



## TiGenix NV

*(Public limited liability company under Belgian law with registered office at Romeinse straat 12 box 2, 3001 Leuven, Belgium and registered with the register of legal entities (rechtspersonenregister – RPR) (Leuven) under enterprise number 0471.340.123)*

### PROSPECTUS

#### SECURITIES TRANSACTION NOTE DATED DECEMBER 16, 2016

**This “Securities Transaction Note” has been prepared by TiGenix NV (“TiGenix” or the “Company”) in relation to the admission to trading of up to 52,900,000 new shares on Euronext Brussels. It has been approved by the FSMA on December 16, 2016 and is to be read in conjunction with the following documents:**

- the Company's Registration Document in relation to the Company's financial year ended on December 31, 2015, as approved by the FSMA on April 12, 2016 (the “**Registration Document**”); and
- the Company's Summary Note to the Prospectus in relation to the admission to trading of up to 52,900,000 new shares on Euronext Brussels, as approved by the FSMA on December 16, 2016 (the “**Summary Note**”).

The Summary Note, together with the Company's Registration Document and this Securities Transaction Note constitute a prospectus within the meaning of Article 28, §1 of the Belgian Act of June 16, 2006 on the public offering of securities and the admission of securities to trading on a regulated market.

No public offering of the new shares will be made in Belgium or any other member state of the European Economic Area that has implemented the Prospectus Directive and no one has taken any action that would, or is intended to, permit a public offering of the new shares in any country or jurisdiction where any such action for such purpose is required.

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## RISK FACTORS

*Any investment in the shares of TiGenix involves substantial risks. You should carefully review and consider the following risk factors and the other information contained in the Registration Document before deciding to invest in the Company.*

*The risks that TiGenix is currently aware of and presently considers material to the New Shares are listed below. The occurrence of one or more of these risks may have a material adverse effect on the Company's cash flows, results of operations, financial condition and/or prospects and may even endanger the Company's ability to continue as a going concern. Moreover, the Company's share price could fall significantly if any of these risks were to materialise, in which case investors in the Company's shares could lose all or part of their investment. An investment in the shares of TiGenix is only suitable for investors who are capable of evaluating the risks and merits of such investment and who have sufficient resources to bear any loss which might result from such investment. Any investor should note that the risks discussed below are not the only risks to which the Company is exposed. Additional risks, including those currently unknown or deemed immaterial, may also impair the Company's business operations. The risks listed below are not intended to be presented in any assumed order of priority. Prospective investors should carefully review this Securities Transaction Note and the entire Prospectus and should reach their own views and decisions on the merits and risks of investing in the Company's shares in the light of their own personal circumstances. Furthermore, investors should consult their financial, legal and tax advisors to carefully review the risks associated with an investment in the Company's shares.*

### RISKS RELATED TO THE SHARES BEING ADMITTED TO TRADING

#### ***Sustainability of a liquid public market.***

An active public market for the TiGenix shares may not be sustained.

#### ***Raising additional capital may cause additional dilution of the percentage ownership of TiGenix's shareholders, restrict its operations, require TiGenix to relinquish rights to its technologies, products or product candidates and could cause its share price to fall.***

TiGenix expects that significant additional capital may be needed in the future to continue its planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating as a U.S.-listed public company. To raise capital, the Company may issue new ordinary shares, American Depositary Shares ("ADSs"), convertible securities or other equity securities in one or more transactions at prices and in a manner it determines from time to time. If the Company issues or sells new ordinary shares, American Depositary Shares, convertible securities or other equity securities, investors may be materially diluted. Such issuances or sales may also result in material dilution to the Company's existing shareholders, and new investors could gain rights, preferences and privileges senior to the holders of ordinary shares of the Company. The incurrence of indebtedness could result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on the ability of the Company to incur additional debt and other operating restrictions that could adversely impact its ability to conduct its business. If the Company raises additional funds through strategic partnerships and alliances and licensing arrangements with third parties, it may have to relinquish valuable rights to its technologies, products or product candidates, or grant licenses on terms unfavorable to the Company.

***Conversion of the EUR 25 million senior unsecured convertible bonds due 2018, contractual obligations with Genetrix resulting from the acquisition of Coretherapix and the anticipated equity investment by Takeda may result in a dilution of existing shareholders.***

The Company has on issue EUR 25 million of senior unsecured convertible bonds due 2018. The bonds were issued on March 6, 2015 at 100 per cent of their principal amount (EUR 100,000 per bond) and have a coupon of 9% per annum. The initial conversion price has been set at 0.9414 euro. On March 14, 2016, the conversion price was adjusted downwards to 0.9263 euro as a result of the private placement of 25 million new shares at 0.95 euro per share. The conversion price is subject to customary adjustment mechanisms. At the current conversion price of 0.9263 euro, the bonds will be convertible into 26,989,096 fully paid ordinary shares. If the bonds are converted into new shares, and assuming that the conversion price will be lower than the then prevailing market price of the shares, the conversion will entail a financial dilution of the existing shareholders.

On July 31, 2015, TiGenix acquired Coretherapix S.L. from Genetrix S.L. for an upfront payment of approximately EUR 1.2 million in cash and 7.7 million new shares issued in connection with the acquisition. Additionally, Genetrix may receive up to EUR 15 million in new TiGenix shares depending on the results of the ongoing clinical trial of Coretherapix, which would result in a dilution of existing shareholders. The issue price for these new TiGenix shares will be calculated on the basis of the average closing share price of the Company's shares on Euronext Brussels over the 90 days period immediately preceding the date of completion of the clinical trial.

On July 4, 2016, TiGenix entered into a licensing agreement with Takeda, a large pharmaceutical company active in gastroenterology, under which Takeda acquired the exclusive right to commercialize and develop Cx601 for complex perianal fistulas outside the United States. Under the agreement, Takeda has agreed to invest EUR 10 million in equity within one year of the effective date of the agreement, which would result in a dilution of existing shareholders. The issue price for these new TiGenix shares will be calculated on the basis of the average closing share price of the Company's shares on Euronext Brussels over the thirty-day period immediately preceding the issuance of the new shares.

***Investors may not be able to participate in equity offerings.***

Belgian corporate law and the Articles of Association of TiGenix provide for preferential subscription rights to be granted to existing shareholders to subscribe on a pro rata basis for any issue for cash of new shares, convertible bonds or warrants, unless such rights are cancelled or limited by resolution of TiGenix's shareholders' meeting or, if so authorized by a resolution of such meeting, the Board of Directors. TiGenix's shareholders' meeting or Board of Directors may cancel or restrict such rights in future equity or other offerings. In addition, certain shareholders (including those in the United States, Australia, Canada or Japan) may not be entitled to exercise such rights even if they are not cancelled unless the rights and related shares are registered or qualified for sale under the relevant legislation or regulatory framework. As a result, there is the risk that investors may suffer dilution of their shareholding should they not be permitted to participate in preference right equity or other offerings that TiGenix may conduct in the future.

***The market price of the shares could be negatively affected by sales of substantial numbers of shares in the public markets.***

Sales of a substantial number of shares or ADSs in the public markets, or the perception that such sales might occur, could cause the market price of the shares to decline. There is no commitment on the part of any of the existing shareholders to remain a shareholder or to retain a minimum interest in the Company.

***TiGenix shares may experience price and volume fluctuations.***

The stock market in general and pharmaceutical and biotechnology companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to

the operating performance of these companies. Broad market and industry factors may negatively affect the market price of the TiGenix shares, regardless of the Company's actual operating performance. The market price and liquidity of the market for the TiGenix shares may be significantly affected by numerous factors, some of which are beyond the Company's control. These factors include:

- Significant volatility in the market price and trading volume of securities of companies in the sector, which is not necessarily related to the operating performance of these companies.
- Delays between the Company's expenditures to develop and market new products and the generation of sales from those products.
- Changes in the amount that the Company spends to develop, acquire or license new products, technologies or businesses.
- Changes in the expenditures of the Company to promote its products and services.
- Success or failure of research and development projects of the Company or its competitors.
- Announcements of acquisitions and divestitures by the Company or one of its competitors.
- The general tendency towards volatility in the market prices of shares of companies that rely on technology and innovation.
- Changes in regulatory policies or tax guidelines.
- Changes or perceived changes in earnings or variations in operating results.
- Any shortfall in revenue or net income from levels expected by investors or securities analysts.
- Disputes or other developments relating to proprietary rights, including patents, and the ability of the Company to obtain patent protection for its technologies.
- Departures of key scientific or management personnel.
- Significant lawsuits, including patent litigation.
- General economic trends and other external factors, many of which are beyond the control of the Company.

In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm the Company's business, operating results or financial condition.

***Significant shareholders could decide to combine their voting rights.***

The Company has a number of significant shareholders. For an overview of the Company's significant shareholders, reference is made to section 9 of the Registration Document.

Currently, the Company is not aware that its existing shareholders have entered into a shareholders' agreement with respect to the exercise of their voting rights in the Company. Nevertheless, to the extent that these shareholders were to combine their voting rights, they could have the ability to elect or dismiss directors, and, depending on how broad the Company's other shares are held, approve certain other shareholders' decisions that require more than 50% or 75% of the Company's outstanding votes that are present or represented at shareholders' meetings where such items are submitted to voting by the shareholders. On the other hand, to the extent that these shareholders have insufficient votes to impose certain shareholders' resolutions, they could have the ability to block proposed shareholders' resolutions that require more than 50% or 75% of the Company's outstanding votes that are present or represented at shareholders' meetings where such items are submitted to voting by the shareholders. Any such voting by these significant shareholders may not be in the interest of the Company or the other shareholders.

