start clinical trial in oncology indication (2020/21)	Kiadis pharma	• Proof-of-concept at MD Anderson Cancer Center for refractory AML (8 patients)

CytoSen and its business

Privately held CytoSen has developed a proprietary NK-cell platform to enable NK-cell therapy with broad anti-cancer potential. It was founded on technology exclusively licensed from the University of Central Florida (UCF) and further developed at the Nationwide Children's Hospital (NCH) and MDACC. CytoSen's founders, including Dean Lee, Stefan Ciurea and Robert Igarashi, are leading physicians and scientists at NCH, MDACC and UCF, respectively. CytoSen's Executive Chairman, Philip McKee, is CytoSen's largest shareholder and invested in CytoSen after undergoing a hematopoietic stem cell transplant at MDACC.

CytoSen's patented nanoparticle processing technology enables improved ex vivo expansion and activation of NK-cells supporting multiple high dose infusions with potent anti-cancer cytotoxicity. We believe that its NK-cell therapy platform has best-in-class potential for the reasons outlined in the table below:

Best-in-class potential for high dose potent NK-cell platform

Expansion and activation of natural ***haplo donor NK-cells*** *with* ***patented PM21 nanoparticles*** *with* ***mbIL21*** *and* ***41bbl*** *antigens*

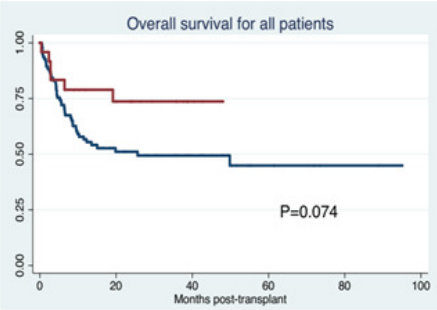
Dosing	High doses (10x endogenous levels possible)
In vivo persistence	Limited telomere shortening, zero senescence
Anti-tumor activity	High cytotoxicity (ADCC, IFNγ and TNFα)
Breadth of response	Effective response in over 10 cancer targets
Activation	Upregulated activating receptors (e.g., NKG2D, CD16)
Cryopreservation	Industry standard cryopreservatives and thawing
Manufacturing	Scalable, wave bags, closed system
Regulatory	Irradiated nanoparticle stimulation, not with tumor feeder cell line

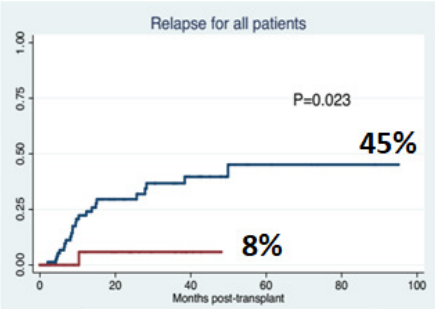
High dosing, cytotoxicity, persistence and activation

CytoSen's lead program is CSTD002-NK. As an adjunctive therapy to HSCT, proof-of-concept data for CSTD002 has been established through clinical studies in 25 patients carried out at MDACC. First results of these studies demonstrated a relapse rate of 8% and progression-free survival of 66% (published in Blood, with follow up data presented at the American Society of Hematology (ASH) annual meeting in 2018). The upcoming clinical study with CSTD002-NK as an adjunctive therapy to HSCT, expected to start in 2020, has been designed with and will be supported by the Blood and Marrow Transplant Clinical Trials Network (BMT CTN). The study will enroll high-risk acute myeloid leukemia (AML) patients undergoing a haploidentical HSCT at a consortium of leading US transplant centers in the BMT CTN network.

Additionally, CytoSen's NK-cell therapy will be investigated for other cancer treatments based on an 8-patient proof-of-concept study conducted at MDACC in refractory AML. In this study, 75% of patients treated with CSTD002 were in complete remission and 50% of patients qualified for a transplant. This is a very difficult-to-treat patient population and these promising, yet very early, results support evaluating CSTD002 further for this indication.

CSDT002: MDACC proof-of-concept* as adjunct to HSCT-PTCy





Improvement versus matched contemporaneous MDACC control and versus CIBMTR control

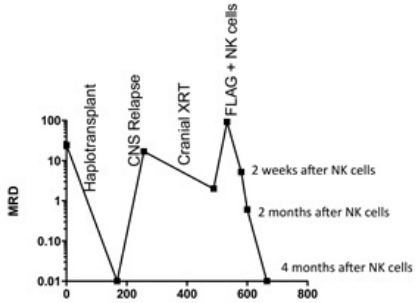
Size	Dose levels	Timing	Follow up	Outcomes
n=25	10^4 to 10^8 cells/kg	Day -2, +7, +28 from graft infusion	28 months (0.9-48)	• Improvement in relapse rate, PFS and OS • Reduction in reactivation of CMV/BKV • No severe acute and chronic GVHD

*NK-cells produced with feeder cells expressing mbIL21 and 41bbl, not with nanoparticles; n=13 Phase 1 dose finding (published in Blood), n=12 Phase 2 at highest dose (presented at ASCO and Haplo2018); Ciurea SO, et. al. Blood 2017, (link to paper); Ciurea SO EMBT Mar2018; Ciurea SO, Haplo2018, Nov2018

CSDT002: PoC* for treatment of AML (R/R, 2nd line salvage)

Site	Size	Patients: AML R/R 2nd line salvage	Timing of dose	Follow up	Outcomes
MD Anderson	n=8	• 4 median prior treatments • 3/8 prior HSCT • 43% median BM blasts	6 doses (11 days)	329 days (71-730)	• CR/CRi: 75% (day 30) • HSCT: 50% • Survival: 37,5% (1 year)
MD Anderson and Brazil	N=13	• 4 median prior treatments • 7/13 prior HSCT • 45% median BM blasts	6 doses (11 days)	202 days (39-590)	• CR/CRi: 69%

Case example (AML, male, 25 yrs):
- 8 lines of prior treatment, incl prior failed HSCT
- Active disease, 90% BM blasts
- Treated with NK cells plus FLAG, no subsequent HSCT
- No treatment side effects
- Complete response
- Ongoing MRD decrease and immunologic activity (at 120 days)
- Alive at 1 year; Relapsed/death at 2 years



* NK-cells produced with feeder cells expressing mbIL21 and 41bbl, not with nanoparticles; Ciurea SO, et. al. ASCO June2018; Ciurea SO Haplo2018. Nov2018

For the proof-of-concept studies, CSTD002 was produced with feeder cells expressing mbIL21 and 41bbl. For future studies, the expansion and activation of natural donor NK-cells will be conducted with patented PM21 nanoparticles with mbIL21 and 41bbl antigens.

Key terms and conditions of the Transaction

The full terms and conditions of the Transaction are laid down in the CytoSen Acquisition Agreement between Kiadis Pharma N.V., its wholly owned subsidiary CST, CytoSen and Philip R. McKee as representative of the CytoSen shareholders. Certain key terms and conditions of the Transaction are described below.

Consideration

Based on the number of CytoSen shares and options outstanding on the Registration Document Date, the total upfront consideration to be paid to holders of CytoSen shares and options for the acquisition of CytoSen consists of 1,724,899 Shares, and 214,941 options to acquire Shares. If prior to completion of the Transaction CytoSen options are exercised, the number of options to acquire Shares to be paid as part of the total upfront consideration (the "**Upfront Payment Options**") will decrease, and the number of Shares to be paid as part of the total upfront consideration (the "**Upfront Payment Shares**") will increase with an equal amount.

85% of the Upfront Payment Shares shall be issued to CytoSen's shareholders on completion of the Transaction and 15% of the Upfront Payment Shares shall constitute Holdback Shares (as defined below). The Upfront Payment Options regard outstanding CytoSen options that shall be assumed by us and converted at substantially the same terms and conditions into options to acquire Shares at exercise prices ranging from €9.52 to €11.20.

In addition, CytoSen's shareholders are eligible for potential future consideration of up to 5,174,670 additional Shares and its option holders for a potential future consideration of up to 644,790 Shares upon the achievement of six clinical development and regulatory milestones, through first FDA approval of an NK-cell product based on CytoSen's technology. The entitlement of CytoSen's option holders to receive up to 644,790 Shares upon the achievement of milestones shall be subject to the terms and conditions of a Milestone Bonus Plan which is being developed. Under certain circumstances, including in the event of a change of control, we have the right or the obligation to pay all unpaid contingent consideration, either in full or at a reduced amount that will be calculated according to a pre-agreed formula.

Representations and warranties and indemnification

Under the CytoSen Acquisition Agreement, the CytoSen shareholders have provided certain representations and warranties relating to, among other things, CytoSen's organization and qualification, its capitalization, financial statements, legal compliance and availability of permits, regulatory compliance, employees, intellectual property, privacy and data protection, taxation, material contracts and related party transactions. Customary monetary limitations, time limitations and other limitations of the CytoSen shareholders liability apply in respect of these representations and warranties.

Subject to the terms of the CytoSen Acquisition Agreement, 15% of the Upfront Payment Shares to be paid to CytoSen's shareholders (the "**Holdback Shares**") shall serve as a source for the satisfaction of indemnification and other claims that we may have on the CytoSen shareholders. Subject to reduction in respect of these indemnification and other claims, the Holdback Shares will be issued 18 months from the completion date. If no Holdback Shares remain reserved for settlement of a claim, the CytoSen shareholders subject to the indemnification or other claim may settle the claim in cash or in Shares that

the relevant shareholders initially acquired as consideration pursuant to the CytoSen Acquisition Agreement. In the event a claim is settled in Holdback Shares or Shares, each such Share shall represent a contractually agreed fixed amount that may differ from the prevailing share price on Euronext Amsterdam or Euronext Brussels of our Shares at the time of settlement. The number of Holdback Shares will range between 258,732 Shares (in the event that none of the outstanding CytoSen options is exercised prior to completion of the Transaction) and 290,978 Shares (in the event that all the outstanding CytoSen options are exercised prior to completion of the Transaction).

Kiadis Pharma N.V. and CST have provided certain representations and warranties for the benefit of the CytoSen shareholders, primarily related to their authority and capacity to enter into the Transaction and performance of their obligations under the CytoSen Acquisition Agreement.

Lock up restrictions

Pursuant to the CytoSen Acquisition Agreement, of the Upfront Shares to be issued to CytoSen's shareholders as upfront consideration on completion of the Transaction, the Upfront Shares issued to CytoSen's Executive Chairman, CEO and founders – being 846,856 Shares if they do not exercise their CytoSen options prior to completion of the transaction and up to 968,567 Shares if they do exercise such options - shall be subject to lock-up restrictions during a two-year period starting on the completion date of the Transaction, and the other Upfront Shares shall be subject to lock-up restrictions during a 180-day period starting on the completion date of the Transaction.

Closing conditions

The Transaction is subject to approval by the General Meeting - which approval has been granted on May 29, 2019 - and other customary closing conditions. Completion shall take place within 10 days after all closing conditions have been satisfied or waived. The Transaction may be cancelled and the CytoSen Acquisition Agreement terminated inter alia in the event that the completion has not taken place by July 31, 2019.

Risks

Please see paragraph 1.6 – Risks related to the Transaction in Chapter 1 (Risk Factors).

7.4 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 BioSciences Inc., 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 license agreement with Hospira – the Hospira Exclusive License Agreement – to develop and commercialize ATIR in certain territories.
2012	Kiadis signed a termination and royalty agreement with Hospira – the Hospira Termination and Royalty Agreement – terminating the 2010 Hospira Exclusive License 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 initial public offering 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.
2017	Kiadis filed a Marketing Authorization 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 €3.7 million Kiadis obtained €15 million debt financing from Kreos Capital – the First Kreos Capital Facility Agreement. 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.
2018	Kiadis raised €23.4 million in a private placement of Shares with institutional investors. Kiadis submitted responses to the EMA's 120 Day List of Questions in March and to the first Day 180 List of Issues in August. Kiadis obtained a second debt facility from Kreos Capital – the Second Kreos Capital Facility Agreement – under which €5 million has been drawn. Kiadis received a second Day 180 List of Issues in October. Kiadis raised €31.2 million in a private placement of Shares with institutional investors.
2019	Kiadis entered into a definitive agreement to acquire CytoSen, subject to approval of the General Meeting - which approval has been granted on May 29, 2019 - and customary closing conditions. Kiadis responded to the second Day 180 List of Issues on May 22, 2019

7.5 Our strengths

Our competitive strengths include:

- **Strong clinical data for ATIR101.** ATIR101 is designed to address key limitations of haploidentical HSCT without prophylactic immunosuppression and its negative consequences. Pooled data from our international Phase II CR-AIR-007 clinical trial, and data from patients who received a single dose of ATIR101 in our CR-AIR-008 trial, show a clinically meaningful improvement in overall survival and non-relapse mortality over non-interventional observational historical control data for haploidentical T-cell depleted HSCT performed without ATIR, without an increase in GVHD. These results, if observed in a randomized, controlled clinical trial, would represent a p-value of 0.005 (OS 0-12 months) and 0.02 (NRM 0-6 months). Furthermore, we have commenced a Phase III trial that is designed to show superiority in GRFS of ATIR101 compared to the PTCy protocol.

- **Near-term commercial opportunity for ATIR101 with a defined regulatory path to market.** ATIR101 is undergoing regulatory review in the European Union. We aim to receive a CHMP opinion in 2019 – in June 2019 at the earliest - which, if positive, would enable us to receive a conditional marketing approval from the European

Commission followed by commercial use of ATIR101 in a first patient in a European country at the end of 2019. We are currently conducting a Phase III study in the United States, Canada and Europe directly comparing ATIR101 to the PTCy protocol that, if successful, we believe will support the submission of a BLA to the FDA in the United States and the conversion of the conditional marketing approval of ATIR101 in Europe into a standard marketing approval. In addition, we received RMAT designation from the FDA, which provides benefits that are materially equivalent to a breakthrough designation from the FDA, and ATIR101 has been granted orphan drug designations both in Europe and the United States.

- **Retained worldwide commercial rights for ATIR101 allowing for independent commercialization.** We have retained worldwide development and commercialization rights for ATIR101. Commercialization will be directed towards the stem cell transplant community, which is a concentrated market with relatively few stem cell transplant centers and driven by a small group of key opinion leading physicians. As a result, if approved, we believe we are well positioned to commercialize ATIR101 with our own commercial organization targeting Europe and North America. We have started building our own commercial, medical affairs, manufacturing and supply chain infrastructure, including our own manufacturing capability in Amsterdam, the Netherlands, to prepare for a potential launch in Europe at the end of 2019.

- **Broad potential applicability of our ATIR platform across indications and haploidentical HSCT approaches.** Although data for ATIR101 to date have been generated in adult acute leukemia patients who have received haploidentical HSCT, we believe the data should support adoption of ATIR101 in a haploidentical HSCT for other blood cancers. We also plan to develop ATIR101 for pediatric blood cancer patients as part of the pediatric investigation plan agreed with the EMA. In blood cancers, while ATIR101 so far has been studied after a haploidentical T-cell depleted HSCT, in principle, it can also be given as an adjunct T-cell therapy administered after any other haploidentical HSCT protocol, such as α/β T-cell depleted HSCT or the PTCy protocol. Moreover, we believe that ATIR can benefit patients in a wide range of other indications that may be treated with haploidentical HSCT, such as inherited blood disorders, inherited immune disorders and auto-immune diseases, further expanding its use.

- **Efficient manufacturing and supply chain infrastructure for patient-specific, cell-based product candidates.** We are creating a patient-specific cell therapy supply chain and commercial organization. We are setting up our own manufacturing capability in Amsterdam, the Netherlands, to support our early commercialization requirements in Europe. ATIR101 is manufactured using a five-day central manufacturing process that does not require genetic engineering and thus no Biosafety Level Two infrastructure. We believe our proprietary manufacturing platform has the potential for an attractive cost of goods profile and lower capital expenditures relative to other personalized cell or gene therapy approaches, such as CAR-T.

- **Seasoned leadership.** Members of our executive and non-executive leadership teams cumulatively have a century of experience in the life sciences industry and have previously served at companies including Ablynx, Actelion, Amgen, AstraZeneca, Crucell, Johnson & Johnson, Medivation, Keryx and Novartis. The team has a track record in senior management roles in late stage drug development,

global manufacturing operations and commercialization of orphan drugs and several innovative treatments, including advanced cell-based therapies.

7.6 Our strategy

Our vision is to leverage the strengths of the human immune system to help patients with life-threatening diseases as we build a fully integrated biopharmaceutical company. We aim to maximize the value of our first potential therapy, ATIR101, our proprietary cell-based immunotherapy platform being developed to help improve outcomes for blood cancer patients undergoing a haploidentical HSCT. Over time, we plan to expand our pipeline with development of ATIR for additional indications and/or through the in-license or acquisition of other cell therapy and haploidentical HSCT products, e.g. by the acquisition of CytoSen.

Our strategy to achieve this vision and long-term value creation is as follows:

- **Obtain regulatory approval in the European Union for ATIR101 and launch at the end of 2019.** Based on the results of our successful Phase II CR-AIR-007 trial, we filed a MAA in the European Union in April 2017 and submitted responses to the EMA's first Day 180 List of Issues in August 2018. In October 2018, we received a second Day 180 List of Issues, to which we responded on May 22, 2019. We aim to receive a CHMP opinion in 2019 – in June 2019 at the earliest - which, if positive, would enable us to receive a conditional marketing approval from the European Commission followed by commercial use of ATIR101 in a first patient in a European country at the end of 2019.

- Continue to advance the Phase III development of ATIR101 as a basis for regulatory approval in the United States and other territories. In September 2017, we received RMAT designation from the FDA for ATIR101. We are conducting an international Phase III trial with 250 patients at approximately 50 sites directly comparing ATIR101 to the PTCy protocol and started enrolling patients in December 2017. The study is intended to provide the basis for submitting a BLA for ATIR101 in the United States and other territories, and to support the conversion of the conditional marketing approval of ATIR101 in Europe into standard marketing approval.

- **Commercialize ATIR101 through our own supply chain and commercial organization.** HSCTs are performed in a relatively small number of stem cell transplant centers and there is a small group of transplant KOLs. As a result, if ATIR101 is approved, we believe we can commercialize it with a relatively small infrastructure. We intend to market ATIR101 in Europe and the United States through our own commercial organization and may seek partners in other regions such as China. In anticipation of a conditional marketing approval in Europe, we are currently building our own commercial, manufacturing and supply chain capabilities with the goal of a commercial launch in selected countries in Europe starting end 2019.

- **Expand the use of ATIR within blood cancers and in other diseases of the blood and immune system.** To expand the adoption of ATIR101 in patients with blood cancer, we intend to initiate additional studies in pediatric patients and with ATIR101 as an adjunctive T-cell product after other haploidentical HSCT protocols, such as the PTCy protocol. In addition, we believe that our ATIR platform can potentially benefit a broader range of patients, including for inherited blood disorders (*e.g.*, thalassemia or sickle-cell anemia), inherited immune disorders (*e.g.*, severe combined immunodeficiency) and auto-immune diseases (*e.g.*, multiple sclerosis and lupus). We believe that the addition of ATIR to current haploidentical HSCT protocols

can potentially result in improved patient outcomes and transform haploidentical HSCT into a much more widely-used treatment option.

- **Leverage our personalized cell-based immunotherapy platform to expand our suite of product candidates.** In line with our company vision, we are building our capabilities in development, manufacturing, supply chain and commercialization of haploidentical HSCT and patient-specific cell-based product candidates to become a fully integrated biopharmaceutical company. Driven by our seasoned leadership, we intend to leverage our infrastructure and medical leadership in this promising biopharmaceutical segment to pursue new product candidates and/or technology opportunities in a haploidentical HSCT and/or cell-based immunotherapy, either via in-licensing or acquisition.

7.7 Strategic objectives

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

- we will be able to attract or generate sufficient cash to fund our activities;
- the EMA will approve the MAA submitted for ATIR101, and we successfully launch and commercialize ATIR in the EU;
- the Phase III clinical trial with ATIR101 will continue to successfully enroll patients;
- We will be able to expand our manufacturing process over multiple sites; and
- we will be able to retain and attract key employees or replacements (if necessary).

A significant portion of the efforts of the Management Board and the Management Team are directed towards these priorities. We take 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. As of December 31, 2018, we had cash and cash equivalents of €60.3 million and as of the Registration Document Date, we had cash and cash equivalents of approximately €42 million. Based on our operating plans, we believe that in the event that the Transaction completes and our operations will include those of CytoSen, or in the event that the Transaction does not complete, existing cash and cash equivalents will allow us to continue operating the business in either case into the first quarter of 2020.

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

After having secured EMA approval (the second assumption above) we anticipate we will be able to launch ATIR101 commercially in the EU. Non-approval by the EMA would, however,

cause a delay and may, ultimately, jeopardize the product development program as well as the commercialization thereof in the EU and would adversely affect our 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 us. Therefore, we do not anticipate that ATIR101 will be available in all of the major European markets within the next two years. Our business model does not currently depend on commercial partners to market our product in the various territories. However, it may seek such partners in the future in order to commercialize ATIR101 in the EU. We continue 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 jeopardize the product development program, delay the conversion from conditional to full approval in the EU, delay the approval and commercialization of ATIR101 in the U.S. and elsewhere, and would adversely affect our business, financial condition and prospects. To execute this Phase III trial, we depend on contracts with and the support and performance of our 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 in the United States, the Medicines & Healthcare products Regulatory Agency (MHRA) in the United Kingdom and the Paul-Ehrlich-Institut (PEI) in Germany. We continue to believe that the existing data for ATIR101 makes the Phase III trial an attractive trial for clinics, physicians and patients.

In line with our company vision, we are building our capabilities in development, manufacturing, supply chain and commercialization of haploidentical HSCT and patient-specific cell- therapy to become a fully integrated biopharmaceutical company.

The ability to retain and attract key employees or replacements if necessary (the fourth assumption above) is also important for our future growth. Our business is highly specialized 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. We aim 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.

7.8 Industry overview

Allogeneic Hematopoietic Stem Cell Transplantations (HSCT)

Allogeneic HSCT is a potentially curative therapy that replaces the diseased blood and immune system of a patient with healthy stem cells and immune cells from a donor. Prior to beginning an HSCT, patients receive high doses of chemotherapy with or without radiation therapy. This myleoablative conditioning regime destroys cancer cells to make relapse less likely, and also destroys the patient's immune system in order to minimize the possibility of rejection of the donor graft. After conditioning, the patient is given a graft of donor cells. The graft can be obtained from donor bone marrow, peripheral blood or umbilical cord blood, with peripheral blood now being the most common source. The graft usually contains stem cells as well as mature leukocytes, such as T-cells, B-cells and NK cells. The stem cells migrate to the patient's bone marrow where they engraft and reconstitute the patient's immune system and the patient's red blood cells. The leukocytes help the donor stem cells engraft

and can also immediately fight any residual tumor cells and infections. However, mature donor T-cells may have a severe and potentially life threatening adverse effect on patients as they are the main cause of GVHD.

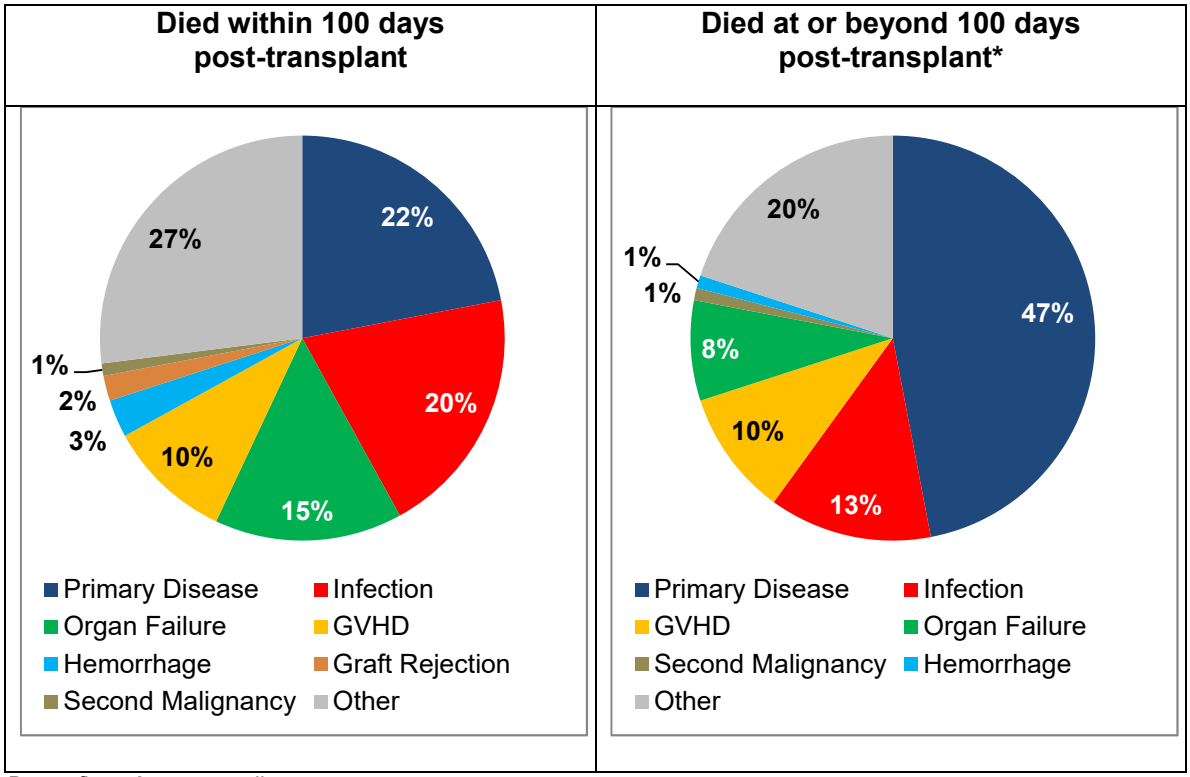
Of the allogeneic HSCT treatments, approximately 85% involved patients with blood cancers and related conditions, which are malignancies of the bone marrow and immune system, in Europe in 2015 and the United States in 2016. For many blood cancers, an HSCT may be initiated for patients who are at high risk of cancer relapse or who relapsed after prior successful treatment with chemotherapy or immunotherapy. The most common are AML, ALL, chronic myeloid leukemia ("**CML**"), chronic lymphocytic leukemia ("**CLL**"), MDS, and Non-Hodgkin's Lymphoma ("**NHL**"). The remainder of existing allogeneic HSCT treatments target other cancers or inherited blood disorders, such as thalassemia or sickle cell anemia, and auto-immune disorders.

Over the past decades, the use of allogeneic HSCT has increased significantly from approximately 4,000 transplants in 1990 to greater than 30,000 in 2016 in Europe and the United States, with availability of donors as the limiting factor. Depending on donor type and protocol, the average healthcare costs of allogeneic HSCT in the United States are estimated to be as high as $549,000 per transplant during the first year of treatment. The hospital charges for treatment of acute GVHD can be as high as $324,000 per patient, while the cost of chronic GVHD can be a multiple of this over the patients' lifetime.

HSCT risks: GVHD, infections and relapse

The main risks of HSCT are GVHD, infections, organ failure and cancer relapse. With a matched unrelated donor (MUD), in the United States in 2014-2015, these risks accounted for 67% of all deaths following an HSCT in the first 100 days post-transplant and 78% of deaths beyond 100 days post-transplant.

Causes of Death after Unrelated Donor HCT done in 2014-2015



* Data reflects 3-year mortality.
Source: Center for International Blood and Marrow Transplant Research ("**CIBMTR**") 2017 Summary Slides Graft Versus Host Disease

Graft Versus Host Disease

GVHD is a potentially lethal side effect of allogeneic HSCT. With GVHD, mature transplanted donor T-cells recognize the patient's tissue as "non-self" and start attacking the patient, which may cause severe skin disease, gastrointestinal disease, liver disease, infections, muscle constriction, bone loss, pulmonary disease, thyroid dysfunction, ophthalmology and solid tumors. Acute GVHD can occur soon after transplantation, typically in the first 100 days. It is graded from I (mildest) to IV (most severe), with acute GVHD grade III/IV regarded as life threatening. Chronic GVHD tends to manifest after 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 persist for years, leads to increased risk of infections, can be severely incapacitating and severely impact quality of life, and leads to high morbidity and mortality. The quality of life impact of GVHD is often considered worse than most chronic diseases such as multiple sclerosis, diabetes or loss of limbs. The disease not only affects the patient, but also their families and other caregivers. It leads to significant loss of income and increase of medical cost to the patient and the system.

Currently, multiple immunosuppressive agents are used to prevent GVHD, such as cyclosporine, tacrolimus, mycophenolate mofetil and sirolimus. If GVHD develops, treatment to suppress the disease relies on administering glucocorticoids, such as methylprednisolone or prednisone, antithymocyte globulin, monoclonal antibodies, mycophenolate mofetil, sirolimus and oral non-absorbable corticosteroids. Even with the use of these medications, GVHD mortality is high, with three-year survival of 54% for patients with acute GVHD grade

I/II versus 26% for patients with acute GVHD grade III/IV. The hazard ratio for acute Grade IV GVHD versus acute Grade I GVHD is 3.39. Chronic severe GVHD has five-year survival of 22% versus 59% for moderate and mild chronic GVHD, and immunosuppression at one year has a hazard ratio of 2.17.

Infections

Life threatening infections after HSCT can be caused by bacterial, fungal and viral agents, including by agents which would rarely cause serious disease in healthy individuals. After HSCT treatment, it can take up years to recover to near-normal immune function. In addition, the use of immunosuppression to prevent or treat GVHD further limits the immune system, making the patient highly susceptible and vulnerable to infections. Many precautions are therefore often taken to minimize the risk of infection, such as routine patient screening for infections, the use of prophylactic antibiotics and antiviral agents, and putting patients in quarantine.

Cancer relapse

Residual cancer cells that have survived after chemotherapy or radiation in the conditioning regime may cause a relapse of the disease after HSCT. The effectiveness of HSCT in preventing cancer relapse is therefore also linked to what is called the Graft-versus-Leukemia (GVL), effect, whereby the patient's new immune system may destroy any remaining cancer cells. This GVL-effect is highly dependent on mature T-cells in the HSCT graft.

The risks of GVHD, infections and cancer relapse are interrelated. Patients may need to continue taking immunosuppressive medications against GVHD for many months or years after transplantation. If patients do not respond to immunosuppression, this may result in death due to GVHD. But suppressing the immune system comes at the expense of the body's ability to fight infections and residual cancer cells, and can lead to deaths due to opportunistic infections or relapse.

HSCT effectiveness endpoints

To assess the effectiveness of HSCT, typical endpoints are overall survival (OS), defined as absence of death as a result of any cause; progression-free survival ("**PFS**"), defined as survival without disease progression or death from any cause; relapse related mortality ("**RRM**"), defined as death due to relapsed or progressive disease; acute GVHD (grade I-IV), chronic GVHD, and transplant related mortality ("**TRM**"), which is also referred to as non-relapse mortality (NRM), defined as any other cause of death for patients in continuous remission. RRM and TRM are competing risks, and interrelated: for example, severe GVHD can be a direct cause of TRM, and RRM and TRM can be caused by the use of immunosuppression to prevent or treat GVHD.

GRFS is an endpoint that captures the relationship between these various effects. GRFS is defined as survival without acute grade III/IV GVHD, without chronic GVHD requiring systemic immunosuppression, and without relapse, and is thus a composite endpoint that captures survival, quality of life and future prognosis.

An important factor for OS and GRFS is the disease risk index ("**DRI**"). The DRI classifies blood cancers into low, intermediate, high and very high risk. For example, an AML patient with active disease after two previous remissions is considered a very high risk DRI.

Therefore, any comparison of HSCT patient outcomes is typically normalized for DRI differences in the patient population.

Historical HSCT standard of care: Genetically matched donors

To reduce the risk of GVHD, clinical practice has historically focused on finding donors that are genetically matched to patients for their human leukocyte antigen ("**HLA**") molecules, also called MHC Class II proteins. These antigen are broadly present on various tissues, and especially on immune cells, to allow the immune system to verify that a given cell is not a foreign invader. With matched related donors ("**MRD**"), also called sibling donors ("**SIB**"), the probability of closely matching the patient's HLA type is highest, because the patient and sibling donor received their genes from the same parents. A MUD is a donor who is not a blood relative but has an HLA type matched to the patient's.

A related or unrelated donor is usually considered a fully matched donor if 10 out of 10 HLA molecules are the same, and partially matched if six or eight out of 10 HLA molecules are the same. Depending on family size, ethnicity and genetics, between 25% and 80% of patients who are eligible for HSCT will not find a fully or partially matched donor in time. In 2012, an estimated 13,500 patients eligible for a HSCT in the United States were not transplanted.

Haploidentical HSCT: T-cell depleted or T-cell replete HSCT protocols

To address the lack of matched donors, new approaches have been developed to enable the use of genetically half-matched or haploidentical donors. The term "haploidentical" indicates that the donor shares at least half of the HLA molecules with the patient. Parents, children and many other family members are haploidentical. Because parents and children are typically highly motivated donors, an ability to use half-matched donors could make transplantation available to many more patients.

However, due to the genetic differences between a patient and a half-matched donor, infusion of a haploidentical graft can cause severe and lethal GVHD due to the mature donor T-cells that recognize the patient as foreign and attack. In order to mitigate this risk of GVHD, the grafts from haploidentical donors need to be depleted of donor mature T-cells that may attack the patient, either in the patient, in vivo, (after a T-cell replete haploidentical HSCT) or outside the patient, ex vivo, (a T-cell depleted haploidentical HSCT). As described above, full depletion of all donor mature T-cells, however, would increase the risk of relapse and infections.

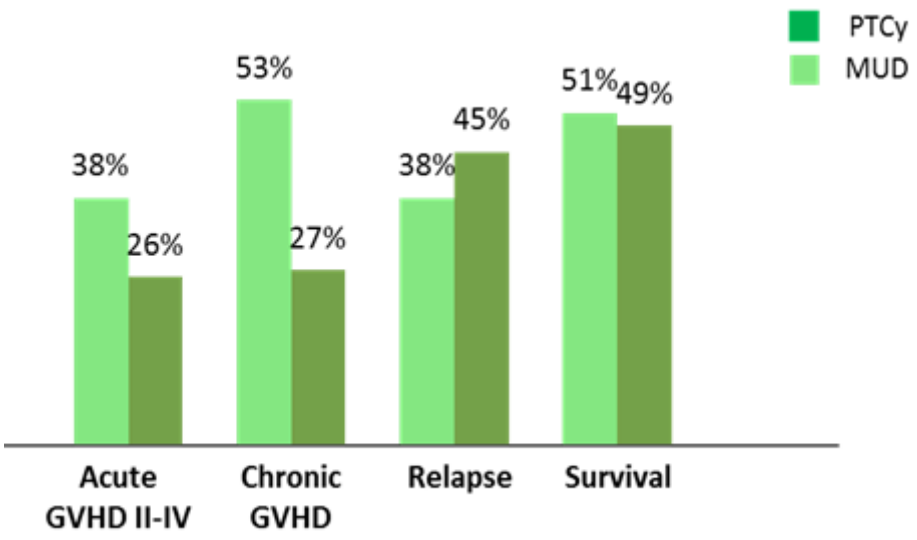
T-cell depleted haploidentical HSCT (ex-vivo depletion)

Ex vivo T-cell depletion is usually done with the CliniMACS cell sorter from Miltenyi Biotec. Miltenyi and its collaborators over time developed different approaches. Initially, T-cell depletion was done by a positive selection of CD34+ marked cells, which are the stem cells, by isolating them from the graft in a selection column, through the use of anti-CD34 antibodies conjugated to magnetic beads. In later years, Miltenyi and its collaborators created alternative approaches to remove certain subpopulations of cells from the graft through negative selection, to preserve as many cell types of the donor immune system as possible: either removal of all CD3+ T-cells and CD19+ B-cells, or removal of only α/β CD3+ T-cells. The α/β CD3+ T-cells are believed to be those mature T-cells that recognize and attack foreign antigen, and are thus mostly involved in GVHD, but also confer the required protection against relapse and infections.

T-cell replete haploidentical HSCT (in-patient depletion)

In-patient depletion of the T-cells was first developed at Johns Hopkins University in Baltimore, and has in recent years become the main protocol used to perform haploidentical HSCT. In the PTCy protocol, an unmanipulated T-cell replete (i.e., T-cell containing) haploidentical graft is infused. Due to the HLA mismatch, donor T-cells that recognize the patient immediately become activated and start attacking the patient, triggering potential severe, lethal acute GVHD. To address that, patients are treated with high doses of cyclophosphamide, a chemotherapy agent, immediately after the transplant, to deplete the alloreactive activated T-cells within the patient. After the haploidentical HSCT, patients receive prophylactic immune suppression to continue to address the risk of GVHD, for many months and sometimes years.

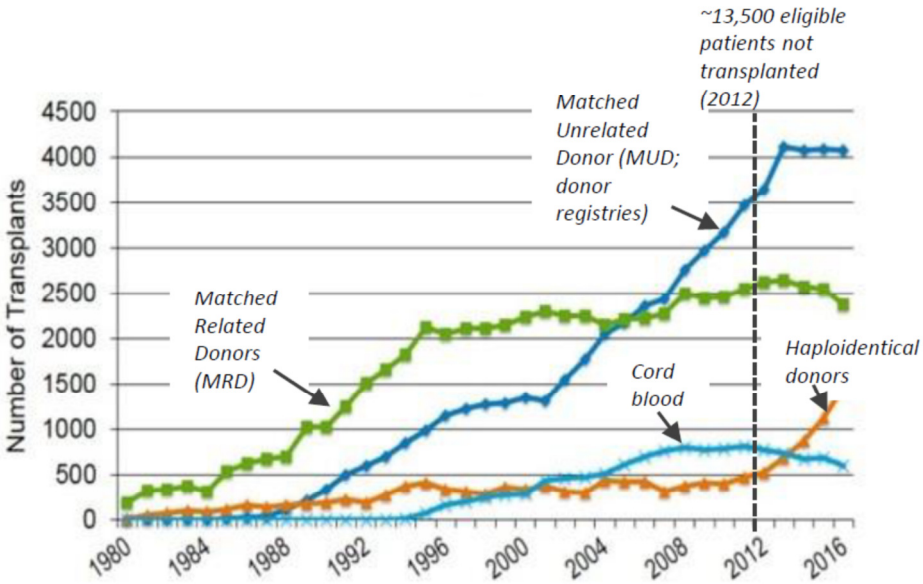
A recent retrospective literature review published in Advances in Hematology, has shown that haploidentical HSCT using PTCy may actually result in a lower rate of GVHD than MUD HSCT. The retrospective review of five publications in this review that report data for patients suffering from either AML, MDS, NHL or HL, ranging in dates from 2008 to 2016, with data for 463 haploidentical HSCT patients who underwent the PTCy protocol with data for 2,647 MUD HSCT patients (follow-up up to 3 years). Although the PTCy protocol compared favorably to MUD HSCT with respect to GVHD, the analysis suggests that the PTCy protocol resulted in a higher relapse rate than MUD HSCT. The chart below summarizes the results of the retrospective literature review, which are weighted by number of patients, in each of five publications.



Moreover, with haploidentical HSCT, patients do not have to wait for a matched donor, which many may not find at all. As the reported data shows a comparison for patients who have actually received transplants, it does not account for patients who are eligible for a transplant for whom a MUD cannot be found on time, and who may have died as a result.

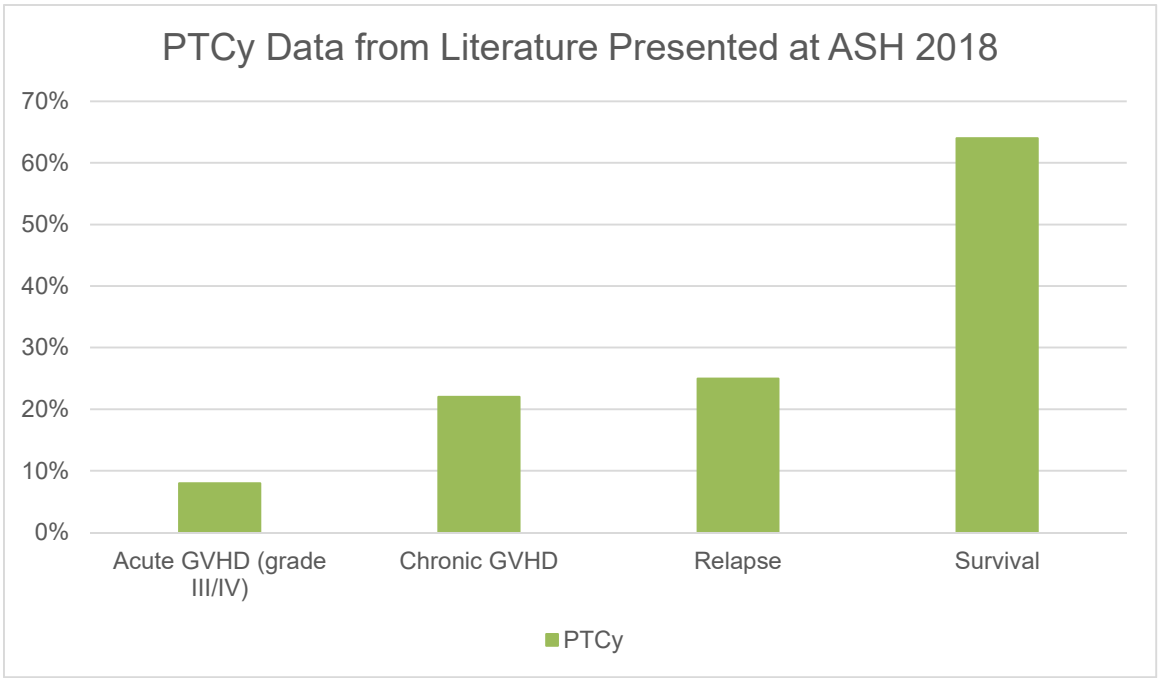
In recent years, between 2012 and 2016, the adoption of the PTCy protocol has led to a substantial three-fold growth in the number of haploidentical HSCT in the United States and Europe. As illustrated in the figure below, despite the unmet need due to lack of donors, the number of matched related and unrelated donor transplants has been declining.

CIBMT US Transplant Data



Source: CIBMTR 2017 Summary Slides; Besse 2015.

Although the use of the PTCy protocol has expanded the use of HSCT, the PTCy protocol's use of cyclophosphamide and immunosuppression is associated with secondary malignancies and severe toxicities which compromises the graft-versus-leukemia (GVL) effect of transplanted donor cells. As shown in the chart below, at the one year follow-up point, we estimate, based on a review of available literature, that almost 30% of PTCy protocol patients relapse and approximately a quarter of patients suffer from chronic GVHD.



Source: ASH Poster, Steven Devine, CIBMTR

High rates of relapse and GVHD are also reflected in the long term GRFS outcomes of approximately a third for PTCy patients, as reported in publications by Solh 2016 (Northside, Atlanta) and McCurdy 2017 (Johns Hopkins, Baltimore). These publications also demonstrate that GRFS is similar for HSCT with a Matched Related Donor, Matched Unrelated Donor and haploidentical donor with PTCy. We believe new haploidentical HSCT approaches that provide clinically meaningful benefits over the PTCy protocol would further contribute to the growth of haploidentical HSCT procedures.

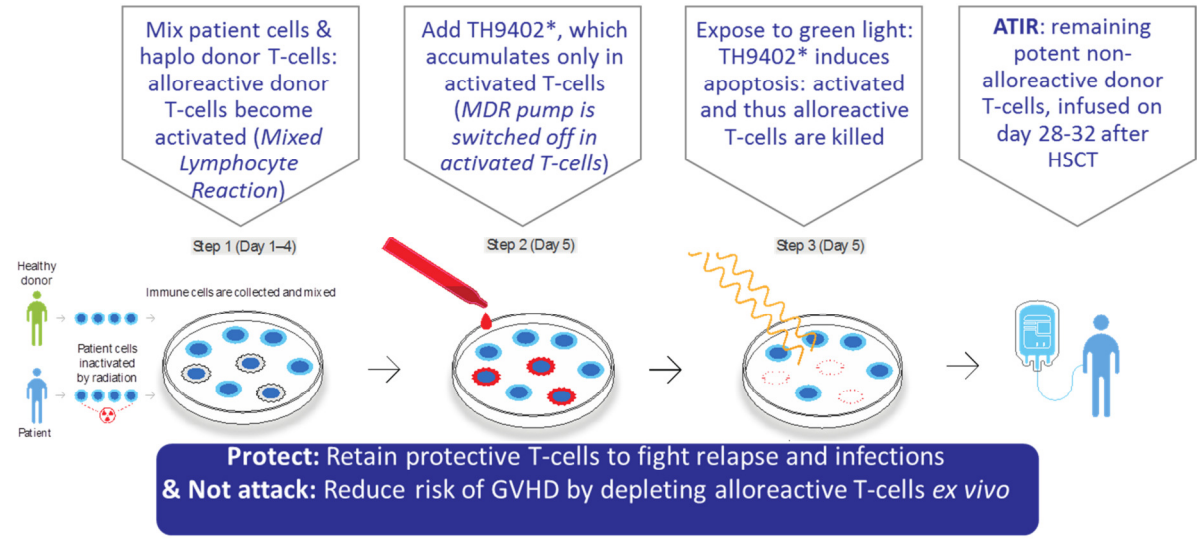
7.9 Our solution

We are initially developing our lead product candidate, ATIR101, for use in conjunction with haploidentical HSCT for adult blood cancers to address key limitations of haploidentical HSCT, without prophylactic immunosuppression and its associated mortality or morbidity. With ATIR101 as adjunctive treatment to a haploidentical T-cell depleted HSCT, we believe we can improve OS and NRM of a haploidentical T-cell depleted HSCT without ATIR101, while retaining low GVHD and relapse rates. Based on the positive results from our single dose Phase II CR-AIR-007 study, we submitted a MAA to the EMA in April 2017 for approval of ATIR101 as an adjunctive treatment in haploidentical HSCT for high risk adult hematological malignancies. We submitted responses to the EMA's Day 180 List of Issues in August 2018. In October 2018, we received a second Day 180 List of Issues, to which we responded on May 22, 2019. We aim to receive a CHMP opinion in 2019 – in June 2019 at the earliest - which, if positive, would enable us to receive a conditional marketing approval from the European Commission followed by commercial use of ATIR101 in a first patient in a European country at the end of 2019. Conditional marketing authorization under the EMA regime permits commercialization subject to completing specified obligations, such as a confirmatory clinical trial.

In December 2017, we commenced an international, multicenter, randomized and controlled Phase III clinical trial of ATIR101 against the PTCy protocol. If successful, we intend to use data from this trial as a basis for the filing of a BLA with the FDA. The FDA has informed us that because GRFS is a novel endpoint, it would review acceptability of GRFS in connection with our marketing application. We also plan to use data from the Phase III trial to support the conversion of the conditional marketing approval of ATIR101 in Europe into a standard marketing approval. ATIR101 received RMAT, designation from the FDA in September 2017, which provides benefits that are materially equivalent to a breakthrough designation from the FDA. In addition, ATIR101 and has been granted five orphan drug designations both in Europe and the United States. We have been granted two orphan drug designations in the United States for (i) immune reconstitution and prevention of GVHD following a HSCT and (ii) prevention or reduction of TRM caused by GVHD or infections following a haploidentical HSCT. In the European Union, we have been granted three orphan drug designations for (i) the prevention of GVHD, (ii) the treatment of AML and (iii) treatment in HSCT, regardless of the underlying disease.