***Takeover provisions in the national law may make it difficult for an investor to change management and may also make a takeover difficult.***

Public takeover bids on the Company's shares and other voting securities (such as warrants or convertible bonds, if any) are subject to the Belgian Law of April 1, 2007 (the "**Takeover Law**"), as amended and implemented by the Belgian Royal Decree of April 27, 2007 and to the supervision by the FSMA. Public takeover bids must be made for all of the Company's voting securities, as well as for all other securities that entitle the holders thereof to the subscription to, the acquisition of or the conversion in voting securities. Prior to making a bid, a bidder must issue and disseminate a prospectus, which must be approved by the FSMA. The bidder must also obtain approval of the relevant competition authorities, where such approval is legally required for the acquisition of the Company.

The Takeover Law provides that a mandatory bid will be triggered if a person, as a result of its own acquisition or the acquisition by persons acting in concert with it or by persons acting on their account, directly or indirectly holds more than 30 per cent of the voting securities in a company that has its registered office in Belgium and of which at least part of the voting securities are traded on a regulated market or on a multilateral trading facility designated by the Royal Decree of April 27, 2007 on public takeover bids. The mere fact of exceeding the relevant threshold through the acquisition of one or more shares will give rise to a mandatory bid, irrespective of whether or not the price paid in the relevant transaction exceeds the current market price.

There are several provisions of Belgian company law and certain other provisions of Belgian law, such as the obligation to disclose important shareholdings and merger control, that may apply to TiGenix and which may make an unfriendly tender offer, merger, change in management or other change in control, more difficult. These provisions could discourage potential takeover attempts that third parties may consider and thus deprive the shareholders of the opportunity to sell their shares at a premium (which is typically offered in the framework of a takeover bid).

***If securities or industry analysts do not publish research or reports about the Company, or if they adversely change their recommendations regarding the shares, the share price and trading volume could decline.***

The trading market for the shares will be influenced by research or reports that industry or securities analysts publish about the Company's business. If one or more analysts who cover the Company downgrade the shares, the market price of the shares would likely decline. If one or more of these analysts ceases coverage of the Company or fails to regularly publish reports on the Company, the Company could lose visibility in the financial markets, which, in turn, could cause the market price or trading volume for the shares to decline.

***The proposed Financial Transaction Tax.***

On February 14, 2013, the EU Commission adopted a proposal for a Council Directive (the "**Draft Directive**") on a common financial transaction tax ("**FTT**"). According to the Draft Directive, the FTT shall be implemented and enter into effect in 11 EU Member States (Austria, Belgium, Estonia, France, Germany, Greece, Italy, Portugal, Spain, Slovakia and Slovenia, together, the "**Original Participating Member States**").

The proposed FTT could, if introduced in its current form, apply to certain transactions (including secondary market transactions) in certain circumstances, to persons both within and outside of the Original Participating Member States. The Draft Directive currently stipulates that once the FTT enters into force, the Original Participating Member States shall not maintain or introduce taxes on financial transactions other than the FTT (or VAT as provided in the Council Directive 2006/112/EC of 28 November 2006 on the common system of value added tax). For Belgium, it could be expected that the tax on stock exchange transactions will be abolished once the FTT enters into force.

In October 2016, a Eurogroup session gathering 10 of the Original Participating Member States (Estonia left the participating group) agreed to push ahead with the project having agreed that the European



Commission will present an updated proposal in the weeks to come. Investors should consult their own tax advisers in relation to the consequences of the FTT associated with subscribing for, purchasing, holding and disposing of the Company's shares.

***The Company has no present intention to pay dividends on its shares in the foreseeable future and, consequently, during that time shareholders only have an opportunity to achieve a return on their investments if the price of the shares appreciates.***

The Company has no present intention to pay dividends on its shares in the foreseeable future. Any recommendation by the Board of Directors to pay dividends will depend on many factors, including the Company's financial condition, results of operations, legal requirements and other factors. Furthermore, pursuant to Belgian law, the calculation of amounts available for distribution to shareholders, as dividends or otherwise, must be determined on the basis of the non-consolidated statutory accounts of the Company prepared in accordance with Belgian accounting rules. In addition, in accordance with Belgian law and the Articles of Association of the Company, an amount of at least 5% of the Company's annual net profit under its non-consolidated statutory accounts must be allocated to a legal reserve until the reserve equals 10% of the share capital of the Company. Therefore, the Company is unlikely to pay dividends or other distributions in the foreseeable future. If the price of the shares declines in the foreseeable future, shareholders will incur a loss on their investment, without the likelihood that this loss will be offset in part or at all by potential future cash dividends.

***If the Company fails to maintain an effective system of internal control over financial reporting in the future, it may not be able to report accurately its financial condition, results of operations or cash flows, which may adversely affect investor confidence in it.***

The Sarbanes-Oxley Act requires, among other things, that the Company maintains effective internal control over financial reporting and disclosure controls and procedures. In particular, in the future, the Company will be required, under Section 404 of the Sarbanes-Oxley Act, to perform system and process evaluations and testing of its internal controls over financial reporting to allow management and its independent registered public accounting firm to report on the effectiveness of its internal control over financial reporting. This assessment will need to include disclosure of any material weaknesses in the Company's internal control over financial reporting identified by its management or its independent registered public accounting firm. Section 404 of the Sarbanes-Oxley Act also generally requires an attestation from the Company's independent registered public accounting firm on the effectiveness of its internal control over financial reporting. However, for as long as the Company remains an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 (the "**JOBS Act**"), it intends to take advantage of the exemption permitting it not to comply with the independent registered public accounting firm attestation requirement. At the time when the Company is no longer an emerging growth company, its independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which the Company's controls are documented, designed or operating. The Company's remediation efforts may not enable it to avoid a material weakness in the future.

The compliance with Section 404 will require that the Company incurs substantial accounting expense and expend significant management efforts. The Company currently does not have an internal audit group, and it may need to hire additional accounting and financial staff or a third-party service provider with the appropriate experience, as well as understanding of internal control processes around supervision and monitoring of its accounting and reporting functions and technical accounting knowledge and application, and compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404.

The Company may not be able to complete its evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if the Company identifies one or more material weaknesses in its internal control over financial reporting, it will be unable to assert that its internal control over financial reporting is effective. The Company cannot assure that there will not be material weaknesses or significant deficiencies in its internal control over financial reporting in the future. If the

Company is unable to conclude that its internal control over financial reporting is effective, or if its independent registered public accounting firm determines it has a material weakness or significant deficiency in its internal control over financial reporting, the Company could lose investor confidence in the accuracy and completeness of its financial reports, the market price of the ADSs or shares could decline, and the Company could be subject to sanctions or investigations by the NASDAQ Stock Market, the SEC or other regulatory authorities. Failure to remedy any material weakness in the Company's internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict its future access to the capital markets.

***TiGenix will incur significant increased costs as a result of operating as a company whose American Depositary Shares are publicly traded in the United States, and its management will be required to devote substantial time to new compliance initiatives.***

As a company whose American Depositary Shares will be publicly traded in the United States, the Company will incur significant legal, accounting, insurance and other expenses that it did not previously incur. In addition, the Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act and related rules implemented by the SEC and the NASDAQ stock market have imposed various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls. These costs will increase at the time when the Company is no longer an emerging growth company as defined in the JOBS Act, eligible to rely on exemption under the JOBS Act from certain disclosure and governance requirements. The Company's management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase the legal and financial compliance costs and will make some activities more time-consuming and costly. For example, it is expected that these rules and regulations make it more difficult and more expensive for the Company to obtain director and officer liability insurance, and the Company may be required to incur substantial costs to maintain the same or similar coverage. These laws and regulations could also make it more difficult and expensive for the Company to attract and retain qualified persons to serve on its Board of Directors or its committees. Furthermore, if the Company is unable to satisfy its obligations as a U.S.-listed public company, it could be subject to delisting of the American Depositary Shares, fines, sanctions and other regulatory action and potentially civil litigation.

***Fluctuations in the exchange rate between the U.S. dollar and the euro may increase the risk of holding TiGenix shares.***

The Company's ordinary shares currently trade on Euronext Brussels in euro and the Company's American Depositary Shares will trade on the NASDAQ Global Select Market in U.S. dollars. Fluctuations in the exchange rate between the U.S. dollar and the euro may result in temporary differences between the value of the Company's American Depositary Shares and the value of its ordinary shares, which may result in heavy trading by investors seeking to exploit such differences.

***TiGenix has broad discretion to determine how to use the net proceeds resulting from the Transaction and may use them in ways that may not enhance its results of operations or the price of the shares.***

Although TiGenix currently intends to use the net proceeds from this Transaction in the manner described in the section titled "Reasons for the capital increase and use of proceeds" in this prospectus, its management will have broad discretion over the use of net proceeds resulting from this Transaction, and could spend the net proceeds in ways the shareholders may not agree with or that do not yield a favorable return. Because of the number and variability of factors that will determine the use of the net proceeds from the Transaction, the Company's use of these proceeds may differ substantially from its current plans. Shareholders will not have the opportunity, as part of their investment decision, to assess whether proceeds are being used appropriately. Shareholders must rely on the judgment of the Company's management regarding the application of the net proceeds resulting from the Transaction.