ATIR Platform

ATIR is produced with our proprietary technology to selectively deplete patient-specific and potentially GVHD-causing T-cells from the donor graft. Thus, ATIR is comprised of donor T-cells that have been depleted of T-cells that recognize the patient as "non-self", but that retain other T-cells able to fight relapse and infections. The selective depletion of potentially GVHD-causing T-cells from the donor graft occurs *ex vivo* prior to infusion into the patient, as outlined below.



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

To start ATIR production, we collect and mix immune cells, including T-cells, from both the patient and the haploidentical HSCT donor, and incubate these for four days. Donor T-cells that can recognize the patient as "non-self" or "foreign" are activated due to contact with patient immune cells. Patient immune cells cannot become activated as they are irradiated before the one way Mixed Lymphocyte Reaction ("**MLR**").

We introduce our photosensitizing reagent TH9402 (a rhodamine derivative) to the cell mixture, which will enter the cells. In an inactivated T-cell, the P-glycoprotein (or multidrug resistance) pump in the cell membrane transports foreign molecules, such as TH9402, out of the cells. However, in activated T-cells, this pump is switched off and TH9402 is trapped and accumulates in the cell.

Upon absorption of a specific wavelength of green light, TH9402 enters an excited state, which results in the production of singlet molecular oxygen. This induces cell death in those (activated) T-cells in which TH9402 was sufficiently accumulated, thus depleting the mixture of immune cells that may cause GVHD.

The remaining donor T-cells, which constitute our ATIR product, are frozen and delivered to the patient. ATIR is dosed approximately one month after the haploidentical HSCT graft has been given to the patient.

ATIR is dosed at two million cells/kg. In comparison, an unmanipulated donor lymphocyte infusion ("**DLI**"), from a haploidentical donor, that still contains all T-cells, may cause life threatening GVHD at significantly lower doses of 10,000 cells/kg.

Market opportunity for ATIR101

We believe that our target patient population consists of all patients eligible for an HSCT who cannot find a genetically matched related donor. This includes all patients who would currently receive haploidentical, cord blood or MUD HSCT, as well as patients that are currently unable to find a suitable donor at all. We estimate that, over time, a target population in excess of approximately 50,000 patients per year collectively in Europe and the United States could potentially benefit from ATIR as an adjunctive therapy to haploidentical HSCT. This reflects the continued growth of allogeneic transplantations from the current

>30,000 a year in US and EU, and a continuation of the current rapid growth of haploidentical HSCTs, from the estimated 3,800 haploidentical HSCT performed in 2016.

We believe the growth of haploidentical HSCT towards this target population will continue to accelerate, driven by further acceptance of the PTCy protocol and its benefits over the MUD HSCT, as well as a decline in the availability of matched donors due to increased genetic diversity in the population. An improved outcome with ATIR101 over the PTCy protocol will further support and drive such growth for haploidentical HSCT.

Currently approximately 85% of current HSCT is performed in patients with blood cancers and related conditions, 85% and 84% of whom are in Europe and the United States, respectively. As a result, we believe our Phase II and Phase III data, if positive, will support adoption in the vast majority of this market. To further support adoption, we intend to initiate additional studies in pediatric patients and with ATIR101 as an adjunctive T-cell product after other haploidentical HSCT protocols, such as α/β T-cell depleted HSCT or the PTCy protocol.

To assess the potential adoption of ATIR, we have performed market research. We surveyed 50 transplant specialists and KOLs at transplant institutions that performed approximately 43% of allogenic HSCTs in malignant diseases in 2016 in the United States. Clinicians were asked to consider whether they would use ATIR if it would have a hypothetical OS benefit over PTCy and hypothetical GRFS benefit over PTCy. In the hypothetical scenario where ATIR had an 18% GRFS benefit but no OS benefit over PTCy, clinicians surveyed stated that they would recommend ATIR for use in 49-51% of their HSCT transplants, and in the hypothetical scenario where ATIR had a 23% GRFS benefit and a 5% OS benefit over PTCy, clinicians surveyed stated that they would recommend ATIR for use in 60-61% of their HSCT transplants. A European survey showed similar results.

We believe that our ATIR platform can potentially benefit a broader range of settings outside of blood cancers, including the use of haploidentical HSCT for inherited blood disorders (e.g., thalassemia or sickle cell anemia), inherited immune disorders (e.g., severe combined immunodeficiency) and auto-immune diseases (e.g., multiple sclerosis and lupus). Currently a haploidentical HSCT is only very rarely performed in those indications, among others, due to the inherent risk of replacing a chronic disease with GVHD. We believe the use of ATIR can potentially result in improved patient outcomes and transform haploidentical HSCT into a much more widely-used treatment option for these indications.

Finally, we also aim to expand to other regions in the future, such as China, where haploidentical HSCT may be the only available treatment due to small family sizes and limited donor registries.

7.10 Clinical data for ATIR101

We are initially developing ATIR101 for blood cancers, and have clinical data to date in acute leukemia and MDS, as described below.

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 (MITT)	Completed

Trial No. Phase (Countries)[1]	Objective	Trial design	Patients[2]	Trial status
CR-AIR-007 Phase II (BE, CA, GE, UK)	Efficacy, safety	Open-label, uncontrolled, multicenter trial, using a single dose of 2 x 106 viable T-cells/kg	N=23/26 (MITT/ITT)	Completed
CR-AIR-008 Phase II (CA, EU)	Efficacy, safety	Open-label, uncontrolled, multicenter trial, evaluating a two-dose regimen of ATIR101	N=15/17 (of which 9/11 single dose (MITT/ITT)	Completed, preparing report
CR-AIR-009 Phase III (planned: CA, EU, US)	Efficacy, safety	Open-label, randomized, controlled trial of a single dose of ATIR101 (2 x 106 viable T-cells/kg) vs. post-haploidentical HSCT PTCy protocol	N=250 (ITT)	Ongoing/ recruiting
Non-interventional studies				
CR-AIR-004 Phase II (BE, CA, GE, NL, UK, US)	Efficacy, safety	Open-label, uncontrolled, multi-center	N=40 (29 matched to CR-AIR-007)	Terminated early
CR-AIR-006 (BE, CA, GE, NL, UK, US)	Control	Observational cohort trial	N=158 (35 haplos matched to CR-AIR-007)	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

Of these studies, CR-AIR-007 is the pivotal trial in the current EMA MAA filing. In our EMA MAA filing, we have presented analyses comparing the results of CR-AIR-007 against those from a cohort of patients in the non-interventional retrospective observational study CR-AIR-006.

In response to 120 Day List of Questions from the EMA, we have also performed and submitted to the EMA additional analyses, pooling results from CR-AIR-007 with those from patients in CR-AIR-008 who received a single dose of ATIR101 and comparing such results from CR-AIR-006 pooled together with those from CR-AIR-004. Only patients suffering from AML, ALL and MDS in study CR-AIR-004 (29 patients) and only patients with a haploidentical HSCT from study CR-AIR-006 (35 patients) were included in these analyses to match the indications in study CR-AIR-007.

We are currently conducting CR-AIR-009, which is intended to be the pivotal study for a future FDA submission and should support converting a potential conditional EMA approval into a standard approval.

CR-AIR-007 Phase II safety and efficacy (completed)

We conducted an open-label, single-arm, Phase II clinical trial in patients with hematologic malignancies (AML, ALL, MDS). The primary endpoint of this trial was defined as TRM at six months after haploidentical HSCT, with secondary endpoints including acute/chronic GVHD, infections, RRM, PFS and OS, at six, 12 and 24 months. During the study, 23 patients were given a single infusion of ATIR101 after a T-cell depleted CD34+ HSCT from a haploidentical donor. Patients' age ranged from 21 to 64 years (with a median age of 41

years). Patients had AML (16 patients) or ALL (seven patients). At the time of transplant, 15 patients were in first remission (CR1) and eight patients were in second or subsequent remission (CR2). The DRI was high in 57% of patients and intermediate in 43% of patients. The trial was performed in eight hospitals: three in Canada, three in Belgium, one in Germany and one in the United Kingdom, with four of those hospitals enrolling and treating patients with ATIR101. 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 was conducted under a U.S. Investigational New Drug application ("**IND**"). The trial began in March 2013 and completed enrollment in July 2015, and the two-year follow-up for the trial was completed in 2017.

Analyses were performed for patients that underwent a haploidentical HSCT and received ATIR101 (Modified Intent to Treat; MITT; n=23), as well as for patients that underwent a haploidentical HSCT, whether they received ATIR101 or not (Intent To Treat population; ITT; n=26). Three patients in the ITT population are not included in the MITT: one patient died within a couple of days after the haploidentical HSCT, one patient had a haploidentical HSCT engraftment failure (the physician subsequently performed a rescue haploidentical HSCT without ATIR101), and one patient could not receive ATIR101 due to an ATIR101 batch failure (the physician had started conditioning the patient prior to notification of successful interim batch release; the physician decided to continue the CD34+ HSCT without a subsequent ATIR101 infusion).

Patients underwent myeloablative conditioning prior to transplantation. A CD34+ selected stem cell graft from a haploidentical donor was given, containing a median of 11.0x106 CD34+ cells/kg (range: 4.7 – 24.4) and 0.29x104 CD3+ cells/kg (range: 0.01 – 1.8). ATIR101 was then infused at a median of 28 days (range: 28-73) post-HSCT at a fixed dose of 2x106 CD3+ cells/kg. Patients did not receive any post-transplant GVHD immunosuppressants.

Analysis of the primary efficacy endpoint and secondary endpoints

All 23 MITT patients engrafted after transplantation, with neutrophil and platelet engraftment achieved at a median of 12 days (range 8-34 and 9-35, respectively). A Kaplan-Meier analysis of the primary and secondary efficacy endpoints is provided below. A Kaplan-Meier analysis allows an estimation of the probability of a clinical event even when patients drop out or are studied for different lengths of time, or when endpoints are competing, as with TRM and RRM.

Kaplan-Meier analysis for primary and secondary efficacy endpoints in CR-AIR-007, MITT

	6 months	12 months	24 months
TRM	13%	32%	48%
RRM	5%	10%	25%
PFS	78%	61%	39%
OS	83%	61%	39%

Source: Clinical Study Report CR-AIR-007.

The actual causes of death are provided in the chart below.

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

Source: Clinical Study Report CR-AIR-007

ATIR101 had no drug-related serious adverse events detected, with the exception of one patient who developed chronic GVHD during the study. This patient had to receive immunosuppression and died of infections in the second year, accounting for one of the three cases of TRM in the second year. All cases of acute GVHD in the first year after HSCT were of grade I or II, and the maximum grade of GVHD was grade I or II in 9% and 13%, respectively. Three patients experienced acute GVHD of grade III or IV in the second year, about 380 to 530 days after HSCT, shortly after the administration of unmanipulated donor lymphocyte infusions, or DLIs, at doses between 3x104 and 3x105 T-cells/kg. Two of those patients died, accounting for the two of the three cases of TRM due to infections in the second year. Based on scientific literature, the administration of unmanipulated DLIs early after a haploidentical HSCT, especially at doses greater than 5x104 cells/kg, may lead to life-threatening acute GVHD. Therefore, these instances of acute GVHD were not attributed to ATIR101. In addition, after these events the trial protocol was amended to restrict the infusion of unmanipulated DLIs to patients with impending relapse or graft failure.

CR-AIR-008 Phase II Trial (Completed, preparing report)

In 2015, we commenced a Phase II trial, CR-AIR-008, to test the safety of administration of two doses of ATIR101. CR-AIR-008 is an exploratory, open-label, multicenter trial in 15 (MITT) adult patients with hematologic malignancies AML, ALL and MDS who received a T-cell depleted CD34+ selected haploidentical HSCT. The first dose of ATIR101 was administered at a dose of 2×106 viable T-cells/kg at between 28 and 32 days post-HSCT as was done in our CR-AIR-007 trial. The second dose of ATIR101 (2×106 viable T-cells/kg) was infused between 70 and 74 days after the HSCT. The protocol provided that the second dose would not be administered in cases of dose limiting toxicity, or DLT. If within the first 6 patients at least 2 patients showed DLT, defined as occurrence of acute GVHD grade III/IV within 120 days post HSCT, then the second ATIR101 infusion was to be adjusted to a dose of 1×106 viable T-cells/kg. If in one of the next 3 patients treated at this lower dose again DLT was observed, the second ATIR101 infusion was to be halted and the remaining patients were to be given only a single dose of ATIR101. Based on this predefined stopping rule in the protocol and the higher than expected incidence of acute GVHD grade III/IV, we abandoned the administration of the second dose after the sixth patient.

The clinical phase of the study is completed and the study report is in preparation. Of the 15 patients that received ATIR101, six patients were infused with two doses and nine patients received a single dose (MITT population of 15). Two patients that were enrolled in the study did not receive ATIR101 (one patient died of an Aspergillus infection and one patient did not receive ATIR101 due to batch failure; ITT population of 17). All patients have been followed up for one year after the HSCT (or until death). We are including results of patients who received a single dose of ATIR101 and would have met the inclusion criteria for CR-AIR-007

in the efficacy analyses included in the EMA MAA submission. Data are available for six patients that had been infused with two doses and nine patients that had been infused with a single dose.

In total, seven ATIR101-treated patients died during the study: four in the double-dose group due to TRM, two in the single dose group due to TRM and one in the single-dose group due to RRM. Of the six patients that died due to TRM, the cause was infection in three patients, GVHD in two patients and cardiac arrest in another patient.

Kaplan-Meier analysis for primary and secondary efficacy endpoints in CR-AIR-008, single dose, MITT (at June 1, 2018 cut-off date)

	6 months post HSCT	12 months post HSCT
TRM[(1)]	11%	22%
RRM[(1)]	11%	11%
PFS	78%	56%
OS	78%	67%

[(1)] Analysis based on cumulative incidence calculation.

Summary of cumulative GVHD incidences for patients in trial CR-AIR-008, MITT (at June 1, 2018 cut-off date)

	Dose schedule	
	Single dose (N=9)	Two doses (N=6)
Acute GVHD grade III/IV	2	2
Acute GVHD grade II	1	1
Acute GVHD grade I	3[1]	1
Chronic GVHD	0	2[2]

1 Acute GVHD grade I occurred in two patients before ATIR101 infusion. ATIR101 was administered after resolution of GVHD.

2 Chronic GVHD occurred in one patient after earlier reported acute GVHD.

As the chart above shows, after infusion of a single dose of ATIR101, two patients developed acute GVHD grade III/IV, one patient developed acute GVHD grade II and one patient developed acute GVHD grade I.

CR-AIR-006 observational cohort trial (completed)

We conducted a non-interventional, retrospective, observational trial to serve as a historical control for CR-AIR-007. The trial, CR-AIR-006, included four cohorts, of which one, the HAPLO group, was designed to be the control comparator for CR-AIR-007. In the HAPLO group, patients received a haploidentical T-cell depleted CD34+ cell selected HSCT (without the addition of ATIR101) between January 1, 2006 and June 30, 2013. The four cohorts were as follows:

- HAPLO: patients who received a T-cell depleted CD34+ selected HSCT from a haploidentical family donor without subsequent ATIR101 administration between January 1, 2006 and June 30, 2013.

- MUD: patients who received HSCT from a fully matched non-family donor (with HLA match of 10/10) between January 1, 2010 and December 31, 2012

- Mismatched Unrelated Donors, or MMUD: patients who received HSCT from a partially matched non-family donor (with HLA match of 9/10) between January 1, 2010 and December 31, 2012

- Umbilical Cord Blood, or UCB: patients who received a double umbilical cord blood transplantation between January 1, 2010 and December 31, 2012.

For all patients, information was collected up to 12 months after HSCT, and included TRM, RRM, OS and PFS, as well as the incidence and severity of acute and chronic GVHD.

	Overall Survival[1]		Transplant Related Mortality[1]	
	6-month post HSCT	12-month post HSCT	6-month post HSCT	12-month post HSCT
HAPLO 006 (n=35)	63%	20%	37%	66%
MMUD 006 (n=37)	73%	65%	22%	24%
MUD 006 (n=64)	91%	86%	6%	9%
UCB 006 (n=22)	64%	55%	32%	36%

[1] Kaplan-Meier estimate.

Source: Clinical Study Report CR-AIR-006

CR-AIR-004 Phase II Safety & Efficacy

In 2009, we 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.

After 40 patients were transplanted and treated, we halted patient enrolment due to a high number of manufactured batches of ATIR101 that could not be released for use (out of specification). We then also investigated the quality of retained samples of the investigational medicinal product, or IMP, that was released for use and administered to patients. Characterization of these samples showed that the IMP mostly consisted of dead or dying cells. Further investigations revealed that storage of the donor cells of up to 72 hours before the start of manufacturing was too long and was the main root cause of the cells being mostly dead or dying. As a result, we prematurely terminated the CR-AIR-004 trial.

Given that the IMP consisted mostly of dead and dying cells and was not produced to specification, we determined that the IMP manufactured during this trial was not ATIR101. This has been confirmed by the EMA. Furthermore, in subsequent EMA interactions and correspondence, the EMA has indicated support for including as a historical control in efficacy analyses of ATIR101 the results of the 29 patients in CR-AIR-004 who would have satisfied the inclusion criteria in CR-AIR-007 (AML/ALL/MDS patients in complete remission).

CR-AIR-004 patient population that satisfied the inclusion criteria in CR-AIR-007

Patients	Hematologic malignancy	Disease status
N=7	Acute lymphatic leukemia	Complete remission 1st and 2nd
N=19	Acute myeloid leukemia	Complete remission 1st, 2nd & 3rd
N=3	Myelodysplastic syndrome	Partial remission & untreated upfront

N=29

Summary of cumulative incidences for patients in trial CR-AIR-004

Kaplan-Meier estimates of TRM and OS at 6 and 12 months after the HSCT

	6 months after the HSCT	12 months after the HSCT	24 months after the HSCT
Transplant-related mortality (TRM)			
Overall (N=40)	33%	56%	71%
Overall survival (OS)			
Overall (N=40)	65%	33%	22%

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

The strategy of using the CR-AIR-006 non-interventional historical observational trial was discussed with the EMA and several European National Competent Authorities during scientific advice meetings. We believe that pooling of the two studies is acceptable because the design of CR-AIR-006 was aligned as much as possible with that of CR-AIR-007. CR-AIR-006 recruited a similar patient population as CR-AIR-007, and centers participating in CR-AIR-006 were, when possible, chosen from among centers participating in CR-AIR-007. Comparison of the demographics and baseline disease characteristics confirms that the patient populations of the two studies were similar, as discussed below. Analyses were done on the basis of the modified intent to treat, or MITT, population, which consisted of the 23 patients in CR-AIR-007 that received ATIR101.

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 in the pivotal CR-AIR-007 trial was 13%, almost three times as low as the 37.1% in the HAPLO group in trial CR-AIR-006, and TRM at 12 months was about two times as low in the pivotal trial.

The hazard ratio ("**HR**") is a measure of the probability of a patient experiencing death due to a progression event and enables estimates as to the risk of death for a set of patients relative to a control group. The HR for TRM at 12 months was 0.30 (95% CI 0.12, 0.75) with a p-value of 0.0066. This indicates a statistically significantly lower TRM in trial CR-AIR-007 for patients that received ATIR101 compared to the HAPLO group in trial CR-AIR-006 for patients that did not receive ATIR101. Statistical significance was determined by using a “p-value,” which represents the probability that random chance could explain the results. The FDA utilizes the reported statistical measures when evaluating the results of a clinical trial, including statistical significance as measured by p-value as an evidentiary standard of efficacy, to evaluate the reported evidence of a product candidate's safety and efficacy. If not otherwise specified, we used a conventional 5% or lower p-value ($p < 0.05$) to define statistical significance for the clinical trials and studies and data presented in this Registration Document.

Transplant Related Mortality - CR-AIR-007 vs. CR-AIR-006, MITT

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

[1] Abbreviation: ne = not estimable.

[2] Analysis based on the MITT for trial CR-AIR-007 and all patients of the HAPLO group in trial CR-AIR-006; hazard ratio of haploidentical HSCT plus ATIR101 (CR-AIR-007) vs. haploidentical HSCT (CR-AIR-006); log-rank test.

Source: Clinical Study Report CR-AIR-007

Overall Survival

The OS was higher in the pivotal CR-AIR-007 trial than in the HAPLO control group of CR-AIR-006, with 12-month survival of 60.9% versus 20.0% respectively. The HR for OS at 12 months was 0.32 (95% CI 0.15, 0.71; p=0.0035), indicating a statistically significant improvement of OS as compared to the control group (see the chart below).

Overall Survival - CR-AIR-007 vs. CR-AIR-006, MITT

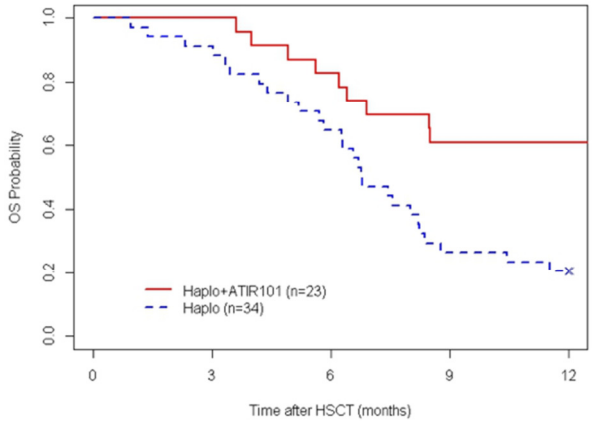
	CR-AIR-007 Haploidentical HSCT plus ATIR101	CR-AIR-006 Haploidentical HSCT observational control
Patients, n (MITT)	23 (100.0)	35 (100.0)
Patients with event	9 (39.1)	28 (80.0)
OS, median (95% CI) (in months)	ne (6.9; ne)	6.8 (5.8; 8.2)
Hazard ratio at 12 months (95% CI)[1]	0.32 (0.15, 0.71)	
p-value at 12 months	0.0035	
OS probability at landmark time points[2]		
6 months	82.6	62.9
9 months	60.9	25.7
12 months	60.9	20.0

[1]Hazard ratio of haploidentical HSCT plus ATIR101 (CR-AIR-007) vs. haploidentical HSCT (CR-AIR-006); log-rank test.

[2]Kaplan-Meier estimates. As one patient in the HAPLO group died before day 30 post haploidentical 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.

The following gives the Kaplan-Meier curve comparing the results from the CR-AIR-007 trial with the HAPLO group in the CR-AIR-006 trial, confirming the benefit of ATIR101 as an adjunctive treatment:

Overall Survival - CR-AIR-007 vs. CR-AIR-006, MITT



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 CR-AIR-007 than in the HAPLO group in CR-AIR-006. However, numerical differences between the groups did not reach statistical significance (see the figure below).

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

	CR-AIR-007 Haploidentical HSCT plus ATIR101	CR-AIR-006 Haploidentical HSCT observational control	p-value[1]
Patients, n (MITT)	23 (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] Based on Gray's test that compares cumulative incidence functions to accurately account for competing risks, such as death and development of GVHD.

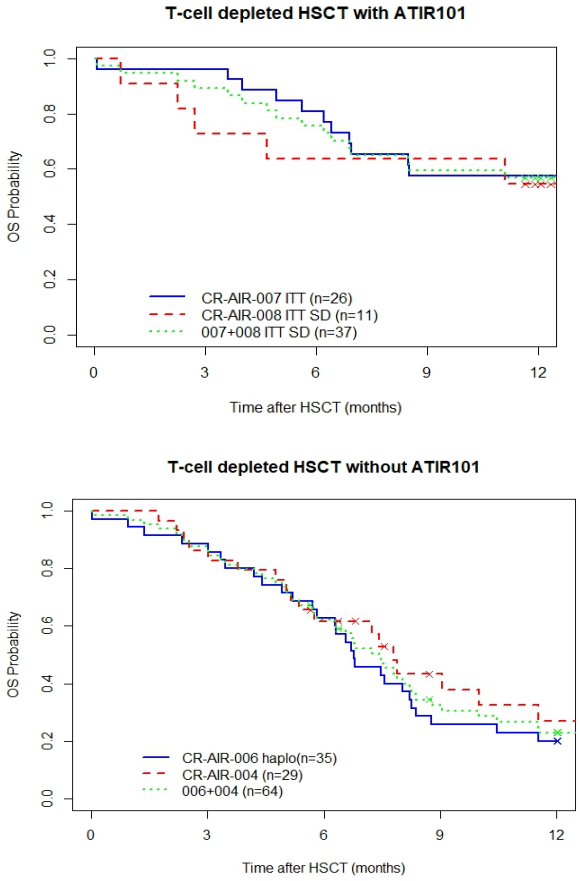
Comparison of trials CR-AIR-007 and CR-AIR-008 with trials CR-AIR-006 and CR-AIR-004 (ITT)

In response to 120 Day List of Questions from the EMA, we have also performed and submitted to the EMA additional analyses, pooling results from CR-AIR-007 with those from patients in CR-AIR-008 who received a single dose of ATIR101 and would have otherwise met the inclusion criteria of trial CR-AIR-007. We have compared these results to those from CR-AIR-006 pooled with patients from CR-AIR-004 that met the inclusion criteria of CR-AIR-007.

We believe that pooling of the study data is acceptable because the design of CR-AIR-004 and CR-AIR-008 are aligned with that of CR-AIR-007, with similar in/exclusion criteria and overlapping centers participating. Comparison of the demographics and baseline disease characteristics confirms that the patient populations of the studies were similar.

The analyses of the ITT pooled data confirm that adding ATIR101 to a T-cell depleted HSCT provides clinically meaningful benefits on OS and NRM, without increasing GVHD. These results, if observed in a randomized, controlled clinical trial, would represent a p-value of 0.004 (OS 0-12 months) and 0.02 (NRM 0-6 months).

Overall Survival of T-Cell depleted HSCT with and without ATIR, Individual and Pooled Analyses (at June 1, 2018 cut-off date)



Charts compare overall survival for ITT patients who received T-cell depleted HSCT with ATIR101 (CR-AIR-007; single-dose CR-AIR008; pooled CR-AIR-007/008) and patients who received T-cell depleted HSCT without ATIR101 (CR-AIR-006; CR-AIR-004; pooled CR-AIR-006/004). CR-AIR-008 data through cut-off date of June 1, 2018.

The following chart summarizes the ITT pooled data from our clinical trials, as discussed above. The data was not collected in a single well-controlled study. These pooled results were provided to the EMA at its request, and may not reflect the data that we may obtain in our CR-AIR-009 study or in any future clinical trial of ATIR101.

Phase 2 Studies in AML/ALL/MDS

CR-AIR-007: Single dose ATIR

- Open label single arm; 2013-2018
- 23/26 patients (MITT/ITT*)
- 2 year follow up
- Sites in BE, CA, GE, UK

CR-AIR-008: Single dose ATIR and two doses ATIR**

- Open label single arm; 2015-2018 (ongoing)
- 9/11 single dose; 6/6 patients two doses (MITT/ITT)
- 3 patients still at risk
- 1 year follow up
- Sites in CA, BE, GE, UK

CR-AIR-004: Historical Control, No ATIR

- Open label single arm; 2009-2012
- 40 patients (29 matched to CR-AIR-007)
- Sites in BE, CA, GE, NL, UK, US

CR-AIR-006: Historical Control, No ATIR

- Observational cohort, EBMT registry; 2006-2013
- 35 patients (all matched to CR-AIR-007)
- 1 year follow up

* MITT: Modified Intent to Treat (transplanted and ATIR); ITT: Intent to Treat (transplanted); ** CR-AIR-008 was designed to test safety of second dose, but due to higher then expected GVHD it was decided to stop infusing second dose (in accordance with protocol)

ATIR Phase 2 Data	T-cell depleted (CD34+) *with* single dose ATIR (n=37)*			T-cell depleted (CD34+) *without* ATIR (n=64)*		
	CR-AIR-007	CR-AIR-008	007-008	CR-AIR-006	CR-AIR-004	004-006
1 year post HSCT	**(ITT n=26)**	**(ITT n=11)**	**(ITT n=37)**	**(n=35)**	**(n=29)**	**(n=64)**
Overall Survival	58% (42-80)	64% (41-100)	58% (44-77)	20% (10-39)	27% (13-54)	23% (14-37)
Non-relapse mortality	35%	27%	33%	66%	59%	63%
Relapse-related mortality	8%	9%	8%	15%	14%	14%
Relapse	8%	9%	8%	NA	NA	NA
Acute GVHD grade II-IV	19%	27%	21%	20%	18%	19%
Acute GVHD grade III-IV	0%	18%	5%	6%	7%	6%
Chronic GVHD	4%	0%	3%	11%	5%	8%
Chronic GVHD severe	0%	0%	0%	9%	5%	7%
6mths post HSCT	**(MITT n=23)**	**(MITT n=9)**	**(MITT n=32)**	**(n=35)**	**(n=29)**	**(n=64)**
Non-relapse mortality	13% (0-27)	11% (0-29)	13% (0-24)	37% (19-51)	35% (15-51)	36% (23-47)

*Notes: NRM at 6 months primary endpoint of CR-AIR-007; Kaplan-Meier estimates for OS and NRM at 6 months; all other estimates cumulative incidence analyses; ITT: patients receiving HSCT; MITT: patients receiving HSCT and ATIR; OS: overall survival; CR-AIR-008 status 1 June 2018 (3 patients at risk);
All trials: Conditioning: Myeloablative; Graft source: Haplo PBMCs; HSCT: T-cell depleted; ATIR: ~30 days after HSCT; No prophylactic immunosuppression

Safety

In our clinical studies serious adverse events ("**SAEs**") were reported, including GVHD. No ATIR-related cases of acute GVHD grade III/IV were reported in studies CR-GVH-001 or CR-AIR-007. Chronic GVHD requiring systemic treatment was reported in one patient in study CR-AIR-007. Two ATIR101-related cases of acute GVHD grade III/IV were reported in the single dose arm of CR-AIR-008, and two ATIR101-related cases of acute grade III/IV GVHD and two cases of chronic GVHD were reported in the double dose arm of CR-AIR-008 (as a result of which we have abandoned the administration of the second dose). In addition, three non-ATIR101 related cases of acute grade III/IV GVHD were reported in the second year of the CR-AIR-007 study as a result of unmanipulated DLIs (as a result of which a protocol amendment prohibited the administration of these unmanipulated DLIs). Other than GVHD, no SAEs were attributed to ATIR101.

The rates of GVHD for CR-AIR-007 and CR-AIR-008 combined is equal to or lower than the rate of GVHD for CR-AIR-004 and CR-AIR-006 combined, suggesting that ATIR101 does not increase GVHD beyond the levels seen with a T-cell depleted HSCT without adjunctive treatment.

Additional SAEs observed in our clinical trials with ATIR101 included autoimmune hemolytic anemia (19% of patients in CR-AIR-007), febrile neutropenia (15% of patients in CR-AIR-007), pyrexia (47% of patients in CR-AIR-001), pneumonia (20% of patients in CR-AIR-001) and pancytopenia (21% of patients in CR-AIR-001), of which none were attributed to treatment with ATIR101.

Additional SAEs in study CR-AIR-008, which were considered not related to ATIR101, included acute lymphocytic and myelocytic leukemia recurrence (7% and 20% of patients, respectively), pneumonia (26%), pyrexia (26%), and sepsis/septic shock (7% and 20% of patients, respectively).

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

We are conducting a pivotal Phase III trial with a head-to-head comparison of a haploidentical HSCT with ATIR101 as adjunctive treatment against a haploidentical HSCT with the PTCy protocol. Based on a meeting with the FDA in 2016 and discussions with KOLs and our advisors, we have designed this trial as a Phase III, multicenter, randomized and controlled study to compare safety and efficacy of a haploidentical CD34+ selected HSCT followed with adjunctive treatment with ATIR101 versus a haploidentical HSCT with the PTCy protocol, in patients with a hematologic malignancy (the HATCY study). The trial will involve 50 sites in the United States, Europe, Canada and certain additional countries, and we have received regulatory approval to conduct the trial in multiple of those countries. Adult patients (18 to 70 years) with a hematologic malignancy (AML, ALL or MDS) who are in complete remission and eligible for a T-cell depleted haploidentical HSCT will be able to participate. We plan to randomize 250 patients (1:1) to either the ATIR101 or PTCy arm. The first patient was enrolled in December 2017. At the end of March 2019, 17 clinical sites were open for recruitment and 33 patients had been enrolled. Patients randomized to the ATIR101 arm will receive a single ATIR101 dose of $2.0x10^6$ viable T-cells/kg, administered 28 to 32 days after the haploidentical HSCT. Patients randomized to the PTCy arm will receive cyclophosphamide 50 mg/kg/day at day three and day four or five after the haploidentical HSCT. All patients will be followed for at least 24 months after the haploidentical HSCT.

The primary endpoint of the trial is GRFS, defined as time from randomization until acute GVHD grade III/IV, chronic GVHD requiring systemic immunosuppressive treatment, disease relapse, or death, whichever occurs first. Secondary endpoints will include OS, PFS, RRM and TRM. Safety will be assessed in terms of AEs, clinical laboratory safety parameters, overall infections, vital signs and viral monitoring (CMV, EBV). The conditioning regimens across the ATIR101 and PTCy arms will be balanced to minimize variability, and patients will be stratified by DRI, underlying disease and treatment site.

To design the power of the trial we identified three publications that reported PTCy GRFS data and compared these with the results of our Phase II CR-AIR-007 trial. These publications reported retrospective analyses from Johns Hopkins and Northside (both single site) and 69 EBMT transplant centers. We also calculated a GRFS in these publications normalized based on the DRI (considered an important prognostic factor for OS), of the patients in CR-AIR-007 (ITT) and the single-dose arm of CR-AIR-008 that would have satisfied the inclusion criteria of CR-AIR-007. The data from these publications and our supplemental calculation of DRI-normalized GRFS is shown below, and indicate 1-year GRFS in the range of 30-40%.

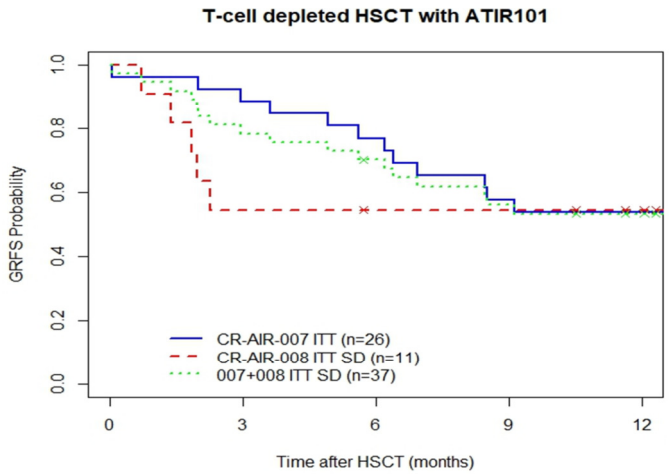
PTCy literature with GRFS as an Endpoint, As Reported and After DRI Normalization

GRFS in PTCy literature: *30 - 40%*			
	Solh 2016 (n=126)	**McCurdy 2017** (n=372)	**Santoro 2017** (n=208)
Sites included	Atlanta (single site)	Johns Hopkins (single site)	69 EBMT sites
Patients	AML/ALL/MDS/ NHL/HL, CML	AML/ALL/MDS/ NHL/HL, MM	ALL
GRFS 1-yr [95% CI]	**33%** [25,41]	**45%** [40,50]	**33%** (average)
Disease risk index (DRI)*	19% low 39% intermediate 40% high/v. high	14% low 67% intermediate 19% high/v. high	Not available
Normalized GRFS 1-yr*	**30%**	**40%**	**Not available**

* Normalized by adjusting based on the average DRI of the CR-AIR-007/008 patient population (57% intermediate risk; 43% high/very high risk); using the hazard ratios per DRI as reported in the Solh/McCurdy publications (2 patients in Solh for which DRI not known excluded); DRI is an important prognostic factor for OS,: e.g., NHL patient in CR1 is low risk, AML in CR2 is very high risk (Armand 2014); DRI normalization routinely done.

We then calculated the GRFS Kaplan Meier estimates for the CR-AIR-007 and single-arm CR-AIR-008 trials. The one-year KM estimate [95% CI] for CR-AIR-007 is 54% [38-77], for the single dose CR-AIR-008 is 55% [32-94], and for the combination of these 53% [39-72].

GRFS of T-Cell depleted HSCT with ATIR, Individual and Pooled Analyses (ITT) at June 1, 2018 cut-off date



The chart above shows GRFS for ITT patients who received T-cell depleted HSCT with ATIR101 (CR-AIR-007; single-dose CR-AIR-008; pooled CR-AIR-007/008)

These publications and analysis therefore suggests a potential GRFS benefit with ATIR101 over PTCy in the range of 13-23% (13% for Johns Hopkins, 23% for Atlanta and 20% for

EBMT centers). However, Johns Hopkins is the inventor of and most experienced site with PTCy, and we believe the results of Northside and EBMT centers are likely more representative for PTCy across North America and Europe. We therefore designed our CR-AIR-009 phase III to enroll 250 patients to provide for an 80% power to detect a 16% absolute GRFS difference between the ATIR101 and PTCy arms of the study, taking into account potential drop offs for patients who do not receive a HSCT or who receive a HSCT but do not receive ATIR.

Primary analysis will be done at 156 GRFS events (acute GVHD grade III/IV, systemic immunosuppressive treatment for GVHD, disease relapse or death), at which point statistical significance will be reached with a 11.4% reduction of GRFS (with a hazard ratio of 0.73) compared to the PTCy protocol arm. The interim analyses will take place at 105 events, which is 2/3 of total, to detect a potentially statistically significant 17.6% GRFS treatment effect (with a hazard ratio of 0.61).

Although the FDA has noted that GRFS is a novel endpoint that has not yet been used to support approval of a drug or biologic, and that the FDA does not have sufficient experience to predict how it will behave in a clinical trial, we believe that recent experience with this endpoint described in the scientific literature demonstrates its relevance in treating these diseases.

Potential future clinical studies

ATIR101 in pediatric blood cancer patients

To demonstrate the safety and efficacy of ATIR101 in pediatric blood cancer patients, and to satisfy the EMA requirement within the EMA Pediatric Investigation Program, in the future we intend to initiate a study with ATIR101 in pediatric blood cancer patients.

ATIR101 as adjunctive to other haploidentical protocols

To further expand use of ATIR101, we may initiate additional studies to combine ATIR101 with other haploidentical HSCT protocols, such as PTCy and/or α/β T-cell depleted HSCT. We anticipate that the first additional study will be an exploratory trial of ATIR101 as an adjunctive to a PTCy based haploidentical HSCT, with the objective to reduce the high relapse rates observed with PTCy. Considering the low relapse rate observed in CR-AIR-007, and therefore the suspected anti-tumor activity of the T-cells in ATIR101, ATIR101 given after a PTCy protocol may support the patients' immune defense against residual tumor cells. However, we do not believe that the use of ATIR101 as an add-on to PTCy will reduce the GVHD rates seen with PTCy, nor that this strategy would allow an immunosuppressant-free haploidentical HSCT.

Other historical clinical study

Trial CR-GVH-001 Phase I/II dose escalation (completed)

In 2005, we started a Phase I/II open-label, dose escalation trial. The five-year follow-up was completed 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 haploidentical T-cell depleted CD34+ selected HSCT. The maximum tolerated dose ("**MTD**") was defined as the highest dose of

ATIR101 in which acute GVHD grade III/IV does not occur in more than one-third of patients. The secondary endpoints of the trial included TRM, RRM and OS.

A total of 19 patients with advanced hematologic 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) had active disease at the time of transplant, indicating patients had a poor survival prognosis.

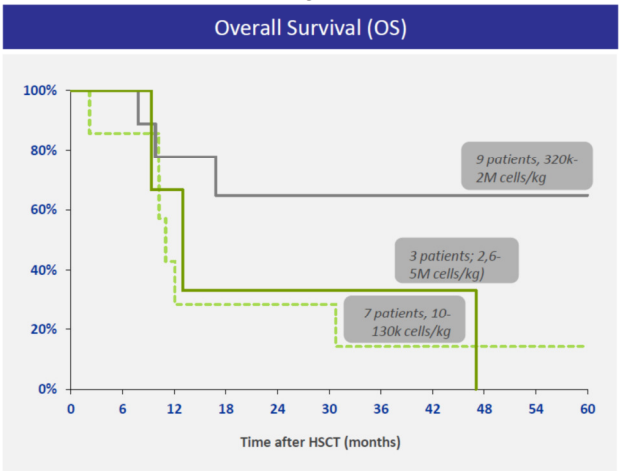
ATIR101 was infused at different cell dose levels (L1-L7) between 28 to 40 days (median of 31 days) after the initial stem cell transplantation. No patient, at any of the dose levels tested, experienced acute GVHD grade III/IV, so dose-limiting toxicity was not observed and the MTD was not formally determined. Additionally, none of the SAEs, reported for any of the dose cohorts were considered to be related to the ATIR101 infusion.

In the dose range between 3.2×105 cells/kg and 2.0×106 cells/kg (L4-6; nine patients), five-year OS was 67% and no patient died as a result of TRM. While TRM was reported in four out of seven patients in the dose range between 1x104 cells/kg and 1.3x105 cells/kg (L1-3), only at the highest dose cohort (L7-5.0×106 cells/kg) did TRM reappear, mostly related to infections resulting from the immunosuppressive treatment for mild GVHD.

This trial showed that ATIR101 is well-tolerated at an effective dose cohort (L4-L6) as adjunctive treatment to a haploidentical T-cell depleted transplant with no drug-related serious adverse events detected. Based on the results of trial CR-GVH-001, the optimal dose of ATIR101 for further development was considered to be 2×106 cells/kg.

Overall Survival - CR-GVH-001

The following graph shows the overall survival of nine patients with advanced hematologic malignancies who were treated with escalating doses of ATIR101 at 31 days after HSCT.



7.11 Significant collaborations

Since the 1990s, we and our predecessors have collaborated with the University of Montreal, Canada and with a group of researchers led by Prof. Denis Claude Roy at the Hospital Maisonneuve-Rosemont and researchers at the Hotel-Dieu de Montreal in Montreal, Canada, each of which are hospitals affiliated with the University of Montreal, for research and clinical development projects relating to our ATIR technology. Professor Roy's research includes research relating to the mechanism of action of the ATIR technology, applications of the ATIR technology in various disease indications and development work to

establish certain assays for the characterization of cellular products related to the ATIR technology. We intend to continue our collaboration with these institutions going forward. We currently license some of the components used in our ATIR platform from the University of Montreal and are subject to certain payment obligations in connection with the commercialization of certain cell-based products, including products based on the ATIR platform.

University of Montreal research and licensing agreement

In relation to the intellectual property arising out of the research and clinical development projects described above, we have been granted an exclusive license by the University of Montreal under a Research and Licensing Agreement (the "**Montreal Agreement**"), to exploit, utilize and commercialize such intellectual property. If we decide to make use of or commercialize any product utilizing the licensed intellectual property, we must provide the University of Montreal with 15 days' notice of such decision. The license for a specific licensed product expires upon the final cessation of use and commercialization activities for such licensed product. Such license also includes the right to grant sublicenses to third parties. We are required to send a copy of the sublicense to the University of Montreal prior to execution and any sublicense may not contain any provision that is inconsistent with or more expansive than the provisions of the Montreal Agreement.

We are also obligated to exercise best efforts to make use of and market each licensed product under the Montreal Agreement to the greatest possible extent. Such obligation for a licensed product is met if (i) such licensed product is actually used or marketed, (ii) we or our sublicensees incur research costs with respect to such licensed product, apply for patents, develop prototypes or seek government authorizations required to make use of or market such licensed product or (iii) no more than 24 months have passed since the most recent initiative or expense incurred in connection with any of the foregoing. If we breach our obligation to develop and commercialize a licensed product and fail to cure such breach within 90 days of receiving written notice from the University of Montreal, the University of Montreal may terminate the license with respect to such licensed product. In addition, subject to the foregoing, the Montreal Agreement terminates automatically (and solely with respect to a licensed product if applicable) if either the University of Montreal or we (a) enter bankruptcy, (b) breach the Montreal Agreement and fail to cure such breach within 90 days after receiving written notice from the non-breaching party or (c) become incapable of performing the substantive obligations of the Montreal Agreement.

In exchange for the license granted to us, we must pay the University of Montreal a royalty of a mid-single digit percentage of net sales of licensed products sold by us or by any of our affiliates to whom we grant sublicenses. In addition, we must pay the University of Montreal a mid-single digit percentage of any payments we receive from any third parties in connection with sublicenses we grant to such third parties. If we fail to timely make such payments, we must pay the University of Montreal a late fee in the form of an interest on the late payment at the preferential rate of the National Bank of Canada plus a low-single digit percentage.

Under the Montreal Agreement, we control the maintenance and prosecution of the licensed intellectual property at our cost and expense. In addition, we have the first right, but not obligation, to bring an action in connection with any forgery or infringement of the licensed intellectual property with necessary assistance to be provided by the University of Montreal. In the event of any lawsuit or other dispute that is not related to forgery or infringement of the licensed intellectual property, the University of Montreal and we must consult with each other to decide on the measures to be taken and whether to share any costs related to such

lawsuit or dispute. In addition, we indemnify the University of Montreal for any liability resulting from any claim relating to the commercialization of any licensed product.

Hospira Termination and Royalty Agreement

On December 21, 2010, we entered into an Hospira Exclusive License Agreement with Hospira, under which we granted Hospira a license under certain of our intellectual property rights, including a sublicense of our rights under the Montreal Agreement, to develop and commercialize certain cell-based products, including products based on the ATIR platform, in certain territories. On January 31, 2012, Hospira and we entered into a Termination and Royalty Agreement which terminated the Hospira Exclusive License Agreement and all of Hospira's and our obligations thereunder, including Hospira's commercialization obligations. Pursuant to the terms of the Hospira Termination and Royalty Agreement, we have agreed to use, and to cause our affiliates and licensees to use, commercially reasonable efforts to commercialize certain cell-based products, including products based on the ATIR platform, worldwide until we repay the $24.5 million we received from Hospira in connection with the Hospira Exclusive License Agreement plus the Reimbursement Amount. As part of the repayment, there is a potential milestone payment of $3 million upon the earlier of (i) the execution of the first license agreement with a third party under which we grant such third party a license under certain intellectual property to commercialize certain cell-based products, including products based on the ATIR platform, or (ii) the first commercial sale of such cell-based product by us, our affiliates or our licensees. In addition, we must pay Hospira a mid-single digit percentage royalty on worldwide net sales of such cell-based products until we have paid the full Reimbursement Amount, after which we must pay Hospira a low-single digit percentage royalty on net sales of such cell-based products in all countries (except for those in North America and South America, China, Mongolia and Antarctica). Under the Hospira Termination and Royalty Agreement, we granted Hospira a right of first negotiation for a potential license agreement with us if we wish to grant a license to a third party under certain intellectual property to commercialize specified cell-based products in the field of human hematological therapy or therapeutic applications for any "orphan disease" (defined in the agreement as a disease which affects no more than 5 in 10,000 persons in the European Union). In the event Hospira does not choose to pursue such license and we grant a license to a third party, the license agreement must contain certain provisions from the Termination and Royalty Agreement (including provisions relating to royalty payments, recordkeeping and commercialization efforts) for the benefit of Hospira, and Hospira must be named as a third party beneficiary of such provisions. As of December 31, 2017, the repayment amount owed to Hospira is $26.8 million.