## **RISKS RELATED TO TIGENIX'S BUSINESS**

For an overview of the other risks related to TiGenix and its business and other risks and uncertainties faced by the Company as of April 12, 2016 reference is made to the section "Risk Factors" included in the Registration Document.

Investors should also carefully consider the risks and uncertainties related to TiGenix and its business as further described below, which result from events that have occurred after April 12, 2016, or which are otherwise considered to be material by the Company, and which may modify or supersede certain business and other risks and uncertainties included in the Registration Document. Any statement so modified or superseded shall not, except as so modified or superseded, constitute a part of this Prospectus.

However, these risks and uncertainties may not be the only ones faced by the Company and are not intended to be presented in any assumed order of priority. Additional risks and uncertainties, including those currently unknown, or deemed immaterial, could have the effects set forth above.

***TiGenix international operations subject TiGenix to various risks, and its failure to manage these risks could adversely affect its results of operations.***

TiGenix faces significant operational risks as a result of doing business internationally, such as the following:

- fluctuations in foreign currency exchange rates;
- potentially adverse and/or unexpected tax consequences, including penalties due to the failure of tax planning or due to the challenge by tax authorities on the basis of transfer pricing and liabilities imposed from inconsistent enforcement;
- potential changes to the accounting standards, which may influence its financial situation and results;
- becoming subject to the different, complex and changing laws, regulations and court systems of multiple jurisdictions and compliance with a wide variety of foreign laws, treaties and regulations;
- difficulties in attracting and retaining qualified personnel;
- rapid changes in global government, economic and political policies and conditions, political or civil unrest or instability, terrorism or epidemics and other similar outbreaks or events, and potential failure in confidence of its suppliers or customers due to such changes or events; and
- tariffs, trade protection measures, import or export licensing requirements, trade embargoes and other trade barriers.

***The results of the United Kingdom's referendum on leaving the European Union may have a negative effect on TiGenix' business.***

In June 2016, a majority of voters in the United Kingdom voted to leave the European Union in a referendum. The terms of any withdrawal are subject to a negotiation period that could last up to two years after the United Kingdom formally initiates a withdrawal process. The referendum has created significant uncertainty about the future relationship between the United Kingdom and the European Union, including with respect to the laws and regulations that will apply in the future. These developments have had and may continue to have a material adverse effect on global economic conditions and the stability of global financial markets, and may significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets. Any of these factors could depress economic activity and restrict TiGenix's access to capital. In addition, it is uncertain whether TiGenix' EMA approvals, if granted, will cover the United Kingdom. If not, it is not yet known what the new U.K. approval process will involve.

***Although TiGenix has entered into a special protocol assessment, or SPA, with the FDA relating to the U.S. Phase III trial of Cx601 for the treatment of perianal fistulas, this agreement does not***

***guarantee any particular outcome with respect to regulatory review of the trial or any associated biologics license application, or BLA.***

The protocol for its U.S. Phase III trial of Cx601 for the treatment of perianal fistulas was reviewed and agreed upon by the FDA under an SPA agreement in 2015. The FDA's SPA process is designed to facilitate the FDA's review and approval of drugs by allowing the FDA to evaluate the proposed design and size of clinical trials that are intended to form the primary basis for determining a drug product's safety and efficacy. Upon specific request by a clinical trial sponsor, the FDA will evaluate the protocol and respond to a sponsor's questions regarding, among other things, primary efficacy endpoints, trial conduct and data analysis. The FDA ultimately assesses whether the protocol design and planned analysis of the trial are acceptable to support regulatory approval of the product candidate with respect to the effectiveness of the indication studied.

Because SPA provides for the evaluation of protocols for trials that have not been initiated, the conduct and results of the subsequent trial are not part of the evaluation. Therefore, the existence of an SPA agreement does not guarantee that the FDA will accept a new drug application or a BLA or that the trial results will be adequate to support approval. Those issues are addressed during the review of a submitted application; however, it is hoped that trial quality will be improved by the SPA process. In rare cases, the FDA may rescind an SPA agreement. In particular, an SPA agreement is not binding on the FDA if public health concerns emerge that were unrecognized at the time of the SPA agreement, other new scientific concerns regarding product safety or efficacy arise, the sponsor company fails to comply with the agreed upon trial protocols, or the relevant data, assumptions or information provided by the sponsor in a request for the SPA change or are found to be false or omit relevant facts.

An SPA agreement may be modified, and such modification will be deemed binding on the FDA review division, except under the circumstances described above, if the FDA and the sponsor agree in writing to modify the protocol and such modification is intended to improve the study. TiGenix plans to discuss proposed revisions to its SPA protocol with the FDA in order to increase sample size and patient recruitment, among other things, for its Phase III clinical trial of Cx601. For that, it needs to submit a new SPA request to the FDA and provide written questions seeking the agency's guidance on proposed changes to its protocol. TiGenix plans to submit this new SPA request to the FDA early 2017 and will be notified in writing of responses to its questions and whether the FDA regards the revised protocol as sufficient to maintain the SPA concurrence.

***TiGenix will depend heavily on its licensing arrangement with Takeda for the success of Cx601 for complex perianal fistulas outside of the United States. If Takeda terminates the licensing agreement or is unable to meet its contractual obligations, it could negatively impact TiGenix' business.***

In July 2016, TiGenix entered into a licensing agreement pursuant to which it granted exclusive rights to Takeda to commercialize and develop Cx601 for complex perianal fistulas outside of the United States.

Under the terms of the licensing agreement, TiGenix is entitled to receive specified regulatory and sales milestone payments, as well as royalty payments and an equity investment. In addition, as part of the licensing agreement with Takeda, TiGenix will expand its production facility in Madrid, the cost of which it has agreed to share equally with Takeda. In addition, Takeda will be solely responsible for all commercialization activities and associated costs, relating to the licensed product in the licensed territories.

Unless earlier terminated, the licensing agreement will expire on a country-by-country basis upon the expiration of the royalty term in such country for such licensed product. Either party may, subject to a cure period, terminate the licensing agreement in the event of the other party's uncured material breach. Takeda may also terminate the licensing agreement under specified circumstances relating to regulatory approval, infringement of intellectual property rights or increases in production costs.

If Takeda were to terminate the licensing agreement or fail to meet its contractual obligations, the assumption by TiGenix of all costs relating to the development of Cx601 and the establishment of a commercial infrastructure in the licensed territories would require substantial resources, financial and otherwise, and could result in TiGenix incurring greater expenses than the increase in revenues from its direct sales of the licensed product in the licensed territories. It could also cause a delay in the

development of Cx601. Seeking and obtaining a viable, alternative collaborator to partner on the development and commercialization of the licensed product may not be available on similar terms or at all.

***If the EMA does not approve Cx601 for the treatment of complex perianal fistulas in patients with Crohn's disease, Takeda may not be able to commercialize Cx601 in Europe and TiGenix may not receive its milestone payment in connection with approval of marketing authorization and subsequent milestone payments and royalties in a timely manner or at all.***

In March 2016, TiGenix submitted a marketing authorization application for Cx601 to the EMA for the treatment of complex perianal fistulas in adult patients with non-active or mildly active luminal Crohn's disease whose fistulas have shown an inadequate response to at least one conventional or biologic therapy. In July 2016, the EMA sent TiGenix its initial response to TiGenix' application for marketing authorization, which TiGenix refers to as "the day 120 list of questions". In this response, the EMA informed TiGenix of certain major objections and, following its standard protocol for review at day 120, stated that TiGenix' application was not approvable at the present time. These objections would preclude a recommendation for marketing authorization unless TiGenix is able to address them adequately. These objections were as follows:

- inadequate data with respect to the stability of the intermediate master cell stock for Cx601 and the questionable relevance of the potency test for stability of the master cell stock
- incomplete information with respect to the details on donor selection and testing
- an insufficient viral safety risk assessment
- uncertainty as to whether the primary endpoint of the trial is adequately representative of complete closure of fistulas and is adequately sensitive as a measure of improvement.

In addition, as part of the marketing authorization application process, TiGenix had a routine Good Clinical Practice inspection in September 2016. The inspectors identified certain critical and major deviations from Good Clinical Practices, in particular, a potential violation of patient privacy. In their report to the EMA's Committee for Human Medicinal Products, the inspectors recommend that the data from the trial should be disregarded as part of the marketing authorization application.

While TiGenix believes it has adequate responses for these objections, the EMA reviewers may not be satisfied with its responses or may require additional information, which TiGenix may not be able to provide in a timely manner or at all. If TiGenix is not able to provide the EMA with satisfactory responses, TiGenix may not receive marketing authorization for Cx601, or if TiGenix needs additional time to provide the required information, approval for marketing authorization could be delayed. This would delay or preclude its receipt of the milestone payment of 15 million euros from Takeda for receipt of marketing authorization of Cx601 in Europe, additional milestone payments for favorable pricing decisions in certain European markets and royalties from sales of Cx601 in Europe. In addition, Takeda has the option to terminate the licensing agreement if TiGenix does not receive marketing authorization in Europe by July 2020.