University of Montreal and Hospital Maisonneuve-Rosemont Letter Agreement

Following the termination of the Hospira Exclusive License Agreement with Hospira, we entered into a letter agreement with the University of Montreal and the Hospital Maisonneuve-Rosemont on September 19, 2012 pursuant to which we agreed to pay the University of Montreal an amount of $750,000, subject to a low-single digit percentage interest amount per annum (effective as of January 1, 2011), as a royalty fee in relation to the sublicense granted to Hospira. The royalty fee will be paid by temporarily increasing the royalty rate under the Montreal Agreement on net sales of licensed products from a mid-single digit percentage to a high-single digit percentage until the royalty fee is paid off, after which the royalty rate will return to the original rate. In addition, (i) 50% of the royalty fee and the interest applicable thereto must be paid if we grant a sublicense to any of the licensed products under the Montreal Agreement, so long as the sublicense includes an upfront fee, and (ii) 100% of the royalty fee and the interest applicable thereto must be paid upon our undergoing a change of control.

7.12 Intellectual property

Intellectual property rights are important to the success of our business. Our future commercial success depends, in part, on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce our patents, preserve the confidentiality of our trade secrets, and operate without infringing, misappropriating or otherwise violating the valid enforceable patents and proprietary rights of third parties. It is part of our policy to actively seek patent protection for inventions we deem valuable. We periodically evaluate the results of our research and development activities, and decide whether to apply for new patents. Our ability to stop third parties from making, using, selling, offering to sell or importing our products may depend on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. Certain of our issued patents relevant for ATIR or other aspects of our technology have already expired, and others will expire in the coming years. For example, certain of our U.S. patents and non-U.S. patents related to ATIR101 are projected to expire in 2020 and 2021.

Our commercial success also depends in part on obtaining and maintaining trade secrets or confidential know-how, including for the methods used to manufacture our product candidates and the methods for treating patients using those product candidates.

We cannot provide any assurance that patents will issue with respect to any of our owned or licensed pending patent applications or any such patent applications that may be filed in the future, nor can we provide any assurance that any of our owned or licensed issued patents or any such patents that may be issued in the future will be commercially useful in protecting our product candidates and methods of manufacturing the same. Moreover, we cannot provide any assurance that we will be able to protect our trade secrets. See paragraph 1.8 above for a discussion of the risks related to our intellectual property.

The patent portfolio for our ATIR platform is summarized below:

ATIR platform

With respect to our ATIR platform, as of the Registration Document Date, we own one pending U.S. patent application and fifteen pending non-U.S. patent applications in Australia, Brazil, Canada, China, Europe Israel, India, Japan, South Korea, Mexico, New Zealand, Russia, Saudi Arabia and Singapore. These patent applications are directed to an improved photodynamic process leading to an ATIR product with improved functionalities and, if issued, are projected to expire in 2036. In addition, we exclusively license two issued U.S. patents and seven issued non-U.S. patents. Certain of these patents are directed to methods of treatment for reducing or preventing GVHD and a pharmaceutical composition to be used in this method. Such patents are projected to expire in 2020 and 2021. Although we rely on trade secrets and any regulatory exclusivity we may obtain to protect our ATIR platform, such trade secrets and regulatory exclusivity may not be sufficient to prevent third parties from developing competing products, and such competition could have a material adverse effect on our business, financial condition, results of operations and prospects.

Other intellectual property

In addition, we own one issued U.S. patent and six issued non U.S. patents in Australia, Brazil, Canada, Japan and Mexico directed to certain rhodamine derivatives, their synthesis and use. Such patents are projected to expire in 2022 and 2024. We do not expect the expiration of these patents to have a material effect on our business.

Trade secrets, confidential know-how and other proprietary rights

In addition to patent protection, we also rely on trade secrets and/or confidential know-how and continuing technological innovation to protect our proprietary position.

We have taken steps to protect what we believe are trade secrets and confidential know-how associated with the development and manufacturing of our products (including cell handling, formulation and release assays), device components, the conduct of clinical trials, patient-specific supply chain and communication with HSCT clinics (including storage and shipment) and the evaluation of clinical and scientific data. However, trade secrets and/or confidential know-how are difficult to protect. We attempt to maintain trade secrets and/or confidential know-how partly through contractual arrangements with our employees, consultants and collaborators. These arrangements may not provide meaningful protection. These contractual arrangements may also be breached, and we may not have an adequate remedy for any such breach. In addition, our 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 we disclose such information.

Our policy is to require our employees, consultants and advisors to execute confidentiality agreements in connection with their employment, consulting or advisory relationships with us. For example, our research activities are performed by researchers employed by us (including our predecessors), as well as by external researchers. The employment contracts of our employees and external researchers contain confidentiality and intellectual property assignment clauses. With respect to our personnel, this policy is also included in our personnel handbook. We also take measures intended to require our employees, consultants and advisors that work on our products to agree to disclose and assign to us (or our licensors) all inventions conceived during their term of service, developed using our property or which relate to our business. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products or to obtain or use information that we regard as proprietary. See paragraph 1.8 above for a discussion of these risks.

7.13 Manufacturing and supply

Our proprietary ATIR *ex vivo* manufacturing process involves:

- collection of patient and donor cells through apheresis and shipment to our central manufacturing site (42 hour hold time, formulation in hypothermosol);
- irradiation of the patient cells to render them inactive;
- mixture of the patient cells with the donor cells in order to activate those donor T-cells that recognize the patient and that may potentially cause GVHD (one way Mixed Lymphocyte Reaction to activate patient specific alloreactive T-cells);
- introduction of our proprietary photosensitive reagent, TH9402, to the cell mixture, which will accumulate in the activated, potentially GVHD causing T-cells;
- application of a specific wavelength of green light to the cell mixture, which will deplete the TH9402 containing T-cells;
- freezing the resulting ATIR product with liquid nitrogen for shipment to the administering physician; and

- functional release assays based on quality target product profile and critical quality attributes that confirm safety (depleted alloreactivity) and potency (other reactivity retained) of ATIR versus the original donor materials.

Our proprietary manufacturing process does not involve genetic engineering, unlike a CAR-T manufacturing process. In addition, most of the operations take place in standard biosafety cabinets, do not require bioreactors, require only limited capital equipment, and work with off the shelf disposables. The process requires limited scale up and its associated risks. The collection of patient and donor materials and shipment and infusion of final ATIR product follow routine HSCT procedures.

We believe the specific nature of our manufacturing and supply provides a significant barrier to entry for competitors and provides additional competitive advantages beyond our patents and orphan drug designations: The manufacturing and supply process is proprietary and complex, and many elements such as the manufacturing critical process parameters, release assays based on critical quality attributes, cell handling, storage, formulation and shipment, patient specific supply chain and communication have not been publicly disclosed, contain proprietary know-how and are difficult to replicate. As a result, we believe the development of a comparable process would involve a significant amount of resources. Moreover, the final product consists of a mixture of cells and is characterized by the combination of the clinical data, release assays and the totality of the manufacturing process, and as a result, any comparable competing product candidate would need to undergo a full clinical program to independently demonstrate efficacy and safety, as has historically been the case for biosimilars. Finally, we are building up relationships and infrastructure with the apheresis and transplant centers, including an integrated communication/IT platform, apheresis, shipment and dosing protocols and training, chain of command (track and trace).

We utilize a specialized photodynamic therapy device ("**PTD**"), to activate TH9402 as part of our manufacturing process. The current devices have been in use for many years, and we have many devices available. The current devices and components can no longer be manufactured, however, and we have started a project with an external firm to create a new device, including a new light emitting component. Since the wavelength and process parameters for the PTD step in the manufacturing process are well defined, we expect to be able to replace our current PTDs with the new device once available, but we cannot guarantee that the new components or devices will be available on time or that they will perform the same as the old components and devices.

We have been working with suppliers with respect to TH9402. We believe we have an adequate stock of TH9402 on hand for the coming years, including for use in our Phase III trial. Over time, we expect to secure additional sources for TH9402 to reduce the risk to supply interruptions and price increases.

We currently rely on, and we expect to continue to rely on in the near term, a third-party contract manufacturer to manufacture our ATIR101 product candidate for our ongoing Phase III clinical trial. We are building out our own manufacturing capability in our Amsterdam facility and are negotiating with an additional contract manufacturer in Europe in order to support our Phase III trial in Europe and North America and commercial launch of ATIR101 in Europe. In order to collect patient and donor cells and ship within 42 hours to our manufacturing site for ATIR product using our *ex vivo* manufacturing process, if our product is approved in both Europe and the United States, and to ensure redundancy of manufacturing capacity, we plan to also establish manufacturing sites in North America in the future.

We are continuing to refine our manufacturing processes in order to increase efficiency and product viability, improve containment (closed system), facilitate scalability and for adherence to GMP. For example, we made modifications to our ATIR manufacturing process from CR-GVH-001 to CR-AIR-007, from CR-AIR-007 to CR-AIR-008 and from CR-AIR-007 to CR-AIR-009, such as the addition of hypothermosol after apheresis to ensure cell viability during shipment and the replacement of human derived medium components with recombinant medium components. Such changes could cause our product candidates to perform differently and affect the results of clinical trials. In addition, a failure of our manufacturing may adversely affect the results of, or even our ability to conduct, our clinical trials. For example, our Phase II CR-AIR-004 trial was terminated early in 2012 because manufactured batches of ATIR101 did not meet quality specifications. We believe this was due to improper shipment conditions of donor cells prior to manufacturing and lack of a potency release assays. We believe we have adequately addressed these issues based in our CR-AIR-007 manufacturing process and clinical trial. However, if we encounter similar manufacturing issues in our current Phase III trial or any future trial we may need to suspend enrollment while we improve our processes, which may delay the completion of the trial and delay or even adversely affect our ability to obtain marketing approval of ATIR101.

7.14 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 the Frankfurt facility of Blood-Donor Services Baden-Württemberg-Hessen (BSD) in 2013 and has been included in the GMP manufacturing license of this site by the local authorities in accordance with European Union regulations. This site manufactured ATIR101 for the European and Canadian clinical centers 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 license 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 optimization 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 used 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 organizations 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.

7.15 Sales and marketing

The stem cell transplant community is concentrated with a relatively few stem cell transplant centers and a small group of key opinion leading physicians. We therefore believe we are well positioned to commercialize ATIR101 in Europe and the United States, through our own commercial organization that is small relative what is needed for marketing and distributing drugs at the local physician level. For instance, market access for an orphan oncology drug is possible in Germany with a shortened dossier through the GBA/AMNOG process until annual sales reach €50 million, while we can have market access in the UK through a NICE evaluation with interim funding potentially via the Cancer Drug Fund. In Italy, we can go through the L-648 name patient basis process and subsequently via submission of a P&R dossier at AIFA after marketing approval, while in France, we can have market access through the ATU named patient basis process and subsequently via a HAS/CEPS filing after marketing approval. We currently intend to establish internal sales, marketing, pricing and reimbursement, customer management, medical affairs and product distribution infrastructure, initially for selected European markets. We are also leveraging our Phase III trial to continue to build relationships with transplant sites and KOLs in Europe and the United States.

7.16 Competition

The biotechnology industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on intellectual property. We face competition from different sources, including from academic centers, as well as from a number of large and specialty biotechnology and pharmaceutical companies. Many of our competitors and potential competitors have substantially greater scientific, research and product development capabilities as well as greater financial, manufacturing, marketing and human resources than we do. In addition, there is intense competition to contract clinical trial sites and register patients for clinical trials. Many specialized biotechnology firms have formed collaborations with large, established companies to support the research, development and commercialization of products that may be competitive with ours, and many other biotech and pharmaceutical companies are competing for the same potential staff. Accordingly, our competitors may be more successful than we may be in developing, manufacturing, commercializing and achieving widespread market acceptance.

With respect to competitors for our ATIR product candidate, there are a number of protocols and treatments that are in late stage development by biotechnology and pharmaceutical companies.

- **MolMed and Bellicum**: Like ATIR, MolMed SpA ("**MolMed**") (Zalmoxis), and Bellicum Pharmaceuticals, Inc. ("**Bellicum**") (BPX501), are pursuing infusion of mature immune cells to provide immediate protection after a T-cell depleted HSCT. To address the risk of GVHD when it occurs after a transplant, MolMed and Bellicum engineer these mature immune cells with a gene that can trigger "cell suicide", or apoptosis, of the immune cells in the patient upon dosing of a suicide agent. In the case of MolMed the suicide agent is ganciclovir, which is also commonly used as an antiviral agent to treat CMV. In the case of Bellicum this agent is rimiducid. MolMed has obtained a conditional EMA approval for Zalmoxis as adjunctive to a haploidentical donor HSCT in August 2016 and is establishing pricing and reimbursement in Europe. Pricing of Zalmoxis has been established in Italy and

Germany, while the French National Health Authority (HAS) has rejected the reimbursement of Zalmoxis pending more clinical data. Bellicum is conducting several Phase I/II studies with BPX-501 as adjunctive to a haploidentical HSCT in patients with blood cancers and inherited blood disorders, both pediatric and adult, and has communicated its intent to submit a MAA with the EMA in 2019.

- **Miltenyi**: Another approach to enable haploidentical transplantations relies on the depletion of CD3 and CD19 or of α/β T-cells from the donor graft while preserving other populations of T-cells. Miltenyi Biotech ("**Miltenyi**"), has developed its CliniMACS cell sorter equipment to perform such T-cell depletions, and is involved in various clinical trials. Miltenyi is marketing CliniMACS in the United States and Europe and CliniMACS is also used to perform the CD34+ cell selection in the ATIR clinical programs to date.

- **Gamida**: Gamida Cell Ltd. ("**Gamida**") has been working to address the limitations in 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's lead product NiCord® is under development for patients that do not find a matching donor and as an alternative to haploidentical transplantation. Gamida has initiated a Phase III study with NiCord® in patients with hematological malignancies in November 2016, which is estimated to be completed in December 2019.

In addition to the above, many other physician supported transplant protocols, GVHD treatment options and blood cancer therapy approaches, such as the CAR-T, are being developed.

7.17 Government regulation and product approval

In each country where we conduct our research and intend to market our products and product candidates, we must 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 our activities. The Competent Authorities include - among others - the EMA, the national competent authorities of each Member State of the European Union, the FDA, and TPD.

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

Advanced therapy medicinal products ("**ATMPs**") are medicines for human use that are based on gene therapy, somatic-cell therapy or tissue engineering. They offer groundbreaking 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 characterization and the development of assays to measure their biological activity (potency). The preclinical and clinical development paths for product candidates are broadly similar in the European Union, the United States and Canada.

Nonclinical studies

Development of the product candidates starts with nonclinical studies, which include laboratory tests to develop a robust product manufacturing process, including formulation and stability. In addition, further nonclinical 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 nonclinical tests and formulation of the compounds for testing must comply with regulations and requirements set by the Competent Authorities. Upon successful completion of nonclinical studies, clinical development can be initiated.

Clinical studies

Prior to initiating clinical trials, a request for clinical trial authorization (national competent authorities in the European Union and Canada) or an Investigational New Drug application (an "**IND**") in the United States needs to be approved by the relevant Competent Authorities for such trials 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 authorization and must be carried out in accordance with the applicable GMPs. Furthermore, a clinical trial may only be started after an institutional review board ("**IRB**"), (United States) or a competent ethics committee (European Union and Canada) has issued a favorable 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. These phases may be compressed, may overlap or may be omitted in some circumstances.

Post-approval regulation

If regulatory approval for marketing of a product or new indication for an existing product is obtained, we will be required to comply with a number of post-approval requirements. We 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 authorization 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 pharmaco-vigilance practice, regulations and guidance, which impose certain procedural and documentation requirements upon drug manufacturers. Accordingly, we and our 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 authorization holder, including withdrawal of the product from the market.

The following section describes specific regulatory regimes and regulations applicable in each jurisdiction.

European Union

European Medicines Agency

The EMA's Committee for Advanced Therapies ("**CAT**"), provides a certification procedure for ATMPs under development by small- or medium-sized enterprises ("**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, nonclinical 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-authorization 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-authorization application. Following the CAT recommendation, the EMA issues a certification. The evaluation and certification procedure takes 90 days.

Marketing approvals under the European Union regulatory system may be obtained through a centralized or decentralized procedure. The EMA and the European Commission administer the centralized authorization 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 autoimmune diseases, other immune dysfunctions and viral diseases. When a centralized authorization is granted, the authorization is automatically valid in all Member States of the European Union and by extension in the three other European Economic Area (EEA) Member States, Norway, Iceland and Liechtenstein.

Under the centralized authorization procedure, the EMA's CHMP serves as the scientific committee that evaluates applications and renders opinions about the safety, efficacy and quality of human products on behalf of the EMA. For ATMPs, the CAT is responsible in conjunction with the CHMP for the evaluation of ATMPs. The CAT is primarily responsible for the scientific evaluation of ATMPs and prepares a draft opinion on the quality, safety and efficacy of each ATMP for which an application is submitted. The CAT's opinion is then taken into account by the CHMP when giving its final opinion regarding the authorization of a product in view of the balance of benefits and risks identified. Both the CHMP and CAT are composed of experts nominated by the Competent Authority of each European Union Member State, one of which is appointed to act as rapporteur for the coordination of the evaluation with the possible assistance of a further member acting as a co-rapporteur. The CHMP has 210 days to give its opinion to the EMA as to whether a marketing authorization should be granted. This period will be suspended until such time as the supplementary information requested by the CHMP, or in the case of ATMPs information also requested by the CAT, has been provided by the applicant. Likewise, this time-limit will be suspended for the time allowed for the applicant to prepare oral or written explanations. The evaluation 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 authorization that has been granted in the European Union may be suspended or withdrawn if ongoing regulatory requirements are not met or if safety problems are identified. Among other things, marketing authorization holders are required to have risk

management plans that use risk minimization strategies beyond product labelling to ensure that the benefits of certain prescription drugs outweigh their risks.

Accelerated assessment procedures

When an application is submitted for a marketing authorization 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 nine 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 authorization. If the CHMP accepts the request, the timeframe for the evaluation will be reduced to 150 days, but it is possible that the CHMP can revert to the standard time-limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment.

Conditional marketing authorization and authorization under exceptional circumstances

A conditional marketing authorization 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 recognized either by the World Health Organization 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 authorization 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 authorization is Article 14 (7) of Regulation (EC) No. 726/2004, as amended. The provisions for the granting of such an authorization are laid

down in Regulation (EC) No. 507/2006. The holder will be required to complete ongoing studies or to conduct new studies within a specified period of time 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 pharmaco-vigilance data. Conditional marketing authorizations are valid for one year on a renewable basis until the required clinical research program has been completed and the CHMP has reviewed the resulting data and confirmed the approvability of the product on the basis of a standard marketing authorization. The granting of a conditional marketing authorization 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, authorization 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;

- 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 authorization 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 authorization 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 authorization of a medicinal product under exceptional circumstances follows the same rules as a "normal" marketing authorization. After five years, the marketing authorization will then be renewed under exceptional circumstances for an unlimited period, unless the Competent Authority decides, on justified grounds relating to pharmaco-vigilance, to proceed with one additional five-year renewal.

Manufacturing and manufacturers' license

Directive 2003/94/EC, as amended, requires that the manufacturing of investigational medicinal products and approved drugs in the EEA is subject to a separate manufacturer's license and must be conducted in strict compliance with cGMP requirements, which mandate the methods, facilities, and controls used in manufacturing, processing, and packing of drugs to assure their safety and identity. Manufacturers must have at least one qualified person permanently and continuously at their disposal. The qualified person is ultimately responsible for certifying that each batch of finished product released onto the market has been manufactured in accordance with cGMP and the specifications set out in the marketing authorization or investigational medicinal product dossier. cGMP requirements are enforced through mandatory registration of facilities and inspections of those facilities. Failure to comply with these requirements could interrupt supply and result in delays, unanticipated costs and lost revenues, and 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.

Marketing and promotion

The marketing and promotion of authorized 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 authorizations regarding their products is truthful, balanced and accurately reflects the safety and efficacy claims authorized by the EMA or by the Competent Authority of the authorizing 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 prescription only medicinal products to consumers or patients (directly or indirectly) is strictly forbidden. Advertising of medicines pre-approval or off-label is also prohibited.

Regulatory data protection and market exclusivity

In the European Union, all new active substances approved on the basis of a complete independent data package benefit from an 8+2+1 year data/market exclusivity regime. 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 10-year period if, during the first eight years of those 10 years, the marketing authorization 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 innovator beginning eight years after notification of the grant of the approval in the European Union, but the third party may market a generic version after only 10 or, where applicable, 11 years have lapsed from the notification of the grant of the approval.

Orphan designation

Medicines that meet the criteria for orphan designation benefit from the incentive of 10 years of market exclusivity once they are approved for marketing in the European Union. This protects them from market competition with similar medicines with the same indication 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 authorization 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. 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.

The period of market exclusivity is extended by two years for medicines that also have complied with an agreed pediatric investigational plan ("**PIP**"). 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.

Notwithstanding the foregoing, a marketing authorization may be granted, for the same therapeutic indication, to a similar drug if:

- the holder of the marketing authorization for the original orphan drug has given its consent to the second applicant;

- the holder of the marketing authorization for the original orphan drug is unable to supply sufficient quantities of the drug; or

- the second applicant can establish in the application that the second drug, although similar to the orphan drug already authorized, is safer, more effective or otherwise clinically superior.

Regulation (EC) No 847/2000 lays down definitions of the concepts 'similar drug' and 'clinical superiority'.

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 10,000 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 authorized in the community or, if such method exists, the medicinal product will be of significant benefit to those affected by that condition.

Small- or medium-sized enterprise status

In the European Union, manufacturers may benefit from further incentives including a certification procedure for ATMPs under development and/or administrative and procedural assistance and fee reductions when they are classified as an 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 10 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 the SME status by the 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-authorization regulatory procedures, including scientific advice, inspections and pharmaco-vigilance;

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

- inclusion in an online SME register, which is an important source of information on the EU-based SMEs involved in the manufacturing, development or marketing of medicines and promotes partnering and networking between the SMEs;

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

- liaison with academic investigators in pediatric-medicine research through the European Network of Pediatric Research at the European Medicines Agency ("**Enpr-EMA**"); and

- workshops and training sessions.

Development of medicines for children

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

- medicines that have been authorized across the European Union with the results of PIP studies included in the product information are eligible for an extension of their patent protection by six months 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 authorized but are not protected by a patent or supplementary protection certificate, can apply for a pediatric-use marketing authorization ("**PUMA**"), which provides 10 years of market protection.

Pediatric regulation

On January 26, 2007, the Pediatric 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 authorized 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 authorization of medicines for use in adults. The Pediatric Regulation established the Pediatric 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 PIP needs to be in place before applying for marketing authorization. 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.

United States

U.S. Food and Drug Administration

In August 2014, the FDA released a new draft guidance document "Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act". In this draft titled guidance, biological products approved under Section 351(a) of PHS Act are given a period of data exclusivity of 12 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;
- 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 pediatric studies that meet the requirements for pediatric exclusivity pursuant to Section 505A of the Federal Food, Drug, and Cosmetic Act.

The results of drug candidate development, preclinical testing and clinical trials are submitted to the FDA as part of the NDA or in case of a biological drug therapeutic, a BLA. A BLA must contain extensive manufacturing information, detailed information on the composition of the product and proposed labelling; filing a BLA also requires payment of a user fee. Once the submission has been accepted for filing, the FDA begins an in-depth review of the BLA. Based on the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act ("**PDUFA**"), the FDA has 12 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 the FDA's requests for additional information or clarification. The review process and the PDUFA goal date may be extended by three months if the FDA's 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 favorable, 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 favorable, 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 minimization 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 the FDA approval, which may require the development of additional data or the conduct additional preclinical studies and clinical trials.

All promotional materials, including promotional labelling and 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**"), advertisement 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.

Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative, criminal, or civil sanctions. FDA sanctions could include, among other actions, refusal to approve pending applications, withdrawal of an approval, a clinical hold,

warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any administrative, criminal or civil enforcement action could have a material adverse effect on us.

Development Process

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the progress of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA, the National Institutes of Health ("**NIH**"), and the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or testing that suggest a significant risk for human patients, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Phase I, Phase II and Phase III clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research patients are being exposed to an unacceptable health risk, including risks inferred from other unrelated immunotherapy trials. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product has been associated with unexpected serious harm to patients.

Human immunotherapy products are a new category of therapeutics. Because this is a relatively new and expanding area of novel therapeutic interventions, there can be no assurance as to the length of the trial period, the number of patients the FDA will require to be enrolled in the clinical trials in order to establish the safety, efficacy, purity and potency of immunotherapy products, or that the data generated in these clinical trials will be acceptable to the FDA to support marketing approval.

Concurrently with clinical trials, companies usually complete additional studies and must also develop additional information about the physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with GMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHS Act emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

Federal law requires that we register all of our clinical trials on a publicly accessible website. We must also provide results information for most of our clinical trials, other than Phase I clinical trials.

Accelerated assessment procedures

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 I, and organizational 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 the 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, the FDA does not anticipate that breakthrough therapy designation requests will be made after the submission of an original BLA or NDA or a supplement. The FDA will respond to breakthrough therapy designation requests within 60 days of receipt of the request.

Fast track designation can be requested early in the development process, if evidence of activity in a nonclinical 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 that a fast track product may be effective after preliminary evaluation of clinical data submitted by a sponsor, 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, the 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. The FDA will respond to fast track designation requests within 60 calendar days of receipt of the request.

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. 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.

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 10 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 60 of the review.

In the 21st Century Cures Act, 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: RMAT, designation, building on the FDA's existing expedited programs available to regenerative medicine products. 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 fulfillment of post-approval requirements under accelerated approval (i) through the submission of clinical evidence, clinical studies, patient registries or other sources of real world evidence such as electronic health records; (ii) through the collection of larger confirmatory datasets; or (iii) through post-approval monitoring of all patients treated with the therapy prior to approval.

The Affordable Care Act in the United States authorized the FDA to approve biosimilars. Under the Affordable Care 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 personalized nature of our 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, we believe that under the current biosimilar regime approval by the FDA of biosimilar products to our ATIR is not feasible, offering our potential market exclusivity for ATIR if approved.

Orphan Drug Designation

There is a need for the development of medicines for rare diseases, intended for small numbers of patients (i.e., orphan drugs), and since the pharmaceutical industry has limited commercial incentive to develop and market such medicines under normal market conditions, both the United States and the European Union 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.

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. Code of Federal Regulations Title 21 §360bb 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 when 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 United States and the European Union, 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 orphan drug designation 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.

U.S. Patent Term Restoration

A patent claiming a new biologic product may be eligible for a limited patent term extension under the Hatch-Waxman Act, which permits a patent restoration of up to five years for patent term lost during product development and FDA regulatory review. The restoration period granted on a patent covering a product is typically one-half the time between the effective date of a clinical investigation involving human beings is begun and the submission date of an application, plus the time between the submission date of an application and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved product and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. In addition, the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. The USPTO reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the CMS, other divisions of the U.S. Department of Health and Human Services (*e.g.*, the Office of Inspector General), the U.S. Department of Justice ("**DOJ**"), and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, sales, marketing and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the privacy provisions of HIPAA, the sunshine provisions of the Affordable Care Act, and similar state laws, each as amended.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any good, facility, item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between biologic manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances.

Additionally, the intent standard under the Anti-Kickback Statute was amended by the Affordable Care Act to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

The civil monetary penalties statute imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The federal false claims laws, including but not limited to the federal civil False Claims Act, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government Pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved (i.e., off-label), and thus non-reimbursable, uses.

HIPAA created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payers and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer.

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health

Information Technology for Economic and Clinical Health Act ("**HITECH**"), and its implementing regulations, imposes requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's security standards directly applicable to business associates independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Additionally, the federal Physician Payments Sunshine Act within the Affordable Care Act, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. CMS published certain data reported by covered manufacturers for the first reporting period on September 30, 2014.

We will also be required to begin satisfying the product tracing, verification, and reporting requirements set out in the newly enacted Drug Quality and Security Act.

In order to distribute products commercially, we must also comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state.

Several states have enacted legislation requiring pharmaceutical and biotechnology companies to, among other things, establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Healthcare Reform

In March 2010, President Obama signed into law the Affordable Care Act, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Among the provisions of the Affordable Care Act of importance to our potential product candidates are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;

- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, which include, among other things, new government investigative powers and enhanced penalties for non-compliance;

- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;

- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;

- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals, thereby potentially increasing manufacturers' Medicaid rebate liability;

- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;

- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals, thereby potentially increasing manufacturers' Medicaid rebate liability;

- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;

- the new requirements under the federal open payments program and its implementing regulations;

- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and

- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Since its enactment there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act. As a result, there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the Affordable Care Act. In January 2017, the federal government began directing federal agencies with authorities and responsibilities under the Affordable Care Act to waive, defer, grant exemptions from, or delay the implementation of any provision of the Affordable Care Act that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Further, in May 2017, the U.S. House of Representatives passed legislation known as the AHCA, which, if enacted, would amend or repeal significant portions of the Affordable Care Act. Prospects for legislative action on this bill are uncertain. In addition, the TCJA includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” Additionally, on January 22, 2018, a continuing resolution on appropriations for fiscal year 2018 was signed that delayed the implementation of certain ACA-mandated fees, Congress may consider other legislation to repeal or replace elements of the Affordable Care Act.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. These changes included aggregate reductions to Medicare payments to providers of 2% per fiscal year effective April 1, 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2025, unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and, accordingly, our financial operations.

We expect that the Affordable Care Act, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for drugs. In addition, there have been several recent Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare and reform government program reimbursement methodologies for drugs. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of ATIR101, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent drug labeling and post-marketing testing and other requirements.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act ("**FCPA**"), prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

7.18 Pharmaceutical coverage, pricing and reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. Countries have different pricing and reimbursement schemes. In the European Union, the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payers provide coverage and establish adequate reimbursement levels for such products.

In the European Union, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. Special pricing and reimbursement rules may apply to orphan drugs. Inclusion of orphan drugs in reimbursement systems tends to focus on the medical usefulness, need, quality and economic benefits to patients and the healthcare system as for any drug. The downward pressure on health care costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

In the United States, third-party payers include federal and state healthcare programs, private managed care providers, health insurers and other organizations. The process for determining whether a third-party payer will provide coverage for a product may be separate

from the process for setting the price of a product or for establishing the reimbursement rate that such a payer will pay for the product. Third-party payers may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication. Third-party payers are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. We may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payer's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payer's determination to provide coverage for a product does not assure that other payers will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payers fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on healthcare pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

7.19 Facilities

Our headquarters are located at Paasheuvelweg 25A in Amsterdam, the Netherlands, where we lease approximately 3,700 square meters of office space and a commercial manufacturing facility, including process development and quality control laboratories, pursuant to a sublease agreement entered into on December 7, 2017, and approximately 1,250 square meters of additional office space, pursuant to a lease agreement entered into in April 2019.

The sublease entered into on December 7, 2017 has a 10-year term (until December 31, 2027) that is automatically extended for four years (until December 31, 2031), and thereafter for five years (until December 31, 2036), unless terminated by us at the end of a lease period with one year's notice. The second extension (i.e., the extension until December 31, 2036) is, however, also subject to the head lease between our lessor and the head lessor being extended after February 29, 2032 for a period of five years.

The lease entered into in April 2019 has a 10-year term (until May 31, 2029) that is automatically extended for five year terms, unless terminated by us at the end of a lease period with one year's notice.

We also lease approximately 550 square meters of laboratory and office space at the Science Park 406 in Amsterdam, the Netherlands, pursuant to a lease agreement originally dated in 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 Employees

As at the Registration Document Date, we had 132 employees – 106 employees located in Amsterdam, 13 field-based employees in Europe and 13 field-based employees in the United States. Our employees are classified as follows: management, chemistry/manufacturing/control (CMC), clinical development, research, quality assurance, medical/regulatory affairs, finance, IT and support staff.

As of December 31 2018, we had 97 employees. Of those employees, 77 employees were engaged in research and development and 20 employees were engaged in finance, human resources, IT, investor relations, business development, facilities and business and general management. We have no collective bargaining agreements with our employees and have not experienced any work stoppages. We consider our relations with our employees to be good.

We had an average of 97 employees for the year ended December 31, 2018, 61 employees for the year ended December 31, 2017 and 39 employees for the year ended December 31, 2016. During the year ended December 31, 2018, we did not employ a significant number of temporary employees.

Our key scientific and technical staff includes our Chief Medical Officer, our Chief Scientific Officer, our Chief Operations Officer, our Vice President Science and Development, our Director Process Development & Technology, our Program Manager, our Director Analytics & Validation, our Director Pharmacovigilance & Safety, our Director of Regulatory Affairs and Clinical Science, our Director Immunology and our Senior Director Engineering. 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.

7.21 Pension schemes

As per 2011, we provide our employees with a collective pension plan based on a defined-contribution agreement. Our Chief Executive Officer and member of the Management Board Mr. Arthur Lahr participates in this pension scheme. Our Chief Financial Officer and member of the Management Board Mr. Scott Holmes receives a monthly contribution for a U.S. 401(k) pension plan. We provide our 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 we pay fixed contributions into a separate entity (Delta Lloyd) administering the pension scheme. We have 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.

7.22 Legal proceedings

In the ordinary course of our business, we may become involved in litigation arising from claims against us or brought by us against others to enforce our rights. We are not currently involved, nor have we been involved during the 12-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 our business, financial position or profitability. We are not aware of any such proceedings that are currently pending or threatened.

8. MANAGEMENT

8.1 Management Board, Management Team and Supervisory Board

The following table presents information about our Management Board, Management Team and Supervisory Board as per the Registration Document Date.

Name	Position	Year of birth	Initial year of appointment	Term
Management Board				
Arthur Lahr	Chief Executive Officer	1968	2017	2021
Scott Holmes	Chief Financial Officer	1974	2019	2023
Management Team				
Robert Friesen	Chief Scientific Officer	1964	2019	N/A
James Joy	General Counsel & Corporate Secretary	1966	2018	N/A
Dirk De Naeyer	Chief Operations Officer	1972	2019	N/A
Martine Nolan	Senior Vice President, Quality	1974	2019	N/A
Andrew Sandler	Chief Medical Officer	1964	2017	N/A
Mark Schaefer	Chief Human Resources Officer	1962	2018	N/A
Amy Sullivan	Senior Vice President Corporate Affairs	1969	2019	N/A
Jonathan Sweeting	Senior Vice President, Commercial Europe	1977	2018	N/A
Marcel Zwaal	Senior Vice President, Corporate Development	1967	2018	N/A
Supervisory Board				
Mark Wegter	Chairman	1969	2015[1]	2019
Martijn Kleijwegt	Director	1955	2015[1]	2019
Robert Soiffer	Director	1957	2016	2020
Berndt Modig	Director	1958	2016	2020
Otto Schwarz	Director	1955	2016	2020
Subhanu Saxena	Director	1964	2016	2020

1 The presented information refers to the year of appointment to the Supervisory Board of Kiadis Pharma N.V. In 2001, Mr. Wegter was appointed member of the supervisory board of Kiadis Pharma B.V., (a company that merged as disappearing entity with the Company in 2016), and Mr. Kleijwegt was appointed member of the supervisory board of Kiadis Pharma B.V. in 2006.

Unless otherwise indicated, the current business address for members of our Management Board, our Management Team and our Supervisory Board is Kiadis Pharma N.V., Paasheuvelweg 25A, 1105 BP, Amsterdam, the Netherlands.

8.2 Board structure

We have 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 our objectives. The Supervisory Board supervises and advises the Management Board.

Each member of the Management Board and Supervisory Board owes a duty to us to properly perform the duties assigned to such member and to act in our 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. The Management Board and the Supervisory Board have a duty to act in the interest of the

company and the sustainable success of its business, with an aim to creating long-term value, taking into account the interests of its employees, clients, Shareholders and other stakeholders.

As we do not qualify as a "large company" within the meaning of Dutch legislation that came into force on April 13, 2017 requiring large Dutch companies to pursue a policy of having at least 30% of the seats on both the management board and the supervisory board to be held by men and at least 30% of those seats to be held by women, these requirements do not apply to us.

8.3 Management Board and Management Team

Management Board

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 company's interests and the business connected with it, taking into consideration the interest of all of our stakeholders, which includes but is not limited to our customers, our employees and the Shareholders.

The Management Board consists of one or more members. The number of members of the Management Board is determined by the Supervisory Board. Members of the Management Board are appointed by the General Meeting. The Supervisory Board may draw up a nonbinding nomination of one or more nominees for each vacancy to be filled for the appointment of a person as 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 will require an absolute majority of the votes cast representing more than half of our issued capital.

The Articles of Association provide that the General Meeting and the Supervisory Board may suspend Management Board members at any time for a maximum of three months, and that the General Meeting may dismiss Management Board members at any time. Under the Articles of Association, a resolution of the General Meeting to suspend or dismiss members of the Management 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 Management Board other than pursuant to, or without, a proposal of the Supervisory Board requires an absolute majority of the votes cast representing more than half of our issued share capital.

The Articles of Association do not contain limitations on the period of a term of appointment nor on the number of consecutive terms.

The following is a brief summary of the business experience of our Management Board.

Arthur Lahr

Mr. Lahr was appointed as a member of the Management Board on April 4, 2017 and has acted as our Chief Executive Officer since April 1, 2017. Prior to joining us, 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, among other positions, 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, a Dutch national plasma and blood product supplier.

Scott Holmes

Mr. Holmes serves as our Chief Financial Officer since January 1, 2019. He was appointed as a member of the Management Board on March 29, 2019. Mr. Holmes has nearly 20 years of life sciences and financial management experience. He previously served as the Chief Financial Officer of Keryx Biopharmaceuticals and as the Senior Vice President of finance, investor relations and treasurer at AMAG Pharmaceuticals, serving during a period of high growth driven by acquisitions and public financings. Prior to this he held senior roles at Molecular Biometrics, On-Q-ity and Dynogen. Mr. Holmes started his career at Ernst & Young, in both the Assurance and Transaction Services practices, and while at Ernst & Young he earned his Certified Public Accountant certificate in the Commonwealth of Massachusetts. He holds an MS/MBA degree from Northeastern University in Boston, USA and a bachelor's degree in History from Middlebury College.

Management Team

The following is a brief summary of the business experience of members of our Management Team.

Robert Friesen

Robert Friesen, PhD, joined us in February 2019 as our Chief Scientific Officer. Dr. Friesen has more than 20 years of experience in the biopharmaceutical industry, leading multiple Research and Development (R&D) organizations. Dr. Friesen joined us from Ablynx where he was CSO until its acquisition by Sanofi. At Ablynx, Dr. Friesen oversaw a team of more than 300 people who were responsible for more than 40 development-stage product candidates across a wide range of diseases. Prior to Sanofi, he served as Senior Vice President of ProQR Therapeutics, a clinical stage biotechnology company, heading the Science and Early Development division. Prior to joining ProQR Therapeutics, Dr. Friesen worked at Janssen BioTherapeutics, a Johnson & Johnson Company as Global Head of Biologics Research, where he established an R&D organization of more than 200 scientists and professionals located in Europe and US; and at the Crucell Vaccine Institute, a Johnson & Johnson Company, as Vice President Preclinical and Clinical Research where he led the team responsible for discovery, production and preclinical development of monoclonal antibodies. Before Crucell Vaccine Institute, he was Head of Preclinical & Early Clinical Development at MorphoSys.

James Joy

Mr. Joy was appointed in 2018 as our General Counsel & Corporate Secretary. He has more than 20 years of experience in corporate legal affairs. After having worked as an attorney at Latham & Watkins and Norton Rose Fulbright, Mr. Joy held various in-house legal positions, including General Counsel at Navigator Asset Management, Vice President Legal & Compliance at Ahold, Group General Counsel at TomTom and General Counsel at C-MAP. Mr. Joy holds a bachelor's degree in economics from Heriot-Watt University in Edinburgh, Scotland and a juris doctor degree from Tulane University Law School in New Orleans, USA.

Dirk De Naeyer

Dirk De Naeyer is our Chief Operating Officer. Prior to joining us, he was at Janssen Pharmaceuticals where he spent 14 years in various leadership positions. Most recently, Mr. De Naeyer was co-lead for the integration of Actelion into Janssen. Prior to that, he was the head of the Janssen Global Clinical Operations team and held multiple supply chain and operations leadership positions. This included heading up the Janssen Clinical Supply Chain, overseeing all active pharmaceutical ingredient (API) and Drug Product manufacturing, Packaging and Distribution for Janssen R&D, which covered Small Molecules, Biologics and Stem Cell therapies. Mr. De Naeyer joined Janssen after five years at McKinsey. He holds a degree in Engineering from the KU Leuven, Belgium, and an MBA from the University of Chicago.

Martine Nolan

Martine Nolan, our Senior Vice President, Quality, brings over 20 years of experience in the pharmaceutical sector, having joined us from Amgen where she served as Regional Head of Quality Operations, leading a team of more than 200 employees at the Dublin, Ireland and Breda, Netherlands sites. Prior to that Ms. Nolan served as Executive Director for International Quality, Turkey, Middle East & Africa where she had responsibility for quality of both manufacturing and distribution activities. Before joining Amgen, Ms. Nolan held several positions of increasing responsibility in quality operations at Schering-Plough (Merck) in Ireland, Singapore and US. Ms. Nolan holds a MSc in Cellular Physiology from University College Cork and a BSc in Biochemistry from University College Dublin.

Andrew Sandler

Dr. Sandler was appointed in 2017 as our Chief Medical Officer. Dr. Sandler has over 20 years of experience within the healthcare industry, dedicated to hematologic malignancies and solid tumors. He has served as the senior medical executive in multiple global Nasdaq-listed oncology companies. Most recently, Dr. Sandler was Senior Vice President, Global Medical Affairs, at Medivation, which is now part of Pfizer. Prior to that he served as Chief Medical Officer at Dendreon Pharmaceuticals and Spectrum Pharmaceuticals. 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 hematology and oncology at the University of California, San Francisco.

Mark Schaefer

Mr. Schaefer was appointed in 2018 as our Chief Human Resources Officer. Mr. Schaefer has gained over 27 years of broad international Human Resources Leadership experience from a variety of industries and countries, the majority of which he gained while working with General Electric in Canada, Sony Europe, and 3M / Imation, both in Germany and in the Netherlands. Mr. Schaefer has held global roles with West Pharmaceutical in the position of Vice President Human Resources, Global Operations and Labor Relations where he was part of the senior leadership team with global human resources responsibility including manufacturing, supply chain and global labor relations. Prior to joining Kiadis, Mark was with the Aenova Group, where he led the global human resources function as Senior Vice President Global Human Resources. Mr. Schaefer has significant experience in developing and implementing international, large-scale strategic human resources agendas with a focus on talent management, change management, mergers and acquisitions, employee relations,

organizational development and compensation and benefits. Mr. Schaefer holds an Honors degree in Economics and a Master's degree in Industrial Relations, both from the University of Toronto.

Amy Sullivan

Ms. Sullivan is Senior Vice President, Corporate Affairs and is a seasoned corporate affairs professional with more than 25 years of experience raising capital and building and managing corporate biotechnology and life sciences brands. Ms. Sullivan joined us from Keryx Biopharmaceuticals where she was senior vice president of corporate affairs, responsible for all aspects of investor relations, corporate communication, and public affairs, during a period of high growth, commercialization of the company's first FDA-approved medicine and, ultimately, a merger. Prior to Keryx, Ms. Sullivan served as head of corporate communications and investor relations at AMAG Pharmaceuticals, Idenix Biopharmaceuticals and Genencor International. Ms. Sullivan has her bachelor of science degree in business from Salem State University in Salem, Massachusetts and her masters of business administration from Bentley University in Waltham, Massachusetts.

Jonathan Sweeting

Jonathan Sweeting is Senior Vice President, Commercial Europe. Prior to joining us, he spent over five years at GSK in various leadership positions, most recently as Senior Vice President and Head of the Global Respiratory Franchise and previously in roles as General Manager Poland and Global Commercialization Leader for Respiratory Biologics. Mr. Sweeting joined GSK from AstraZeneca where he spent over eight years in global and local roles in the UK and Russia. Prior to that he was at Accenture for five years. Mr. Sweeting holds an MA (Hons) degree in Chemistry from the University of Cambridge and an MBA from INSEAD Fontainebleau, France.

Marcel Zwaal

Marcel Zwaal is Senior Vice President, Corporate Development. Prior to joining us, he was CEO of Hubrecht Organoid Technologies. Previously, Mr. Zwaal worked in Corporate Development at Galapagos, served as CEO of cell therapy biotech startup DCPrime and held several senior management positions at Crucell in finance and business development prior to its acquisition by Johnson & Johnson in 2011. Mr. Zwaal has over 20 years' experience in finance and business, 10 years of which has focused on medical innovation and biotechnology. He holds an Executive Master of Finance and Control degree and a Finance BA Master's degree from Vrije Universiteit Amsterdam.

8.4 Supervisory Board

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

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 reappointed for a total of three consecutive four-year terms. 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 reappointment. The members of the Supervisory Board must retire periodically in accordance with a rotation plan to be drawn up by the Supervisory Board. As

per our Articles of Association and in accordance with the revised version of the Dutch Corporate Governance Code ("**DCGC**") that has become applicable recently – see also paragraph 8.14 below -, a Supervisory Board member shall be appointed for a period of four years and may then be reappointed once for another four-year period. The Supervisory Board member may then subsequently be reappointed again for a period of two years, which appointment may be extended by at most two years. In the event of a reappointment after an eight-year period, reasons should be given in the report of the Supervisory Board. The members of our Supervisory Board do not have a retirement age requirement under our Articles of Association.

The Articles of Association provide that the General Meeting appoints members of the Supervisory Board, and that the Supervisory Board may draw up a nonbinding 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 will 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 requires an absolute majority of the votes cast representing more than 50% of our issued share capital.

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 following is a brief summary of the business experience of the members of our Supervisory Board.

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 Kiadis Pharma N.V. in 2016, in 2001. Since our incorporation on June 12, 2015, Mr. Wegter has been a member of the Supervisory Board and our chairman. 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 merged as a disappearing entity with Kiadis Pharma N.V. in 2016, in 2006. He has been a member of the Supervisory Board since our incorporation on June 12, 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 management companies

of our significant Shareholders Life Sciences Partners B.V. and Life Sciences Partners II B.V. and holds positions at various Life Sciences Partners entities that manage Life Sciences Partner funds. 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), Pharvaris (2016 – present), Oxthera (2016 – present), Orphazyme (2017 – present) and Eloxx (2017 – present), Arvelle Therapeutics (2019 – present).

Robert Soiffer

Dr. Soiffer became a member of the Supervisory Board on June 28, 2016. Dr. Soiffer is currently a Professor at Harvard University Medical School, Chief of the Division of Hematologic Malignancies at the Dana-Farber Cancer Institute ("**DFCI**") and Codirector of the Adult Stem Cell Transplantation Program at the DFCI. Dr. Soiffer joined the DFCI in 1988, after completing a medical oncology fellowship. Dr. Soiffer sits on the board of the U.S. National Marrow Donor Program's Be the Match Registry ("**NMDP**") and on the Massachusetts Board of the Leukemia and Lymphoma Society. Dr. Soiffer is also Chairman of the Advisory Committee for International Blood and Marrow Research. From May 7, 2014 through May 7, 2015, Dr. Soiffer served as a member of Kiadis Pharma Netherlands B.V.'s Scientific Advisory Board while it was conducting clinical trials in Canada and Europe.

Berndt Modig

Mr. Modig became a member of the Supervisory Board on June 28, 2016. Mr. Modig was previously Chief Financial Officer of Prosensa Holding N.V. and before that Chief Financial Officer at Jerini AG and Surplex AG. He is also currently a Board Member of Axovant Sciences Ltd. and Affimed N.V., member of the supervisory board of Centogene A.G., and founder and CEO of Pharvaris B.V. Mr. Modig holds a degree in international business 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 Auris Medical AG (until 2018).

Otto Schwarz

Dr. Schwarz became a member of the Supervisory Board on June 4, 2018. 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., 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. Since June 2016, Dr. Schwarz has held a board seat at the Max7 Foundation.