***The regulatory landscape that will govern TiGenix' product candidates is evolving, and changes in regulatory requirements could result in delays or discontinuation of development of its product candidates or unexpected costs in obtaining regulatory approval.***

Because TiGenix is developing novel stem cell therapy product candidates that are unique biological entities, the regulatory requirements that it will be subject to may change. Even with respect to more established products that fit into the categories of cell therapies, the regulatory landscape is still developing and will likely continue to change in the future. In particular, such products may be subject to increased scrutiny by regulatory authorities. For example, the EMA established a special committee called the Committee for Advanced Therapies to assess the quality, safety and efficacy of advanced therapy medicinal products, a category that includes cell therapy products including TiGenix' product candidates. This committee advises the Committee for Medicinal Products for Human Use, or CHMP, which is responsible for a final opinion on the granting, variation, suspension or revocation of an application for marketing authorization in the European Union.

Likewise, in the United States, the FDA has established the Office of Cellular, Tissue and Gene Therapies within its Center for Biologics Evaluation and Research, or CBER, to consolidate the review of cell therapy and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. Cell therapy clinical trials are also subject to review and oversight by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees basic and clinical research conducted at the institution participating in the clinical trial. Although the FDA decides whether individual cell therapy protocols may proceed, review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical study, even if the FDA has reviewed the study and approved its initiation. Conversely, the FDA can place an IND application on clinical hold even if such other entities have provided a favorable review. Furthermore, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which a clinical trial will be conducted. Similarly complex regulatory environments exist in other jurisdictions in which TiGenix might consider seeking regulatory approvals for TiGenix' product candidates, further complicating the regulatory landscape.

As TiGenix advances its product candidates, it will be required to consult with these regulatory and advisory groups and comply with all applicable guidelines, rules and regulations. If it fails to do so, TiGenix may be required to delay or discontinue development of its product candidates. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease its ability to generate sufficient product revenue to maintain its business.

These various regulatory review committees and advisory groups may also promulgate new or revised guidelines from time to time that may lengthen the regulatory review process, require TiGenix to perform additional studies, increase its development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of its product candidates or lead to significant post-approval limitations or restrictions. Because the regulatory landscape for its stem cell therapy product candidates is evolving, TiGenix may face even more cumbersome and complex regulations in the future. Furthermore, even if its product candidates obtain required regulatory approvals, such approvals may later be withdrawn as a result of changes in regulations or the interpretation of regulations by applicable regulatory agencies.

In addition, adverse developments in clinical trials of cell therapy products conducted by others may cause the FDA or other regulatory bodies to change the requirements for approval of any of TiGenix' product candidates.

***Tissue-based products are regulated differently in different countries. These requirements may be costly and result in delay or otherwise preclude the distribution of TiGenix' products in some foreign countries, any of which would adversely affect its ability to generate operating revenues.***

Tissue based products are regulated differently in different countries. Many foreign jurisdictions have a different and may have a more difficult regulatory pathway for human tissue based products, which may prohibit the distribution of these products until the applicable regulatory agencies grant marketing approval, or licensure. The process of obtaining regulatory approval is lengthy, expensive and uncertain, and TiGenix may never seek such approvals, or if it does, it may never gain those approvals. Any adverse events in its clinical trials for a future product under development could negatively impact its products.

***Safe and efficacious human medical applications may never be developed using cell therapy products or related technology.***

If serious adverse events related to cell therapy products were to arise in clinical trials or after marketing approval, the EMA or FDA could impose more restrictive safety requirements on cell therapy products generally, including in the manner of use and manufacture, could require safety warnings in product labelling, and could limit, restrict or deny permission for new cell therapy products to enter clinical trials or to be marketed.

***TiGenix' cell therapy product candidates represent new classes of therapy and may not be accepted by patients or medical practitioners.***

TiGenix ability to commercialize Cx601 and future product candidates will depend, in part, on market acceptance, including the willingness of medical practitioners to invest in training programs to use the products. Cell therapy products are a novel treatment, and such products may not be immediately accepted as complementary or alternative treatments to the current standards of care. TiGenix may not be able to obtain or maintain recommendations and endorsements from influential physicians, which are an essential factor for market acceptance of its product candidates, or its product candidates may not gain sufficient market recognition in spite of favorable opinions from key leaders. The degree of market acceptance of its cell therapy product candidates will depend on a number of factors, including the following:

- the clinical safety and effectiveness of its products and their demonstrated advantage over alternative treatment methods
- its ability to demonstrate to healthcare providers that its products provide a therapeutic advancement over standard of care or other competitive products or methods
- its ability to educate healthcare providers on the use of patient-specific human tissue, to avoid potential confusion with and differentiate itself from the ethical controversies associated with human fetal tissue and engineered human tissue
- its ability to educate healthcare providers, patients and payers on the safety and adverse reactions involving its products
- its ability to meet supply and demand and develop a core group of medical professionals familiar with and committed to the use of its products
- the cost-effectiveness of its products and the reimbursement policies of government and third-party payers.

If the medical community or patients do not accept the safety and effectiveness of TiGenix' product candidates or TiGenix' product candidates fail to demonstrate a favorable risk/benefit profile, this could negatively affect any future sales.

***Ethical, legal, social and other concerns surrounding the use of human tissue in synthetic biologically engineered products may negatively affect public perception of TiGenix or its product candidates, or may result in increased scrutiny of TiGenix' product candidates from a regulatory perspective.***

The public perception of ethical and social issues surrounding the use of tissue-engineered products or stem cells may limit or discourage the use of TiGenix' product candidates. The use of human cells, such as differentiated cartilage cells, eASCs, CSCs and other adult stem cells, as starting material for the development of its product candidates could generate negative public perceptions of its product candidates and public expressions of concern could result in stricter governmental regulation, which may, in turn, increase the cost of manufacturing and marketing its product or impede market acceptance of its product candidates.

***The manufacture of cell therapy products is characterized by inherent risks and challenges and may be a more costly endeavor than manufacturing other therapeutic products.***

The manufacture of cell therapy products, such as TiGenix' product candidates, is highly complex and is characterized by inherent risks and challenges such as raw material inconsistencies, logistical challenges, significant quality control and assurance requirements, manufacturing complexity, and significant manual processing. Unlike products that rely on chemicals for efficacy, such as most pharmaceuticals, cell therapy products are difficult to characterize due to the inherent variability of biological input materials. As a result, assays of the finished product may not be sufficient to ensure that the product will perform in the intended manner. Accordingly, TiGenix employs multiple steps to control its manufacturing process to assure that the process works and that its product candidate is made strictly and consistently in compliance with the process. Problems with the manufacturing process, even minor deviations from the normal process, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims or insufficient inventory, which could be costly to

TiGenix or result in reputational damage. TiGenix has experienced lot failures in the past and might experience such failures in the future.

TiGenix may encounter problems achieving adequate quantities and quality of clinical-grade materials that meet EMA, FDA or other applicable standards or specifications with consistent and acceptable production yields and costs. In addition, EMA, FDA and other foreign regulatory authorities may require TiGenix to submit samples of any lot of any approved product together with the protocols showing the results of applicable tests at any time. Under some circumstances, EMA, FDA or other foreign regulatory authorities may require that TiGenix does not distribute a lot until the agency authorizes its release.

Successfully transferring complicated manufacturing techniques to contract manufacturing organizations and scaling up these techniques for commercial quantities is time consuming and subject to potential difficulties and delays. TiGenix has entered into an agreement with Lonza, a leading U.S.-based contract manufacturing organization active in biological and cell therapy manufacturing, to produce Cx601 in the United States in connection with the proposed Phase III clinical trial to register Cx601 in the United States. TiGenix' technology transfer to Lonza may result in setbacks in replicating the current manufacturing process at a new facility and in scaling up production. Likewise, TiGenix or any other third parties with whom TiGenix enters into strategic relationships, including Takeda, might not be successful in streamlining manufacturing operations or implementing efficient, low-cost manufacturing capabilities and processes that will enable TiGenix to meet the quality, price and production standards or production volumes to achieve profitability. Its failure to develop these manufacturing processes in a timely manner could prevent TiGenix from achieving its growth and profitability objectives as projected or at all.



# 1. GENERAL INFORMATION

## 1.1. INTRODUCTION

### 1.1.1. The Prospectus

This Securities Transaction Note is to be read together with the Company's Registration Document and the Summary Note, which, together constitute a prospectus (the "**Prospectus**") that has been prepared by the Company in accordance with Article 20 of the Belgian Act of June 16, 2006 on the public offering of securities and the admission of securities to be traded on a regulated market (*Wet op de openbare aanbidding van beleggingsinstrumenten en de toelating van beleggingsinstrumenten tot de verhandeling op een gereglementeerde markt*) (the "**Act of June 16, 2006**").

### 1.1.2. No public offering of shares

On December 5, 2016 the Board of Directors conditionally increased the share capital of the Company in a maximum amount of EUR 8.3 million (excluding issuance premium).

On or about December 20, 2016, the Underwriters will subscribe on behalf of the final investors for 46,000,000 new shares (the "**New Shares**") for an aggregate issue price of USD 35.65 million in relation to an initial public offering of 2,300,000 American Depositary Shares ("**ADSs**"), each ADS representing 20 New Shares, to retail and institutional investors in the United States and to institutional and professional investors in or from any other country or jurisdiction where such offering is permitted in compliance with any applicable rules and regulations of any such country or jurisdiction (the "**Transaction**"). Any investor (including any existing shareholder) who is eligible to participate in the Transaction will have the opportunity to purchase ADSs. No opportunity will be offered to subscribe for the underlying New Shares directly.