Subhanu Saxena

Mr. Saxena became a member of the Supervisory Board on June 4, 2018. 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 Commercialization 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. Mr. Saxena served on the board of Cipla from 2013 to 2016.

8.5 Supervisory Board committees

As per our Articles of Association and the rules of procedure of the Supervisory Board, the Supervisory Board shall establish an Audit Committee, a Nomination Committee and a Remuneration Committee, it being understood that the Nomination Committee and Remuneration Committee may be a joint committee. In accordance with the aforementioned, the Supervisory Board has appointed from among its members an Audit Committee and a Remuneration and Nominating Committee.

Audit Committee of the Supervisory Board

The Audit Committee, as per its charter, is required to consist of at least two members. At least one member of the Audit Committee must be a financial expert who has relevant knowledge and experience of financial administration and accounting for listed companies or other large legal entities. The members of the Audit Committee are appointed and may be replaced at any time by the Supervisory Board. The Supervisory Board appoints one of the members of the Audit Committee as Chairman of the Audit Committee. The Audit Committee is not 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's responsibilities include:

- 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 us (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) our tax principles; (vi) relations with the external auditor, including, in particular, his independence and remuneration; (vii) our financing; 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 us; and

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

The Audit Committee consists of Mr. Berndt Modig as chairperson and Mr. Martijn Kleijwegt and Dr. Otto Schwarz as members.

Nomination and Remuneration Committee of the Supervisory Board

The Nomination and Remuneration Committee, as per its charter, consists 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 are appointed and may be replaced at any time by the Supervisory Board. The Supervisory Board appoints one of the members of the Nomination and Remuneration Committee as Chairman of the Nomination and Remuneration Committee. The Nomination and Remuneration Committee is not 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 depend, among other things, on the composition of the Supervisory Board as a whole and that of other committees from time to time.

The Nomination and Remuneration Committee's responsibilities include:

- 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. Subhanu Saxena as member.

8.6 Compensation of members of our Management Board and Supervisory Board

Dutch law provides that we must establish a policy in respect of the remuneration of members of our Management Board. Such policy addresses the following topics: (i) the fixed and variable components of the remuneration (if any), (ii) remuneration in the form of shares and (iii) severance payments. The Supervisory Board determines the remuneration of the members of our Management Board in accordance with the remuneration policy. A proposal by the Supervisory Board with respect to remuneration schemes in the form of Shares or rights to Shares is submitted by the Supervisory Board to the General Meeting for its approval. This proposal must set out at least the maximum number of Shares or rights to Shares to be granted to the members of our Management Board and the criteria for granting or amendment. The General Meeting determines the compensation of the Supervisory Board.

The general principles on which our current remuneration policy is based and the objectives that it seeks to accomplish are:

- to provide competitive compensation aligned with our peer group so as to enable us to recruit, motivate and retain qualified and expert individuals that we need in order to achieve our 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 SARs), 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; and

- to align the economic interest of the Management Board as related to long-term incentives with the economic interest of the Shareholders.

The aggregate compensation, including benefits in kind, accrued or paid to members of our Management Board and Supervisory Board with respect to the year ended December 31, 2018, for services in all capacities was €1.5 million. As disclosed in our consolidated financial statements, the table below shows the remuneration paid to certain individual members of the Management Board for the year ended December 31, 2018 in such capacity.

In thousands of €	Base salary	Cash bonus	Share-based payment	Pension contributions	Social security costs	Total remuneration
Mr. Arthur Lahr	310,00	93,000	763,354	7,608	10,109	1,184,071
Mr. Robbert van Heekeren[1]	183,183	-	-	6,624	7,582	197,389
	493,183	93,000	763,354	14,232	17,691	1,381,460

1. Mr. Robbert van Heekeren resigned as our Chief Financial Officer and member of the Management Board effective September 30, 2018. The above table does not include remuneration information regarding our current Chief Financial Officer and member of the Management Board Mr. Scott Holmes, because he joined us in 2019.

The table below shows the remuneration received by the individual members of the Supervisory Board for the year ended December 31, 2018.

In thousands of €	Base Salary	Cash bonus	Share-based payment	Pension contributions	Social security costs	Other benefits	Total remuneration
Mr. Mark Wegter[1]	-	-	-	-	-	-	-
Mr. Martijn Kleijwegt[1]	-	-	-	-	-	-	-
Mr. Stuart Chapman[1, 2]	-	-	-	-	-	-	-
Dr. Robert Soiffer	40,000	-	-	-	-	-	40,000
Mr. Berndt Modig	40,000	-	-	-	-	-	40,000
Dr. Otto Schwarz[3]	20,000						20,000
Mr. Subhanu Saxena[3]	20,000						20,000
	120,000	**-**	**-**	**-**	**-**	**-**	**120,000**

[1] Previously, our remuneration policy for members of the Supervisory Board did not entitle non-independent members to receive financial compensation for their services. On June 4, 2018 and March 29, 2019, the General Meeting approved amendments to our remuneration policy as a consequence of which all member of the Supervisory Board are equally entitled to receive financial compensation for their services. Mr. Wegter and Mr. Kleijwegt have waived their entitlement to receive any remuneration for their position as members of the Supervisory Board.
[2] Mr. Stuart Chapman resigned from the Supervisory Board on June 4, 2018, following the General Meeting held that day in which Dr. Otto Schwarz and Mr. Subhanu Saxena were appointed as members of the Supervisory Board.
[3] Prior to his appointment to the Supervisory Board on June 4, 2018, Dr. Schwarz served as an observer of the Supervisory Board beginning on July 25, 2017. Dr. Schwarz received a prorated portion of his €40,000 annual fee for his service as an observer. Prior to his appointment to the Supervisory Board on June 4, 2018, Mr. Subhanu Saxena served as an observer of the Supervisory Board beginning on January 15, 2018 and did not receive any compensation in 2017.

As of December 31, 2018, we have nothing set aside or accrued to provide pension, retirement or similar benefits to members of our Management Board and Supervisory Board. Arthur Lahr received 300,000 SARs in 2017 that were modified into 300,000 options on June 1, 2018. Other than as described above, no other equity awards were granted to any of the members of our Management Board or Supervisory Board in 2018.

8.7 Equity holdings and interests

At the Registration Document Date, the number of Shares, options and SARs (see paragraph 8.11 below) held by the current members of the Management Board, the Management Team and the Supervisory Board are as follows:

Name	Shares	Options	SARs
Arthur Lahr	-	655,000	-
Scott Holmes	-	150,000	-
Robert Friesen	-	80,000	-
James Joy	-	50,000	-
Dirk De Naeyer	-	80,000	-
Martine Nolan	-	50,000	-
Andrew Sandler	-	320,000	-
Mark Schaefer	500	50,000	-
Amy Sullivan	-	50,000	-
Jonathan Sweeting	-	80,000	-
Marcel Zwaal	1,100	50,000	-
Mark Wegter[(1)]	-	-	-
Martijn Kleijwegt[(2)]	-	-	-
Robert Soiffer	-	26,000	-
Berndt Modig	-	26,000	-
Otto Schwarz	-	26,000	-
Subhanu Saxena	5,200	26,000	-

[(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 us. See also Chapter 9 (Substantial Holdings).

(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 us. See also Chapter 9 (Substantial Holdings).

8.8 Service contracts with members of our Management Board

Members of our Management Board have entered into services agreements with us.

Mr. Arthur Lahr and Mr. Scott Holmes

On December 8, 2016 we entered into a service agreement with Arthur Lahr as our Chief Operating Officer commencing as of January 1, 2017. Mr. Lahr's agreement was subsequently amended on April 4, 2017 by which his appointment as Chief Executive Officer, as per April 1, 2017, was confirmed. His term will be until four years after his appointment by the General Meeting as a member of the Management Board, which appointment took place on April 4, 2017. On August 30, 2018, through Kiadis Pharma U.S. Corporation we entered into an employment agreement with Mr. Holmes, our Chief Financial Officer commencing as of January 1, 2019. The key terms of these agreements, are as follows:

	Arthur Lahr	Scott Holmes
Base salary	€350,000.00	$390,000
Cash bonus	At the company's discretion, based on company and individual performance	At the company's discretion, based on company and individual performance
Pension Contributions	Participation in our collective pension plan based on a defined-contribution agreement - costs equally shared	Monthly payment as contribution to a 401(k) pension plan
Duration	4 years and can be renewed	At-will employment – may be terminated by either party at any time

Under our service agreement with Mr. Lahr, we may terminate his services upon death or disability or upon his removal from the Management Board. Mr. Lahr may resign his position, which resignation shall be in writing and as of the end of a calendar month, taking into account a notice period of at least six months or such other period as may be reasonably agreed upon between the parties. Upon termination, Mr. Lahr will be eligible for a gross severance payment of one fixed annual salary. Payment of such severance amount shall be in in full and final settlement of any entitlement which Mr. Lahr may have arising from or relating to the termination of his service agreement, including without limitation any entitlement to notice of termination, payment in lieu of notice or severance, whether arising under statute, contract or otherwise. Mr. Lahr shall also be eligible for such severance payment if termination of his service agreement is justified by such change of circumstances that he cannot reasonably be expected to continue the performance of his service (for example, in connection with a change of control which results in the material deterioration of their responsibilities; however, Mr. Lahr will not be eligible for a severance payment if he

accepts a similar position with our successor). Mr. Lahr will not be eligible for such severance payment if he has resigned his position or if his service agreement is terminated due to gross negligence or willful misconduct.

Under our employment agreement with Mr. Holmes, we may terminate his employment upon death or disability, for cause or without cause, upon Mr. Holmes' resignation for good reason, any other reason than good reason or no reason at all, or in case of a change of control. Termination shall be communicated by written notice, without a notice period being required. In case of termination for cause, upon death or disability, or by resignation by Mr. Holmes without good reason or for no reason, Mr. Holmes shall not be entitled to any severance payments or benefits. If we terminate Mr. Holmes' employment without cause or due to Mr. Holmes resigning for good reason, then Mr. Holmes shall receive a cash amount equal to his annual base salary, and partial payment or reimbursement of healthcare plan costs. The aforementioned also applies in the event of termination following a change of control which results in an adverse change in Mr. Holmes' reporting relationship, authority or areas of responsibility, unless Mr. Holmes has accepted a new position offered by the party that has acquired control over us that is similar to his position prior to the change of control.

8.9 Service contracts with members of our Supervisory Board

The members of the Supervisory Board do not have any employment, service or severance contracts with us, except that Dr. Robert Soiffer, Mr. Berndt Modig, Dr. Otto Schwarz and Mr. Subhanu Saxena each have an agreement with us relating to their position as members of the Supervisory Board. None of the agreements provide for benefits upon a termination of employment or service.

8.10 Potential conflicts of interest and other information

Mr. Kleijwegt is managing director of our significant Shareholders Life Sciences Partners B.V., Life Sciences Partners II B.V. and Lenildis Holding B.V. (see Chapter 9 (Substantial Holdings)).

Mr. Saxena, Mr. Schaefer and Mr. Zwaal hold Shares and Mr. Kleijwegt and Mr. Wegter have an indirect interest in Shares. Except for Mr. Wegter and Mr. Kleijwegt, each member of the Management Board, the Supervisory Board and the Management Team holds options (see paragraph 8.7 above).

Mr. Wegter and Mr. Kleijwegt have been nominated as members of the Supervisory Board by significant Shareholders Lenildis Holding B.V., Life Sciences Partners B.V. and Life Sciences Partners II B.V. respectively and hold various positions at Life Sciences Partners. As a consequence hereof, Mr. Wegter and Mr. Kleijwegt are "not independent" within the meaning of the Dutch Corporate Governance Code (see paragraph 8.14 below).

Other than these circumstances, we are 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 or the Management Team vis-à-vis us. No family relationships exist among the members of the Management Board, Supervisory Board or Management Team.

With respect to each of the members of the Supervisory Board, the Management Board and the Management Team, we are 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 8.10, we are 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.

8.11 Equity incentive plans

Share option and stock appreciation right plan

In order to advance our interests and the Shareholders by enhancing our ability to attract, retain and motivate persons who are expected to make important contributions to us, and by providing such persons with equity ownership opportunities that are intended to better align the interests of such persons with ours and those of our Shareholders, the Kiadis Pharma N.V. Share Option and Appreciation Right Plan was created. This plan is a combination of our employee share option plan and employee stock appreciation rights plan that were operated separately until both plans were combined on April 20, 2018. Under the plan, employees, Management Board and Supervisory Board members and advisors may, subject to the requisite approvals as set forth in the plan, be offered options to purchase Shares whereby each (vested) option grants the right to acquire one Share and/or and SARs, providing the right to receive a cash payment equal to the increase in value of a stated number of Shares over a specific period of time.

The option exercise price shall be the average closing sales price at which Shares are traded during the three trading days prior to the day the option is granted, subject to adjustment. The initial price of SARs shall be the average closing sales price at which Shares are traded during the three trading days prior to the day the SARs is granted. Vesting of the options and SARs may take place on one date or in part over time, but all options and SARs granted and not forfeited up to the Registration Document Date are scheduled to vest as follows: one-third on the first anniversary of the date the options or SARs were granted, one-third on the second anniversary of the date the options or SARs were granted, and one-third on the third anniversary of the date the options or SARs were granted. The Supervisory Board shall in its discretion determine whether options and stock appreciation rights shall be granted to the members of the Management Board and determine the number of options and stock appreciation rights to be granted to the relevant member. As a general principle, the number of options and stock appreciation rights to be granted shall be based on, and be aligned with, benchmark practice of our peer group. Granted options and SARs have a duration of 10 years. Leavers shall remain entitled to vested options and SARs with the non-vested options and SARs lapsing and vested options and SARs to be exercised within one year.

The option and SARs pool shall not exceed 2,011,509 Shares, provided that, starting on April 1, 2019, on January 1 of each year, the total number of Shares in respect of which options and SARs may be granted will be increased by 4% of the Shares in issue on December 31 of the immediately preceding year.

As of December 31, 2018, the Management Board, the Management Team, Supervisory Board and other (former) employees together held 1,161,805 options. On the Registration

Document Date, 2,486,357 options are outstanding. As of December 31, 2018, no SARs were outstanding, nor are SARs outstanding on the Registration Document Date.

8.12 Insurance and indemnification

Under Dutch law, members of the Management Board and the Supervisory Board may be liable to us for damages in the event of improper or negligent performance of their duties. They may be jointly and severally liable for damages to us 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, the Management Team, certain other of our officers 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. We indemnify 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 willful 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.

8.13 Code of conduct

We have adopted a code of conduct that applies to all of our employees, officers and directors and have posted the full text of our code of conduct on the investor relations section of our website. We intend to disclose future amendments to our code of conduct, or any waivers of such code, on our website or in public filings.

8.14 Dutch corporate governance

On December 9, 2003, the Dutch Corporate Governance Committee, also known as the Tabaksblat Committee, released the DCGC. With effect from January 1, 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 DCGC, which has since come into force.

The DCGC 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 (i.e., with balance sheet

value greater than €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 DCGC applies to us. We acknowledge the importance of good corporate governance and agree with the principles of the DCGC and have taken and will take such further steps as we may consider appropriate to implement the DCGC.

Non-compliance with the Dutch Corporate Governance Code

We do not comply with the following best practice provisions of the DCGC:

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 our 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 us are (a) that the Supervisory Board should have a diverse composition of members with a valuable contribution to us in terms of experience and knowledge of the industry in which we are active, or other business knowledge, and (b) that we should have flexibility in attracting Supervisory Board members who will be able to provide such contribution to us, given our 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 appointed as of when we were listed on Euronext in 2015 and who are diverse in nationality, age, educational background and work background.

For the reasons provided above, we do not intend to comply with this best practice provision.

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 the Management Team is similar, in that our overriding principle is that the Management Board and the Management Team should have a diverse composition with their members specifically having the necessary expertise, education and work background in the industry in which we are active and we should have flexibility in

attracting Management Board and Management Team members who will be able to provide a valuable contribution to us, given our 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 the Management Team that have joint us in 2017 and who are diverse in nationality, age, educational background and work background.

For the reasons provided above, we do not intend to comply with this best practice provision.

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 two of the six 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, Messrs. Wegter and Kleijwegt, are employed by and have been appointed upon nomination of two of our significant Shareholders. These significant Shareholders have a long-term interest in us and were willing to back this up by making senior partners with relevant knowledge and experience available to us. The Supervisory Board considers that Messrs. Wegter and Kleijwegt fit the profile of the Supervisory Board and that their contributions outweigh any perceived disadvantage of non-independence. In addition, we deem continuity in the composition of the Supervisory Board to be of great importance, also taking into account our small size and our specificity in terms of focus, strategy and stage of development.

For the reasons provided above, we do not intend to comply with this best practice provision.

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 June 12, 2015, he was a member of the management board of Kiadis Pharma B.V. from September 4, 2009 through February 22, 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, we deem continuity in the position of chairman to be of great importance, also taking into account our small size and our specificity in terms of focus, strategy and stage of development.

For the reasons provided above, we do not intend to comply with this best practice provision.

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 definitive 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 since our Euronext listing for all Supervisory Board and Management Board members. In addition, with regard to the Supervisory Board and its current composition, two members were appointed upon our incorporation in June 2015, a further two members were appointed in June 2016 and another two were appointed in June 2018. 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.

We intend to comply with this best practice provision by drawing up such succession plans/retirement schedule before the first term will have ended.

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 2018 due to the Supervisory Board having been in a phase of transition as new (independent) members to the Supervisory Board were being selected to be nominated to the General Meeting in 2018.

However, we do intend to comply with this best practice provision in respect of future years.

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 Management Team.

We intend to comply with this best practice provision by the end of 2019.

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.

The Nomination and Remuneration Committee consists of Mr. Martijn Kleijwegt as chairperson and Mr. Subhanu Saxena as member. Mr. Saxena does but Mr. Kleijwegt does not qualify as independent within the meaning of best practice provision 2.1.8. Accordingly, half but not more than half of the members of Nomination and Remuneration Committee is independent as prescribed by this best practice provision.

We do not intend to comply with this best practice provision as long as the Supervisory Board continues to be constituted as it currently is, but will endeavor to comply once the constitution of our Supervisory Board changes.

Best practice provision 3.1.2 – Remuneration policy, exercise of options

The following aspects should in any event be taken into consideration when formulating the remuneration policy: (i) the objectives for the strategy for the implementation of long-term value creation within the meaning of best practice provision 1.1.1; (ii). the scenario analyses carried out in advance; (iii) the pay ratios within the company and its affiliated enterprise; (iv) the development of the market price of the shares; (v) an appropriate ratio between the variable and fixed remuneration components. The variable remuneration component is linked to measurable performance criteria determined in advance, which are predominantly long-term in character; (vi) if shares are being awarded, the terms and conditions governing this. Shares should be held for at least five years after they are awarded; and (vii) if share options are being awarded, the terms and conditions governing this and the terms and conditions subject to which the share options can be exercised. Share options cannot be exercised during the first three years after they are awarded.

The members of the Management Board are not restricted to exercise their options during the first three years after they are awarded in order to apply the same treatment to all our employees and to ensure our share option plan helps to attract, motivate and retain qualified and expert individuals throughout the Company.

Best practice provision 3.3.2 – Remuneration of supervisory board members

Supervisory board members may not be awarded remuneration in the form of shares and/or rights to shares.

On March 29, 2019, the General Meeting resolved to amend the remuneration of the Supervisory Board. The amended remuneration included options being granted to the independent members of the Supervisory Board. The amended remuneration was driven by a review and analysis conducted by the Nomination and Remuneration Committee, assisted by an independent compensation consultancy firm, as to whether the remuneration of our officers and employees, and specifically the members of the Supervisory Board, the members of the Management Board and the members of the Management Team, was competitive with its peer group. For this purpose, a peer group of EU based biotech companies of similar size and complexity was defined. Based on benchmark practice of the relevant peer group, the Nomination and Remuneration Committee assessed and concluded that to become and be competitive from a compensation perspective with peers and to align

its remuneration offering with market compensation levels, we had to make certain amendments to our remuneration philosophy and practice generally, and specifically in relation to the members of the Supervisory Board, the members of the Management Board and the members of the Management Team, The main amendments to be made included an option grant to the members of the Supervisory Board.

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.

We do not announce, for practical reasons, meetings with analysts and presentations to analysts and (institutional) investors, nor do we provide for Shareholders to follow these meetings and presentations in real time. However, the presentation used by us for our meetings with analysts and (institutional) investors is the company presentation that is posted on our website and regularly updated and which is therefore a public document.

We will have meetings with analysts and give presentations to (institutional) investors also shortly before the publication of our regular financial information, but such meetings and presentations will not regard such regular financial information.

For the reasons provided above, we do not intend to comply with this best practice provision.

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 favor 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 our issued share capital. We deem this appropriate considering the remaining Shareholdings and involvement of our principal Shareholders.

For the reason provided above, we do not intend to comply with this best practice provision.

9. 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 our share capital and/or voting rights.

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	13.73	13.73	Actual	Actual	Direct	October 23, 2018
Achmea Pensioen- en Levensverzekeringen N.V.	2,208,607	2,208,607	9.07	9.07	Actual	Actual	Indirect[3]	October 23, 2018
Life Sciences Partners II B.V.	1,656,458	1,656,458	9.58	9.58	Actual	Actual	Direct	October 12, 2017
Lenildis Holding B.V.[4]	1,214,027	1,214,027	4.99	4.99	Actual	Actual	Direct	October 23, 2018

(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 us 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 8.7 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 11.4 below. 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, we are 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 Kiadis Pharma N.V. 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.

We are not aware of any party, or parties acting in concert that, directly or indirectly, control the vote at any General Meeting, nor are we aware of any arrangement, the operation of which may result in a change of control in relation to us.

10. 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 us. Furthermore, our significant Shareholders that have a significant influence over us were regarded as such. The following is a description of related-party transactions we have entered into since January 1, 2015 with any of the members of the Management Board and the Supervisory Board and the holders of more than 5% of our Shares. Related-party transactions are also set out in Note 25 of the consolidated financial statements for the financial year ended December 31, 2018, Note 24 of the consolidated financial statements for the financial year ended December 31, 2017 and Note 23 of the consolidated financial statements for the financial year ended December 31, 2016.

Transactions with our principal Shareholders

In 2015, several of our principal Shareholders purchased our Shares in our Euronext initial public offering. Life Sciences Partners B.V. purchased 138,238 Shares, Life Sciences Partners II B.V. purchased 103,512 Shares. Mr. Kleijwegt, a member of our Supervisory Board, through Pro-Ventures I.B.V., purchased 21,978 Shares. Esprit Nominees Limited, Lenildis Holding B.V. and Alta Partners, purchased 269,597, 163,074 and 81,473 Shares, respectively, all at a price of €12.50 per Share.

Agreements with members of the Management Board and the Supervisory Board

On December 8, 2016 we entered into a service agreement with Arthur Lahr as our Chief Operating Officer commencing as of January 1, 2017. Mr. Lahr's agreement was subsequently amended on April 4, 2017 by which his appointment as Chief Executive Officer, as per April 1, 2017, was confirmed. His term will be until four years after his appointment by the General Meeting as a member of the Management Board, which appointment took place on April 4, 2017. On August 30, 2018, through Kiadis Pharma U.S. Corporation we entered into an employment agreement with Mr. Holmes, our Chief Financial Officer commencing as of January 1, 2019. See paragraph 8.8 for a description of the key terms of these agreements.

The members of the Supervisory Board do not have any employment, service or severance contracts with us, except that Dr. Robert Soiffer, Mr. Berndt Modig, Dr. Otto Schwarz and Mr. Subhanu Saxena each have an agreement with us relating to their position as members of the Supervisory Board. See also paragraph 8.9.

11. DESCRIPTION OF SHARE CAPITAL AND ARTICLES OF ASSOCIATION

11.1 General

We were incorporated on June 12, 2015 as a public company with limited liability (*naamloze vennootschap*) under the laws of the Netherlands. We are registered with the Trade Register of the Chamber of Commerce, the Netherlands, under number 63512653. Our registered address is in Amsterdam, the Netherlands and our business address is at Paasheuvelweg 25A, 1105 BP Amsterdam, the Netherlands (tel: +31-20-240 2550). Our commercial name is Kiadis Pharma.

Set out below is a summary of certain information concerning our share capital and certain significant provisions of Dutch corporate law and a 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.

11.2 Share capital

Share capital and Shares

Our authorized share capital pursuant to the Articles of Association amounts to €12,000,000 and is divided into 120,000,000 ordinary shares, each with a nominal value of €0.10. Under Dutch law, a company's authorized share capital reflects the maximum amount of shares that it may issue without amending its articles of association. All of our authorized shares will, when issued and outstanding, be created under Dutch law.

On the Registration Document Date, our issued capital amounts to €2,436,674.20 and is divided into 24,366,742 Shares, each with a nominal value of €0.10. On the Registration Document Date, neither we nor any of our subsidiaries hold any Shares. On the Registration Document Date, all the Shares are fully paid.

Other outstanding securities

We have three classes of warrants to acquire Shares in issue: two classes that are exercisable until June 15, 2022 (the "**2022-I Warrants**" and the "**2022-II Warrants**", collectively, the "2022 Warrants"), one class that is exercisable until July 31, 2023 (the "**2023 Warrants**").

On the Registration Document Date, the following warrants are outstanding.

	Outstanding number warrants	Exercise price	Exercise period
2022-I Warrants	71,350	€7.307	Until June 15, 2022
2022-II Warrants	3,731	€7.312	Until June 15, 2022
2023 Warrants.....	41,212	€9.71	Until July 31, 2023
Total	116,293		

In connection with our €5.0 million equity raise in June 2017, 746,269 2022-I Warrants and 55,970 2022-II Warrants were issued. 674,919 of the 2022-I Warrants have been exercised, and 52,239 of the 2022-II Warrants have been exercised. The 2023 Warrants were issued to Kreos Expert in connection with the Second Kreos Capital Facility Arrangement that we

entered into with Kreos Capital in July 2018. None of the 2023 Warrants have been exercised.

If we subdivide our 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 our 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.

As of December 31, 2018, the Management Board, the Management Team, Supervisory Board and other (former) employees together held 1,161,805 options. On the Registration Document Date, 2,486,357 options are outstanding. As of December 31, 2018, no SARs were outstanding, nor are SARs outstanding on the Registration Document Date.

Issuance of Shares

Under the Articles of Association, we 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.

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.

On March 29, 2019 a General Meeting was held at which it was resolved authorize the Management Board, subject to the approval of the Supervisory Board, to issue shares and to grant rights to acquire shares for a period of 5 years from the date of the General Meeting (i.e. up to and including 29 March 2024), up to our authorized share capital included in the Articles of Association from time to time, and to exclude pre-emptive rights in relation thereto.

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 our employees, (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 our 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.

On March 29, 2019 a General Meeting was held at which it was resolved authorize the Management Board, subject to the approval of the Supervisory Board, to issue shares and to grant rights to acquire shares for a period of 5 years from the date of the General Meeting (i.e. up to and including 29 March 2024), up to our authorized share capital included in the Articles of Association from time to time, and to exclude pre-emptive rights in relation thereto.

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 our 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 us or of which we hold the depositary receipts.

The decision to reduce our 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.

Acquisition of our own Shares

We cannot subscribe for Shares in our own capital at the time Shares are issued. Any acquisition by us of our Shares that are not fully paid-up shall be null and void. We can acquire fully paid-up Shares in our 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 our capital and the reserves that we are required to maintain by law, (ii) the nominal value of the Shares to be acquired in our own capital, which we hold or hold in pledge, or which are held by one of our 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 authorized by the General Meeting. A subsidiary cannot subscribe for its own account or acquire Shares in our capital.

Authorization 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 authorization will be valid for no more than eighteen months.

We may not cast votes on, and are not entitled to dividends or other distributions paid on, Shares held by us 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 us in our own capital shall not be included. The Management Board is authorized, subject to approval of the Supervisory Board, to dispose of our own Shares held by us.

Shareholders' register

Pursuant to Dutch law and the Articles of Association, we must keep our shareholders' register accurate and current. The Management Board keeps our shareholders' register and records names and addresses of all holders of Shares, showing the date on which the Shares were acquired, the date of the acknowledgement by or notification of us as well as the amount paid on each Share. The register also includes the names and addresses of those with a right of use and enjoyment (*vruchtgebruik*) in Shares belonging to another or a pledge (*pandrecht*) in respect of such Shares.

History of Share Capital

We were incorporated on June 12, 2015 in connection with our European public offering and Euronext listing in 2015 and upon our incorporation, 10,694,508 Shares were issued. Subsequently, 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 Kiadis Pharma N.V. as a result of which 290 Shares were issued to the shareholders of Kiadis Pharma B.V. (but excluding Kiadis Pharma N.V., 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 in us to further finance the clinical development of ATIR101, our lead product candidate. In June 2016, a total of 338,239 Shares were issued to the participants of the 2013 Exit Participation Plan, a bonus share plan to provide incentives to our certain executives and senior management, which was terminated after our European public offering and Euronext listing in 2015 and settled by means of the aforementioned June 2016 issuance of Shares. On June 15, 2017, we issued 746,269 new Shares pursuant to a private placement with a group of existing and new institutional investors in which we 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 October 12, 2017, we issued 2,250,000 new Shares pursuant to a private placement with a group of existing and new institutional investors in which we raised €18 million in gross proceeds. In March 2018 we issued 2,600,000 new Shares pursuant to a private placement with institutional investors in which we raised €23.4 million in gross proceeds. In October 2018, we issued 3,900,000 new Shares pursuant to a private placement with institutional investors in which we raised €31.2 million in gross proceeds. In 2018, we further issued an aggregate number of 544,013 Shares upon the exercise of warrants and 10,000 Shares upon the exercise of share options. In 2019, we issued 25,332 Shares upon the exercise of share options.

11.3 Articles of Association and Dutch law

Corporate objectives

Pursuant to Article 3 of the Articles of Association, our corporate objectives 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.

Liability, insurance and indemnity

Under Dutch law, members of the Management Board and the Supervisory Board may be liable to us for damages in the event of improper or negligent performance of their duties. They may be jointly and severally liable for damages to us 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 our 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.

Shareholder's meetings and consent

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 authorized 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 our equity 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 our corporate governance structure 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 60 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 us to disseminate information that is prepared by them in connection with an agenda item for a General Meeting. We 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, we 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.

Quorum and voting requirements

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 authorized to exclude or restrict pre-emptive rights;

- a resolution of the General Meeting to reduce our outstanding share capital; and
- a resolution of the General Meeting to have us merge or demerge.

Pursuant to Dutch law, no votes may be cast at a General Meeting in respect of Shares which are held by us.

Identity of Shareholders

We may request Euroclear Netherlands, admitted institutions, intermediaries, institutions abroad, and managers of investment institutions, to provide certain information on the identity of our Shareholders. Such request may only be made during a period of 60 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 60 days until (and not including) the 42nd day before the day on which a General Meeting will be held.

Management Board and Supervisory Board

Duties and liabilities of members of the Management Board and Supervisory Board

We have 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 our objectives. The Supervisory Board supervises and advises the Management Board.

Each member of the Management Board and Supervisory Board owes a duty to us to properly perform the duties assigned to such member and to act in our 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. The Management Board and the Supervisory Board have a duty to act in our interest and the sustainable success of our business, with an aim to creating long-term value, taking into account the interests of our employees, clients, Shareholders and other stakeholders.

Appointment of members of the Management Board and Supervisory Board

Our Articles of Association provide that the General Meeting appoints members of the Supervisory Board and that the Supervisory Board may draw up a nonbinding 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 our issued share capital.

Members of the Management Board are appointed by the General Meeting. The Supervisory Board may draw up a nonbinding nomination of one or more nominees for each vacancy to be filled for the appointment of a person as 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 will require an absolute majority of the votes cast representing more than half of our issued capital.

Dividends

Amount available for distribution

Pursuant to Dutch law and our Articles of Association, the distribution of profits will take place following the adoption of our annual accounts by the General Meeting, and only to the extent that those accounts show sufficient profits to make the contemplated distribution. We may only make distributions to the Shareholders, whether from profits or from our freely distributable reserves, insofar as our 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 our Articles of Association.

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 our 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.

Exchange controls

Under existing laws of the Netherlands, there are no exchange controls applicable to the transfer to persons outside of the Netherlands of dividends or other distributions with respect to, or of the proceeds from the sale of, shares of a Dutch company.

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 of the Amsterdam Court of Appeal (*Ondernemingskamer van het Gerechtshof te Amsterdam*) (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 who will offer an opinion to the Enterprise Chamber on the value to be paid for the shares of the minority shareholders.

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 Civil Code 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.

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 at our offices 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.

Dissolution and Liquidation

Under the Articles of Association, we 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, our 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 our 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.

11.4 Conditional amendment of our Articles of Association and anti-takeover protection

Many Dutch listed companies have anti-takeover protection in the form of a call option, which is not limited in time and that is granted to an independent foundation, the statutory goal of which is to protect the listed company's interests by, amongst others, protecting the company from influences that may threaten its continuity, independence and identity. Such a call option typically entitles the foundation to acquire a number of preference shares in the company, which have the same voting rights as ordinary shares, not exceeding the total issued number of ordinary shares, and on which upon exercise of the call option, 25% of the nominal value of such preference shares needs to be paid by the foundation. As per this structure, in the event of any circumstances where the company in question is subject to influences as described above, the board of the foundation may decide to exercise the call option, with a view to enable the company to determine its position in relation to the circumstances as referred to above, and seek alternatives.

We currently do not have anti-takeover protection as described above. However, the Management Board and the Supervisory Board are enabled to implement such anti-takeover protection (without further shareholder approval being required) if and when they deem this appropriate, following the General Meeting having resolved on March 29, 2019 to approve and adopt an amendment to the Articles of Association which introduces preference shares such that our authorized share capital will be divided into ordinary shares and preference shares. This amendment of the Articles of Association is conditional in the sense that although the notarial deed to amend the Articles of Association was executed on April 9, 2019, the amendment will not become effective unless and until the Management Board at any future moment decides, after having obtained approval from the Supervisory Board, to have the amendment enter into force by depositing a copy thereof at the Trade Register of the Chamber of Commerce. If this occurs and the amendment of the Articles of Association comes into force, the authorization to issue shares or grant rights to subscribe for shares that was granted to them on March 29, 2019 by the General Meeting (see paragraph 11.2 – subparagraph "*Issuance of Shares*") shall enable the Management Board and the Supervisory Board to grant a call option that is not limited in time to subscribe for preference shares to an independent foundation then to be established, and which can be exercised in whole or in part, up to the authorized share capital of preference shares as per the articles of association at the time of exercise and at multiple times and occasions (including after the issuance and subsequent cancellation of preference shares).

The full text of the conditional amendment of the articles of association is available on our website at http://www.kiadis.com.

11.5 European Union disclosure regulations

The Netherlands is our home member state (*lidstaat van herkomst*) for the purposes of the European Union Transparency Directive (Directive 2004/109/EC, as amended). As a result and as a consequence of our Euronext listings, we are 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 European Union Transparency Directive in the Netherlands.

Disclosure of financial information

We are required to publish our 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 our half-yearly figures within three months after the end of the first six months of each financial year. Within five calendar days after adoption of our financial statements, we must file our financial statements with the AFM.

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 us regarding our application of the applicable financial reporting standards and (ii) recommend us to make available of further explanations and to file these with the AFM. If we do not comply with such a request or recommendation, the AFM may

request that the Enterprise Chamber orders us to (i) make available further explanations as recommended by the AFM, (ii) provide an explanation of the way we have applied the applicable financial reporting standards to our financial statements or (iii) prepare our financial reports in accordance with financial reporting requirements following the Enterprise Chamber's instructions.

Shareholder disclosure and reporting obligations

Pursuant to the Financial Supervision Act, each party who holds a substantial holding in us 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% of the issued share capital 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% of the issued share capital 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, on the following trading day.

Under the Financial Supervision Act, we are required to notify the AFM without delay of any changes in our share capital if it has changed by 1% or more compared to the previous disclosure in respect of our share capital. We are 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 our 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.

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 us 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 of shareholders, 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.

11.6 European Union insider trading and market manipulation rules

Reporting of insider transactions

As of July 3, 2016, 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) (the "**Market Abuse Regulation**"), which is directly applicable in the Netherlands and Belgium. We, the members of our Management Board, Management Team, Supervisory Board and other insiders and persons performing or conducting transactions in the company's financial instruments, as applicable, will be subject to the insider trading prohibition, the prohibition on divulging inside information and tipping and the prohibition on market manipulation. In certain circumstances, our investors may also be subject to market abuse rules.

Pursuant to the Market Abuse Regulation, 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 ordinary 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 our ordinary

shares or us. Furthermore, no person may engage in or attempt to engage in market manipulation.

We are 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 us. Pursuant to the Market Abuse Regulation, inside information is knowledge of i information of a precise nature 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 decisions). An intermediate step in a protracted process can also be deemed to be inside information by itself. We are required to post and maintain on our 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 Market Abuse Regulation) are obliged to notify us and the AFM, ultimately on the third trading day after the transaction date, of every transaction conducted on their own account relating to our shares or debt instruments (or other financial instruments linked thereto), once the threshold of €5,000 has been reached within a calendar year (without netting). Once the threshold has been reached, all transactions will need to be notified, regardless of amount and wherever concluded.

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 our shares or debt instruments 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.

Persons discharging managerial responsibilities within the meaning of the Market Abuse Regulation 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 our future developments and business prospects. 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.

Non-compliance with the market abuse rules

In accordance with the Market Abuse Regulation, 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 Market Abuse Regulation.

We have adopted a code of conduct in respect of the reporting and regulation of transactions in our securities by members of the Management Board and Supervisory Board and our employees. We and any person acting on our behalf or on our 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. We and any person acting on our behalf or on our 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.

12. GENERAL INFORMATION

12.1 Organizational structure

Kiadis Pharma N.V. is a holding company at the head of the Kiadis corporate group. The following legal entities are subsidiaries of Kiadis Pharma N.V.:

Legal entity	Jurisdiction	Shareholder	% shares held
Kiadis Pharma Netherlands B.V.	The Netherlands	Kiadis Pharma N.V.	100%
Kiadis Pharma Intellectual Property B.V.	The Netherlands	Kiadis Pharma N.V.	100%
Kiadis Pharma Germany GmbH	Germany	Kiadis Pharma N.V.	100%
Kiadis Pharma Canada Inc.	Canada	Kiadis Pharma N.V.	100%
Kiadis Pharma US Corporation	Unites States of America	Kiadis Pharma N.V.	100%
CST Acquisition Corp.	Unites States of America	Kiadis Pharma N.V.	100%
Kiadis Pharma UK Limited	United Kingdom	Kiadis Pharma N.V.	100%
Kiadis Pharma Netherlands B.V.	The Netherlands	Kiadis Pharma N.V.	100%

On completion of the Transaction, CytoSen will merge with and into CST in accordance with the CytoSen Acquisition Agreement and the Delaware General Corporation Law. Upon completion of the Transaction, CST will cease to exist, and CytoSen will become our wholly owned subsidiary.

12.2 Material contracts

Save as disclosed in paragraphs 6.8, 7.3 and 7.11, we have 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 we have an obligation or entitlement that is material as of the Registration Document Date.

12.3 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 December 31, 2018, 2017 and 2016 incorporated by reference in this Registration Document.

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. DEFINITIONS AND GLOSSARY

In this Registration Document, the following defined terms are used

"2022 Warrants"	the 2022-I Warrants and the 2022-II Warrants
"2022-I Warrants"	the warrants exercisable until June 15, 2022 with an exercise price of €7.307
"2022-II Warrants"	the warrants exercisable until June 15, 2022 with an exercise price of €7.312
"2023 Warrants"	the warrants exercisable until July 31, 2023
"Actelion"	Actelion Ltd.
"Affordable Care Act"	the 2010 U.S. Patient Protection and Affordable Care Act
"AFM"	the Netherlands Authority for the Financial Markets (*Stichting Autoriteit Financiële Markten*)
"AHCA"	the American Health Care Act
"America Invents Act"	the Leahy-Smith America Invents Act
"Articles of Association"	the Company's articles of association (*statuten*)
"ATIR"	Kiadis' product candidates based on its Theralux platform that provide for "Allodepleted T-cell ImmunotheRapeutics", presently consisting of ATIR101, Kiadis' principal product
"Bellicum"	Bellicum Pharmaceuticals, Inc.
"BLA"	a Biologic License Application
"CAT"	the EMA's Committee for Advanced Therapies
"CHMP"	the EMA's Committee for Medicinal Products for Human Use

"CIBMTR"	Center for International Blood and Marrow Transplant Research
"CMS"	the Centers for Medicare and Medicaid Services
"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 2016
"CST"	Kiadis Pharma N.V.'s wholly owned subsidiary CST Acquisition Corp.
"Cures Act"	the 21st Century Cures Act
"CytoSen"	CytoSen Therapeutics, Inc.
"CytoSen Acquisition Agreement"	the agreement dated April 16, 2019 between Kiadis Pharma N.V., its wholly owned subsidiary CST, CytoSen and Philip R. McKee as representative of the CytoSen shareholders, regarding Kiadis' acquisition of the entire share capital of CytoSen, subject to the approval of the General Meeting - which approval has been granted on May 29, 2019 - and customary closing conditions
"DPD"	the Data Protection Directive
"EEA"	the European Economic Area
"EU"	the 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
"FCPA"	the U.S. Foreign Corrupt Practices Act
"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*)
"First Kreos Capital Facility Agreement"	the facility agreement entered into between the Company and Kreos Capital dated August 17, 2017
"Gamida"	Gamida Cell Ltd.
"GDPR"	the General Data Protection Regulation
"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
"Health Care Reform Law"	the U.S. 2010 Health Care and Education Reconciliation Act
"HIPAA"	the U.S. Health Insurance Portability and Accountability Act
"HITECH"	the U.S. Health Information Technology for Economic and Clinical Health Act
"Hospira Exclusive License Agreement"	the December 2010 license agreement that the Company (successor by merger of Kiadis Pharma B.V.) entered into with Hospira to develop and commercialize 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
"ITT"	Intent To Treat population
"Kiadis"	the Company and its consolidated subsidiaries (excluding CytoSen, unless stated otherwise)
"KOL"	key opinion leader
"KPMG"	KPMG Accountants N.V.
"Kreos Capital"	Kreos Capital V (UK) Limited
"Kreos Capital Facility Agreements"	the First Kreos Capital Agreement and the Second Kreos Capital Agreement
"Kreos Expert"	Kreos Capital V (Expert Fund) LP
"Management Board"	the Company's board of managing directors
"Management Team"	Kiadis' senior management, that supports the Management Board in the day-to-day management of the operations
"Market Abuse Regulation"	the Market Abuse Regulation (no. 596/2014)
"Mayo"	the U.S. Supreme Court decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*
"Miltenyi"	Miltenyi Biotech GmbH
"MITT"	Modified Intent to Treat
"MolMed"	MolMed SpA
"Montreal Agreement"	the Research and Licensing Agreement between us and the University of Montreal dated December 1, 1997
"NOLs"	net operating losses
"PIP"	pediatric investigational plan

"Prospectus"	the Registration Document if supplemented by a Summary and Securities Note
"Prospectus Directive"	Directive 2003/71/EC of the European Parliament and of the Council of the European Union as amended from time to time (including as per Directive 2010/73/EU)
"PUMA"	pediatric-use marketing authorization
"Reimbursement Amount"	the $24.5 million received from Hospira under the Hospira Exclusive License Agreement plus a low-single digit percentage interest amount compounded annually
"Registration Document"	this registration document
"Registration Document Date"	May 31, 2019, 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
"Second Kreos Capital Facility Agreement"	the facility agreement entered into between the Company and Kreos Capital dated July 31, 2017
"Securities Giro Act"	the Dutch securities giro Act (*Wet giraal effectenverkeer*)
"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
"Summary and Securities Note"	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
"Supervisory Board"	the Company's board of supervisory directors
"TCJA"	the U.S. Tax Cuts and Jobs Act of 2017
"Transaction"	our acquisition of CytoSen on the terms of and pursuant to the CytoSen Acquisition Agreement
"U.S. Exchange Act"	the U.S. Securities Exchange Act of 1934, as amended
"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
"we", "us" or "our"	Kiadis Pharma N.V. together with its wholly owned subsidiaries (excluding CytoSen, unless stated otherwise)
"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 our 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 leukemia (ALL)	an aggressive (fast-growing) type of leukemia (blood cancer) in which too many lymphoblasts (immature white blood cells) are found in the blood and bone marrow. Also called acute lymphoblastic leukemia and acute lymphocytic leukemia
anemia	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 leukemia (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
APLB	Advertising and Promotional Labelling Branch
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

CAR-T	chimeric antigen receptor T-cell therapy
CDSA	the Controlled Drugs and Substances Act
CBER	Center for Biologics Evaluation and Research
cGMP	current Good Manufacturing Practices
Chimeric Antigen Receptor (CAR) T-cells	engineered, artificial T-cell receptors which graft an arbitrary specificity onto an immune effector cell
chronic lymphocytic leukemia (CLL)	a type of slow growing leukemia that affects developing B-cells, which are specialized white blood cells
chronic myeloid leukemia (CML)	a slowly progressing blood and bone marrow disease in which the bone marrow makes too many white blood cells
CMO	contract manufacturing organization, a company that serves other companies in the pharmaceutical industry on a contract basis to provide comprehensive services from drug development through drug manufacturing
CRO	contract research organization, a company that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis
cytotoxic	quality of being toxic to cells
day-120 questions	a consolidated list of questions posed by the EMA following the primary evaluation phase
DCGC	the Dutch Corporate Governance Code
DLI	donor lymphocyte infusion
DOJ	Department of Justice
DRI	disease risk index
DTC	direct to consumer
EMA	the European Medicines Agency
engraftment	process by which transplanted or transfused cells begin to grow and reproduce within the recipient

Enpr-EMA	the European Network of Pediatric Research at the European Medicines Agency
ex vivo	pertaining to experimentation performed on living tissue in an artificial environment outside the organism
FDA	the 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 authorization agencies and regulatory authorities
Graft-versus-leukemia (GVL)	T-cells having anti-malignancy (anti-leukemia) effect
Graft-versus-host disease (GVHD)	complication during bone marrow transplantation in which transplanted cells attack the recipient
GVHD-Free and Relapse-Free Survival (GRFS)	GVHD-Free and Relapse-Free Survival, the primary endpoint in our ongoing Phase III trial
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
HLA	human leukocyte antigen

HR	hazard ratio, the ratio of the hazard ratios corresponding to the conditions described by two levels of an explanatory variable
IMM	irreversible morbidity or mortality
immune reactive cells	cells that defend a host organism against pathogens and tumor 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 patient's 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
IRB	institutional review board
lymphocyte	type of white blood cells that divide to form T-cells, which destroy antigens, or B-cells, which produce antibodies
MAA	Marketing Authorization Application
MLR	mixed lymphocyte reaction
MTD	maximum tolerated dose
MRD	matched related donor
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

MUD	genetically matched unrelated donor
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
NIH	National Institutes of Health
Non-Hodgkin's Lymphoma (NHL)	a cancer that originates in the lymphatic system
NRM	nonrelapse mortality
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
PDCO	the Pediatric Committee established by the Pediatric Regulation
PTD	photodynamic therapy device
PDUFA	Prescription Drug User Fee Act
PFIC	a passive foreign investment company for U.S. federal income tax purposes
PFS	progression-free survival
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
PTCy protocol	the Post-Transplant Cyclophosphamide protocol, also commonly referred to as the Baltimore protocol
RMAT designation	Regenerative Medicine Advanced Therapy Designation
RRM	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
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
USPTO	the U.S. Patent and Trademark Office

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