In the framework of the Transaction, the Underwriters have been granted an option to subscribe for up to 6,900,000 additional new shares in the form of ADSs (the "**Over-Allotted Shares**"), which option may be exercised any time until January 13, 2017, to cover over-allotments or short positions of ADSs, if any. The Prospectus has been prepared for the purpose of the admission to trading of the New Shares and the Over-Allotted Shares (if any) on the regulated market of Euronext Brussels and does not constitute, and should not be construed as, an offer to sell or the solicitation of an offer to buy or subscribe for any New Shares, Over-Allotted Shares or ADSs.

Other than the initial public offering of the ADSs in the United States, no public offering of the New Shares, Over-Allotted Shares or ADSs will be made and no one has taken any action that would, or is intended to, permit a public offering in any country or jurisdiction where any such action for such purpose is required, including in Belgium or any other member state of the European Economic Area that has implemented the Prospectus Directive (each a "**Relevant Member State**"). Belgian investors, other than qualified investors within the meaning of the Act of June 16, 2006 will not be eligible to participate in the Transaction (whether in Belgium or elsewhere).

For purposes of this provision, (a) the expression an "offer of securities to the public" in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the New Shares to be offered, so as to enable an investor to decide to purchase or subscribe for the New Shares, as the expression may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that member state, (b) the expression "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State) and includes any relevant implementing measure in the Relevant Member State, and (c) the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

### 1.1.3. Language of the Prospectus

TiGenix has prepared the Prospectus in English. TiGenix has also made a translation in Dutch of the Prospectus. Both the English version and the Dutch version of the Prospectus are legally binding. TiGenix has verified and is responsible for the translation and the conformity of both versions. However, in case of inconsistencies between the language versions, the English version shall prevail.

### 1.1.4. Availability of the Prospectus

The Prospectus consists of the Summary Note, this Securities Transaction Note and the Registration Document. The Summary Note and the Securities Transaction Note can only be distributed together, in combination with the Registration Document. To obtain a copy of the Prospectus in Dutch and/or in English free of charge, please contact:

TiGenix NV  
Attn. Claudia D'Augusta  
Romeinse straat 12, box 2  
3001 Leuven  
Belgium  
Phone: +32 16 39 60 60  
Fax: +32 16 39 79 70  
E-mail: investor@tigenix.com

The Prospectus is also available from the website of TiGenix ([www.tigenix.com](http://www.tigenix.com)).

Posting the Prospectus on the internet does not constitute an offer to sell or a solicitation of an offer to buy any of the Company's shares to any person in any jurisdiction. The electronic version may not be copied, made available or printed for distribution. The Prospectus is only valid in its original version circulated in Belgium in compliance with applicable laws. Other information on the website of the Company or any other website does not form part of the Prospectus.

## 1.2. PERSONS RESPONSIBLE FOR THE CONTENTS OF THE PROSPECTUS

The Company, represented by its Board of Directors, assumes responsibility for the contents of the Prospectus.

At the date of this Securities Transaction Note, the Board of Directors of TiGenix is composed of the following five (5) members:

Name	Position
Innosté SA <sup>1</sup> , permanently represented by Jean Stéphane	Chairman / Independent director
Eduardo Bravo Fernández de Araoz	Managing Director (executive) / CEO
Willy Duron	Independent director
Greig Biotechnology Global Consulting, Inc. <sup>2</sup> , permanently represented by Russell Greig	Independent director

<sup>1</sup> Having its registered office at Avenue Alexandre 8,1330 Rixensart, Belgium.

<sup>2</sup> Having its registered office at 1241 Karen Lane, Wayne, PA 19087, USA.

<sup>3</sup> Appointed by the board of directors subject to confirmation by the shareholders at the next meeting of shareholders.

Name	Position
June Almenoff <sup>3</sup>	Independent director

The Board of Directors declares that having taken all reasonable care to ensure that such is the case, the information contained in the Prospectus is, to the best of its knowledge, in accordance with the facts and contains no omission likely to affect its import.

### 1.3. APPROVAL OF THE PROSPECTUS

The English version of the Company's Registration Document was approved by the Belgian Financial Services and Markets Authority ("FSMA") on April 12, 2016 as registration document within the meaning of Article 28, §2 of the Act of June 16, 2006.

The English versions of the Summary Note and this Securities Transaction Note were approved by the FSMA on December 16, 2016 in accordance with Article 23 of the Act of June 16, 2006 for the purposes of the admission to trading of maximum 52,900,000 new shares (i.e., the New Shares and the Over-Allotted Shares (if any)) on Euronext Brussels.

This Prospectus has been prepared in accordance with chapter II of the Commission Regulation (EC) No 809/2004 of 29 April 2004 implementing the Prospectus Directive, as amended by the Commission regulations (EC) No 1787/2006, No 211/2007 and No 1289/2008 as well as the Commission delegated regulations (EU) No 311/2012, No 486/2012, No 862/2012, No 621/2013 and 759/2013.

The approval by the FSMA does not imply any judgment on the merits or the quality of the transactions contemplated by the Prospectus nor of the securities or the status of TiGenix.

The Prospectus has not been submitted for approval to any other supervisory body or governmental authority outside Belgium.

### 1.4. AVAILABLE INFORMATION

The Company must file its (restated and amended) Articles of Association and all other deeds that are to be published in the annexes to the Belgian Official Gazette with the clerk's office of the Commercial Court of Leuven (Belgium), where they are available to the public. A copy of the most recently restated Articles of Association and the corporate governance charter is also available on the Company's website.

In accordance with Belgian law, the Company must prepare annual audited statutory and consolidated financial statements. The annual statutory and consolidated financial statements and the reports of the Board of Directors and statutory auditor relating thereto are filed with the Belgian National Bank, where they are available to the public. Furthermore, as a listed company, the Company publishes summaries of its annual and semi-annual financial statements. These summaries are generally made publicly available in the financial press in Belgium in the form of a press release. Copies thereof are also available on the Company's website.

The Company also has to disclose price sensitive information, information about its shareholders' structure, and certain other information to the public. In accordance with the Belgian Royal Decree of November 14, 2007 relating to the obligations of issuers of financial instruments admitted to trading on a Belgian regulated market (*Koninklijk besluit betreffende de verplichtingen van emittenten van financiële instrumenten die zijn toegelaten tot de verhandeling op een Belgische gereguleerde markt*), such information and documentation will be made available through press releases, the financial press in Belgium, the Company's website, the communication channels of Euronext Brussels or a combination of these media.

A registration statement on Form F-1 under the Securities Act for the offering in the United States of the ADSs has become effective. A copy of the registration statement can be consulted via the SEC's website at [www.sec.gov](http://www.sec.gov).

The Board of Directors declares that having taken all reasonable care to ensure that such is the case, the registration statement contains, to the best of its knowledge, no information of a material nature relevant to investors in the Company's ordinary shares that is not disclosed in the Prospectus or in press releases or that is not otherwise disclosed on the Company's website.

The Company's website can be found at [www.tigenix.com](http://www.tigenix.com).

## **1.5. NOTICES TO INVESTORS**

### **1.5.1. Decision to invest**

In making an investment decision, potential investors must rely on their own examination of the Company and the terms of the admission to trading, including the risks and merits involved. Any summary or description set forth in the Prospectus of legal provisions, corporate structurings or contractual relationships is for information purposes only and should not be construed as legal or tax advice as to the interpretation or enforceability of such provisions or relationships. In general, none of the information in the Prospectus should be considered investment, legal or tax advice. Investors should consult their own counsel, accountant and other advisors for legal, tax, business, financial and related advice regarding investing in the Company's shares. The Company's shares have not been recommended by any federal or state securities commission or regulatory authority in Belgium or elsewhere.

No dealer, sales person or other person has been authorized to give any information or to make any representation in connection with the admission to trading of the New Shares and the Over-Allotted Shares (if any) that is not contained in the Prospectus. If anyone provides different or inconsistent information, it should not be relied upon. The information appearing in the Summary Note, Securities Transaction Note and Registration Document should be assumed to be accurate only as at the date of approval by the FSMA of the relevant document as indicated on the cover page of this Securities Transaction Note. The Company's business, financial condition, results of operations and the information set forth in the Prospectus may have changed since those dates. In accordance with Belgian law, if a significant new factor, material mistake or inaccuracy relating to the information included in the Prospectus which is capable of affecting the assessment of the Company's shares and which arises or is noted between the time when the Prospectus is approved and the start of the trading of the New Shares and the Over-Allotted Shares (if any) on the relevant market, such will be set out in a supplement to the Prospectus. Any supplement is subject to approval by the FSMA, in the same manner as the Prospectus and must be made public, in the same manner as the Prospectus.

### **1.5.2. Certain restrictions on the distribution of the Prospectus**

The distribution of the Prospectus may be restricted by law in certain jurisdictions outside Belgium. TiGenix does not represent that the Prospectus may be lawfully distributed in jurisdictions outside Belgium. TiGenix does not assume any responsibility for such distribution. The Prospectus does not constitute an offer to sell or a solicitation of an offer to buy any of the Company's shares. The Prospectus may not be distributed to the public in any jurisdiction outside Belgium where a registration, qualification or other requirement exists or may exist in relation to the admission to trading of shares on the regulated market of Euronext Brussels, and may in particular not be distributed to the public in the U.S., Switzerland, Canada, Australia or Japan or the United Kingdom. Persons in whose possession this Prospectus or any New Shares or Over-Allotted Shares (if any) may come must inform themselves about, and observe, any such restrictions on the distribution of this Prospectus. Any person that, for any reason whatsoever, circulates or allows circulation of this Prospectus, must draw the addressee's attention to the provisions of this section.

### **1.5.3. Forward looking statements**

The Prospectus contains forward-looking statements and estimates made by the Company with respect to the anticipated future performance of TiGenix and the market in which it operates. Certain of these statements, forecasts and estimates can be recognised by the use of words such as, without limitation, “believes”, “anticipates”, “expects”, “intends”, “plans”, “seeks”, “estimates”, “may”, “will”, “predicts”, “projects” and “continue” and similar expressions. They include all matters that are not historical facts. Such statements, forecasts and estimates are based on various assumptions and assessments of known and unknown risks, uncertainties and other factors, which were deemed reasonable when made but may or may not prove to be correct. Actual events are difficult to predict and may depend upon factors that are beyond the Company's control. Therefore, actual results, the financial condition, performance or achievements of TiGenix, or industry results, may turn out to be materially different from any future results, performance or achievements expressed or implied by such statements, forecasts and estimates. Factors that might cause such a difference include, but are not limited to, those discussed in the sections “Risk Factors” of this Securities Transaction Note and/or the Registration Document. Given these uncertainties, no representations are made as to the accuracy or fairness of such forward-looking statements, forecasts and estimates. Furthermore, forward-looking statements, forecasts and estimates in the Summary Note, the Securities Transaction Note or the Registration Document only speak as at the date of approval by the FSMA of the relevant document as indicated on the cover page of this Securities Transaction Note. TiGenix disclaims any obligation to update any such forward-looking statement, forecast or estimates to reflect any change in the Company's expectations with regard thereto, or any change in events, conditions or circumstances on which any such statement, forecast or estimate is based, except to the extent required by Belgian law.

### **1.5.4. Industry data, market share, ranking and other data**

Certain of the information contained in the Prospectus is based on the Company's own estimates and assumptions, believed by the Company to be reasonable. Certain information, industry data, market size/share data and other data provided in the Prospectus was derived from publications by leading organisations and scientific journals. The information published by such organisations and journals has been accurately reproduced and as far as the Company is aware and able to ascertain, no facts have been omitted which would render the reproduced information inaccurate or misleading. Neither the Company (with respect to information derived from publications by leading organisations) nor its advisors have independently verified any of the abovementioned information. Furthermore, market information is subject to change and cannot always be verified with complete certainty due to limits on the availability and reliability of raw data, the voluntary nature of the data gathering process and other limitations and uncertainties inherent in any statistical survey of market information. As a result, prospective investors should be aware that market share, ranking and other similar data in the Prospectus, and estimates and beliefs based on such data, may not be reliable.

### **1.5.5. Rounding of financial and statistical information**

Certain numerical figures included in the Prospectus have been subject to rounding adjustments and currency conversion adjustments. Accordingly, the sum of certain data may not be equal to the expressed total.

## 2. ESSENTIAL INFORMATION

### 2.1. WORKING CAPITAL STATEMENT

The Company is of the opinion that it has sufficient working capital to cover its working capital needs for a period of at least 12 months following the date of publication of the Prospectus.

### 2.2. CAPITALIZATION AND INDEBTEDNESS

The table below shows the consolidated capitalization and indebtedness for TiGenix for the full previous 3 years (audited) and September 30, 2016 (unaudited). This table should be read in conjunction with TiGenix's audited and unaudited financial statements and the information included elsewhere in this Prospectus.

<b>Statement of Financial Position</b>	<b>TiGenix</b>	<b>TiGenix</b>	<b>TiGenix</b>	<b>TiGenix</b>
<b>Thousands of euro</b>	<b>As at Sep 30, 2016</b>	<b>As at Dec 31, 2015</b>	<b>As at Dec 31, 2014</b>	<b>As at Dec 31, 2013</b>
<b>Equity</b>	<b>26,497</b>	<b>13,145</b>	<b>34,757</b>	<b>48,222</b>
Share capital	20,230	17,730	16,048	16,048
Share premium	132,364	112,750	100,118	100,125
Accumulated deficit <sup>(1)</sup>	(129,382)	(120,002)	(87,041)	(74,049)
Other reserves <sup>(1)</sup>	3,285	2,667	5,632	6,098
<b>Non-current debts</b>	<b>31,797</b>	<b>40,084</b>	<b>10,652</b>	<b>8,263</b>
Financial loans and other payables	31,797	40,084	10,652	8,263
<i>of which</i>				
-- Guaranteed <sup>(2)</sup>	28,118	33,576	2,111	6,152
-- Guaranteed and secured <sup>(3)</sup>	2,224	4,739	7,448	-
-- Unguaranteed/unsecured	1,455	1,769	1,093	2,111
<b>Current debts</b>	<b>5,771</b>	<b>5,829</b>	<b>2,927</b>	<b>1,217</b>
Current portion of financial loans	4,600	4,611	2,256	343
<i>of which</i>				
-- Guaranteed <sup>(2)</sup>	772	1,279	451	-
-- Guaranteed and secured <sup>(3)</sup>	3,325	2,824	1,515	-
-- Unguaranteed/unsecured	501	508	291	343

<b>Statement of Financial Position</b>	<b>TiGenix</b>	<b>TiGenix</b>	<b>TiGenix</b>	<b>TiGenix</b>
<b>Thousands of euro</b>	<b>As at Sep 30, 2016</b>	<b>As at Dec 31, 2015</b>	<b>As at Dec 31, 2014</b>	<b>As at Dec 31, 2013</b>
Other financial liabilities.....	557	985	671	874
<i>of which</i>				
-- Secured <sup>(4)</sup>	-	-	-	874
-- Guaranteed and secured	557	985	671	-
Current deferred grants	616	233	-	-
-- Unguaranteed/Unsecured	616	233	-	-
<b>Total Financial Debt</b>	<b>37,568</b>	<b>45,913</b>	<b>13,579</b>	<b>9,480</b>
Gearing Ratio (Financial debt /Equity) <sup>(5)</sup>	141.78%	349.28% <sup>(7)</sup>	39.07%	19.66%
Cash & Cash Equivalents	43,038	17,982	13,471	15,565
Net current financial indebtedness <sup>(6)</sup>	37,267	12,153	10,544	14,348
Non-current financial indebtedness	(31,797)	(40,084)	(10,652)	(8,263)

Notes:

<sup>(1)</sup> *Accumulated deficit* and *Other reserves* in the September 30, 2016 column, represent figures as of June 30, 2016.

<sup>(2)</sup> Convertible bonds issued by TiGenix NV, guaranteed by TiGenix SAU; Soft loans entered into by TiGenix SAU with Madrid Network, guaranteed by TiGenix NV and by a bank guarantee; Soft loans entered into by Coretherapix with RETOS, guaranteed by a bank guarantee.

<sup>(3)</sup> Kreos loan (and related liabilities) entered into by TiGenix NV, guaranteed by TiGenix SAU and secured by pledges over TiGenix SAU shares, TiGenix NV and TiGenix SAU intellectual property, TiGenix NV and TiGenix SAU bank accounts and TiGenix NV other receivables.

<sup>(4)</sup> Other financial liabilities represented factoring debts at the level of TiGenix NV secured by the outstanding amount of factored receivables, as the bank reserved the right to request TiGenix NV to pay for the unsettled balance.

<sup>(5)</sup> Gearing Ratio: Total Financial Debt / Equity. The "Gearing Ratio" is a financial ratio that compares the Company's Total Financial Debt to its Equity. It demonstrates the degree to which the Company's activities are funded by shareholders' funds versus creditors' funds. The Gearing Ratio is therefore a measurement of the Company's financial leverage. It shows how exposed the company is to financial risk.

<sup>(6)</sup> Net current financial indebtedness: Cash and cash Equivalents – Current Debts.

<sup>(7)</sup> Note that on page 142 of the Registration Document reference is made to a Gearing Ratio of 320% as at December 31, 2015, which is incorrect and which should be read as a Gearing Ratio of 349.28%.

### 2.3. INTEREST OF NATURAL AND LEGAL PERSONS INVOLVED IN THE ISSUE

Merrill Lynch, Pierce, Fenner & Smith, Inc., Cowen and Company, LLC, Cannacord Genuity Inc. and BTIG, LLC (the "Underwriters") have agreed, subject to the terms of the underwriting agreement, to subscribe for the New Shares, and if applicable for the Over-Allotted Shares, on behalf of the final investors in the ADSs (representing the New Shares and the Over-Allotted Shares, if any).

Certain of the Underwriters and their affiliates may provide from time to time certain commercial banking, financial advisory, investment banking and other services for the Company and its affiliates in the ordinary course of their business, for which they may receive customary fees and commissions. In addition, from time to time, certain of the Underwriters and their affiliates may effect transactions for their own account or the account of customers, and hold on behalf of themselves or their customers, long or short positions in the Company's debt or equity securities or loans, and may do so in the future.

#### **2.4. REASON FOR THE CAPITAL INCREASE AND USE OF PROCEEDS**

The net proceeds to the Company resulting from the New Shares will be USD 31.55 million.

The Company intends to use the net proceeds resulting from the Transaction for the following purposes:

- With respect to Cx601 in the United States, to complete the process of technology transfer to Lonza, a U.S.-based contract manufacturing organization, to file an investigational new drug application to conduct a pivotal Phase III trial in the United States supporting a biologics license application with the FDA and to commence recruitment of patients for the Phase III trial (approximately USD 21.2 million). The pivotal Phase III trial in the United States is expected to start in the first half of 2017.
- To advance the Phase II clinical development of Cx611 in severe sepsis until well into the stage of recruitment (approximately USD 6.3 million). The initiation of a Phase I/II clinical trial in severe sepsis in Europe is expected in the fourth quarter of 2016.
- To advance the development of AlloCsC-01 in acute myocardial infarction until the end of Phase I/II clinical development (approximately USD 4.0 million). Final results of the ongoing Phase I/II trial are expected to be available during the first half of 2017.
- The remainder for general corporate purposes, including research and development and working capital requirements.

The foregoing represents the Company's current intentions with respect to the use and allocation of the net proceeds resulting from the issue of the New Shares based upon its present plans and business conditions, but the Company's management will have significant flexibility and discretion in applying the net proceeds. The occurrence of unforeseen events or changed business conditions could result in the application of the net proceeds in a manner other than as described above. Pending use of the net proceeds as described above, the Company intends to invest the net proceeds in short-term bank deposits or interest-bearing, investment-grade securities.

The Transaction and the listing of the ADSs on the NASDAQ Global Select Market will further diversify the Company's investor base and will offer certain institutional investors based in the U.S. the opportunity to invest indirectly in shares issued by the Company, which might otherwise not be permitted according to applicable rules. Moreover, the listing of the ADSs on the NASDAQ Global Select Market will offer the Company the benefit of a new venue for raising equity capital and will increase the Company's research coverage. All this is expected to enhance the liquidity of the Company's shares and the visibility and market profile of the Company among investors. The Company believes that these advantages would not be available to the same extent if the New Shares would be publicly offered in Belgium instead of in the US.



### 3. INFORMATION CONCERNING THE NEW SHARES TO BE ADMITTED TO TRADING

#### 3.1. AUTHORIZED CAPITAL

On September 8, 2014, the shareholders' meeting renewed the authorization of the Board of Directors to increase the Company's registered capital in one or more transactions with a maximum amount equal to the Company's registered capital, *i.e.* EUR 16,047,662.00.

If the capital is increased within the limits of the authorized capital, the Board of Directors will be authorized to request payment of an issuance premium. This issuance premium will be booked on a non-available account, which may only be decreased or disposed of by a resolution of a shareholders' meeting taken in accordance with the provisions governing an amendment of the Articles of Association.

This Board of Directors' authorization will be valid for capital increases subscribed for in cash or in kind, or made by capitalisation of reserves and issuance premiums, with or without issuing new shares, with or without voting rights. The Board of Directors is authorized to issue convertible bonds, subordinated or not subordinated, warrants, bonds to which warrants or other tangible values are connected or other securities within the limits of the authorized capital.

The Board of Directors is authorized, within the limits of the authorized capital, to restrict or exclude the preferential subscription rights granted by law to the holders of existing shares if in doing so it is acting in the interests of the Company and in accordance with Article 596 and following of the Belgian Companies Code (the "**Companies Code**"). The Board of Directors is authorized to limit or cancel the preferential subscription rights in favour of one or more persons, even if such limitation or cancellation is in favour of persons who are not members of the personnel of the Company or its subsidiaries.

The powers of the Board of Directors within the framework of the authorized capital are valid for a period of five years as of the publication thereof in the annexes to the Belgian Official Gazette, *i.e.* until October 8, 2019.

Since the authorization by the extraordinary shareholders' meeting on September 8, 2014, the Board of Directors has used the authorized capital for:

- a conditional capital increase of maximum EUR 3,319,612.20 conditional upon the conversion of the convertible bonds due 2018 issued on March 6, 2015;
- a capital increase of EUR 771,275.70 in relation to the acquisition of Coretherapix S.L. on July 31, 2015;
- a total capital increase of EUR 910,618 completed in two tranches on, respectively, November 27, 2015 and December 3, 2015 further to a private placement of 9,106,180 new shares announced on November 25, 2015;
- a conditional capital increase of maximum EUR 225,000 on December 7, 2015 in relation to the issue of 2,250,000 warrants to the benefit of the current and future employees of the Company and its subsidiaries, the current and future independent directors of the Company and the CEO of the Company; and
- a capital increase of EUR 2,500,000 completed on March 14, 2016 further to a private placement of 25,000,000 new shares announced on March 9, 2016.

Consequently, the available authorized capital now amounts to EUR 8,321,156.10 prior to the additional capital increase for the issuance of the New Shares.

### 3.2. THE TRANSACTION

On December 5, 2016 the Board of Directors conditionally increased the share capital of the Company in a maximum amount of EUR 8.3 million (excluding issuance premium), using the authorized capital, through the conditional issuance of maximum 83,000,000 new shares at a subscription price of no less than the accounting par value (*fractiewaarde*) (i.e. EUR 0.10) (the "**Capital Increase**"). The Capital Increase is subject to and to the extent of (i) subscription of the New Shares in the framework of the offering of such New Shares in the form of ADSs as further described below (the "**First Closing of the Capital Increase**") and (ii) the exercise of the over-allotment option of the Underwriters as further described below (the "**Second Closing of the Capital Increase**"), provided however that the number of new shares to be issued in the Second Closing of the Capital Increase shall not exceed 15% of the new shares issued in the First Closing of the Capital Increase.

The Board of Directors cancelled the preferential subscription rights of the existing shareholders of the Company in accordance with Article 596 *juncto* 603 of the Companies Code to allow the Company to offer the New Shares in the framework of the initial public offering of American Depository Shares (ADSs) representing the New Shares and, if applicable, the Over-Allotted Shares to retail and institutional investors in the United States and to other unspecified institutional and professional investors in or from any other country or jurisdiction where such offering is permitted in compliance with any applicable rules and regulations of any such country or jurisdiction. No percentage of the public offering of ADSs will be reserved for retail investors.

The Company appointed Merrill Lynch, Pierce, Fenner & Smith Incorp. and Cowen and Company, LLC as joint book-running managers, Canaccord Genuity Inc. as lead manager and BTIG, LLC as co-manager (collectively the "**Underwriters**") in relation to the Transaction. The ADSs representing the New Shares are placed with the final investors following a book-building carried out by the Underwriters. Investors have not been offered the possibility to subscribe for any New Shares directly. Each ADS represents 20 New Shares.

The Company filed with the U.S. Securities and Exchange Commission (the "**SEC**") a registration statement on Form F-1 under the U.S. Securities Act of 1933, as amended, including relevant exhibits and schedules, covering the underlying New Shares represented by the ADSs to be sold in the offering of ADSs. The registration statement has become effective on December 14, 2016.

The Company obtained the approval to list the ADSs on the NASDAQ Global Select Market subject to completion of customary procedures in the United States. On or about December 15, 2016 the ADSs will be traded on the NASDAQ Global Select Market under the symbol "TIG".

Pricing of the New Shares took place on December 14, 2016 and closing of the Transaction is expected to take place on December 20, 2016.

On or about December 20, 2016, the 46,000,000 New Shares and corresponding First Closing of the Capital Increase will be subscribed for by the Underwriters on behalf of the final investors. On or about December 20, 2016, the Company will directly or indirectly deliver the New Shares offered in the form of ADSs pursuant to the U.S. Offering to Deutsche Bank AG, Amsterdam Branch, who will act as custodian for Deutsche Bank Trust Company Americas and who will hold the New Shares underlying the ADSs for the account of the investors. Deutsche Bank Trust Company Americas will, as depositary, register and deliver the ADSs representing the New Shares to investors.

A holder of ADSs has the right to cancel the ADSs and to withdraw the underlying ordinary shares, subject to the payment to the depositary of the applicable fees (in principle USD 5 per 100 ADSs (or fraction thereof), as may be amended from time to time) and expenses or taxes incurred by the depositary as a result of the cancellation. The cancellation of ADSs and withdrawal of the underlying ordinary shares will in principle not have an effect on other shareholders trading their shares on Euronext Brussels. A holder of ADSs will not be treated as a shareholder of the Company and will not have shareholder rights. The rights and obligations of a holder of ADSs are provided for in the deposit agreement between the depositary, the Company and the holders of ADSs (as amended from time to

time). The terms and conditions of the ADSs are also endorsed on physical certificates (called American Depositary Receipts or ADRs) issued to investors should they elect to hold ADSs in certificated form.

In the framework of the Transaction, the Underwriters have been granted an option to subscribe for up to 6,900,000 additional new shares in the form of ADSs to cover over-allotments or short positions of ADSs, if any. This option may be exercised any time until January 13, 2017, including simultaneously with, the First Closing of the Capital Increase. If the over-allotment option is exercised, the Over-Allotted Shares and corresponding capital increase will be subscribed for by the Underwriters on behalf of the final investors and the Company will directly or indirectly deliver these Over-Allotted Shares subscribed for to cover over-allotments or short positions of ADSs to Deutsche Bank AG, Amsterdam Branch.

In the framework of the Transaction, the Company, the members of the Board of Directors, the members of the executive management, and certain of the Company's shareholders have agreed to certain restrictions on their ability to sell additional ADSs or ordinary shares for a period of 180 days as of December 14, 2016. They have agreed not to offer directly or indirectly for sale, sell, contract to sell, grant any option for the sale of, or otherwise issue or dispose of, any ADSs or ordinary shares, options or warrants to purchase ADSs or ordinary shares, or any related security or instrument, subject to customary exceptions, including the issuance of 10 million euros in ordinary shares to Takeda within one year of the effective date of the licensing agreement, without the prior written consent of the representatives of the Underwriters (being Merrill Lynch, Pierce, Fenner & Smith, Incorp. and Cowen and Company, LLC) during the afore-mentioned lock-up period.

### **3.3. ISSUE PRICE OF THE NEW SHARES**

The total issue price of the New Shares (accounting par value (*fractiewaarde*) plus issuance premium (*uitgiftepremie*)) at which the New Shares will be issued and subscribed for in the framework of the Transaction shall be the EUR equivalent of USD 0.775 per share, as will be evidenced by the certificate to be issued by the bank pursuant to Article 600 of the Companies Code in the framework of the First Closing of the Capital Increase or as otherwise determined by the Board of Directors at a date prior to the completion of the First Closing of the Capital Increase.

The issue price per Over-Allotted Share (if any) shall be the EUR equivalent of USD 0.775, as will be evidenced by the certificate to be issued by the bank pursuant to Article 600 of the Companies Code in the framework of the Second Closing of the Capital Increase or as otherwise determined by the Board of Directors at a date prior to the completion of the Second Closing of the Capital Increase.

The portion of the issue price per New Share and Over-Allotted Share (if any) up to the accounting par value of EUR 0.10 will be recorded on the "Capital" account. The balance will be recorded on the "Issuance Premium" account, which in the same manner as the Company's share capital serves as guarantee for third parties and which, save for the possibility of conversion into capital, can only be decided on in accordance with the conditions required for an amendment of the Articles of Association.

### **3.4. DESCRIPTION OF THE NEW SHARES**

The New Shares and the Over-Allotted Shares (if any) are being issued under Belgian law in the form of dematerialized shares without nominal value, having the same rights and advantages as the existing shares, it being understood, for the avoidance of doubt, that these New Shares and Over-Allotted Shares will participate in the results of the Company as of and for the entire financial year that started on January 1, 2016.

Where applicable, distributed dividends on the New Shares and the Over-Allotted Shares (if any) will be subject to a Belgian withholding tax at the applicable ordinary rate which currently amounts to 27% (this rate will increase to 30% as from January 1, 2017), save for any reduction or exemption. See section 3.8 for more information.

All of the Company's shares are fully paid up and freely transferable. Likewise, all of the New Shares and the Over-Allotted Shares (if any) will be fully paid up and freely transferable.

Every shareholder may request conversion of its shares, at its own cost, either into registered shares, or into dematerialised shares. Conversion of dematerialised shares into registered shares will be done by entering them in the related register of registered shares.

For a more detailed description of the rights attached to the shares of the Company, reference is made to section 3.5 below.

Holders of ADSs are not treated as shareholders of the Company, unless they withdraw the ordinary shares underlying the ADSs. A holder of ADSs will have the rights and obligations as set out in the deposit agreement between the Company, the depository and the holders of ADSs, pursuant to which a holder of ADSs shall benefit from the rights attached to the underlying ordinary shares represented by the ADSs through the depository. The terms and conditions of the ADSs are also endorsed on physical certificates, called American Depositary Receipts or ADRs, issued to investors should they elect to hold ADSs in certificated form. For more information on the ADSs, investors are advised to contact the depository, Deutsche Bank Trust Company Americas, with principal office at 60 Wall Street, New York, New York 10005, U.S.A.

### **3.5. RIGHTS ATTACHED TO THE SHARES OF THE COMPANY**

As described in section 3.4, holders of ADSs are not treated as shareholders of the Company, unless they withdraw the ordinary shares underlying the ADSs. The rights described below are only available to shareholders holding ordinary shares in the Company.

#### **3.5.1. Dividend rights**

All shares, including the New Shares and the Over-Allotted Shares (if any), participate in the same manner in the Company's profits (if any). Pursuant to the Companies Code, the shareholders can in principle decide on the distribution of profits with a simple majority vote at the occasion of the annual shareholders' meeting, based on the most recent statutory audited annual accounts, prepared in accordance with the generally accepted accounting principles in Belgium and based on a (non-binding) proposal of the Board of Directors. The Articles of Association also authorize the Board of Directors to declare interim dividends subject to the terms and conditions of the Companies Code.

Dividends can only be distributed if following the declaration and issuance of the dividends the amount of the Company's net assets on the date of the closing of the last financial year according to the statutory annual accounts (*i.e.*, the amount of the assets as shown in the balance sheet, decreased with provisions and liabilities, all as prepared in accordance with Belgian accounting rules), decreased with the non-amortised costs of incorporation and expansion and the non-amortised costs for research and development, does not fall below the amount of the paid-up capital (or, if higher, the called capital), increased with the amount of non-distributable reserves. In addition, prior to distributing dividends, 5% of the net profits must be allotted to a legal reserve, until the legal reserve amounts to 10% of the share capital.

The right to payment of dividends expires five years after the Board of Directors declared the dividend payable.

#### **3.5.2. Voting rights**

Each shareholder is entitled to one vote per share.

Voting rights can be suspended in relation to shares:

- which were not fully paid up, notwithstanding the request thereto of the Board of Directors of the Company;
- to which more than one person is entitled, except in the event a single representative is appointed for the exercise of the voting right;
- which entitle their holder to voting rights above the threshold of 3%, 5%, or any multiple of 5% of the total number of voting rights attached to the outstanding financial instruments of the Company on the date of the relevant general shareholders' meeting, except to the extent where the relevant shareholder has notified the Company and the FSMA at least 20 days prior to the date of the general shareholders' meeting on which he or she wishes to vote of its shareholding reaching or exceeding the thresholds above; and
- of which the voting right was suspended by a competent court or the FSMA.

Generally, the shareholders' meeting has sole authority with respect to:

- the approval of the annual accounts of the Company;
- the appointment and resignation of directors and the statutory auditor of the Company;
- the granting of discharge of liability to the directors and the statutory auditor;
- the determination of the remuneration of the directors and of the statutory auditor for the exercise of their mandate;
- the distribution of profits (it being understood that the Articles of Association authorize the Board of Directors to distribute interim dividends);
- the filing of a claim for liability against directors;
- the decisions relating to the dissolution, merger and certain other re-organisations of the Company; and
- the approval of amendments to the Articles of Association.

### **3.5.3. Right to attend and vote at shareholders' meetings**

#### ***Annual shareholders' meeting***

The annual shareholders' meeting is held at the registered office of the Company or at the place determined in the notice convening the shareholders' meeting. The meeting is held every year on the first Thursday of June at 14:00 pm CET. If this date is a legal holiday, the meeting is held at the next business day. At the annual shareholders' meeting, the Board of Directors submits the audited statutory and consolidated financial statements and the reports of the Board of Directors and of the statutory auditor with respect thereto to the shareholders. The shareholders' meeting then decides on the approval of the statutory financial statements, the remuneration report, the proposed allocation of the Company's profit or loss, the discharge from liability of the directors and the statutory auditor, and, when applicable, the (re-)appointment or resignation of the statutory auditor and/or of all or certain directors.

#### ***Special and extraordinary shareholders' meetings***

The Board of Directors or the statutory auditor can, at any given time when the interest of the Company so requires, convene a special or extraordinary shareholders' meeting. Such shareholders' meeting must also be convened every time one or more shareholders holding at least 20% of the Company's share capital so demand. This request is sent by registered letter to the registered office of the Company to the attention of the Board of Directors; it has to mention the agenda items and proposed decisions, which the shareholders' meeting should deliberate and decide upon, as well as an elaborate justification for the

request. Shareholders who, individually or jointly, do not hold at least 20% of the Company's share capital do not have the right to have the shareholders' meeting convened.

### ***Notices convening the shareholders' meeting***

The notice of the shareholders' meeting must state, among others, the place, date and hour of the meeting and shall include an agenda indicating the items to be discussed as well as any motions for resolutions.

The notice must be published in the Belgian Official Gazette (*Belgisch Staatsblad / Moniteur belge*) at least 30 days prior to the shareholders' meeting. In the event a second convening notice is necessary and the date of the second meeting is mentioned in the first convening notice, that period is 17 days prior to the shareholders' meeting. The notice must also be published in a national newspaper 30 days prior to the date of the shareholders' meeting, except if the meeting concerned is an annual shareholders' meeting held at the municipality, place, day and hour mentioned in the Articles of Association and whose agenda is limited to the examination of the annual accounts, the annual report of the Board of Directors, the annual report of the statutory auditor, the vote on the discharge of the directors and the statutory auditor, and the vote on the items referred to in Article 554, par. 3 and 4 of the Companies Code (*i.e.* in relation to a remuneration report or a severance pay). Finally, the notice must also be published in media expected to have a wide diffusion. The annual accounts, the annual report of the Board of Directors and the annual report of the statutory auditor must be made available to the public as from the date on which the convening notice for the annual shareholders' meeting is published.

Convening notices must be sent 30 days prior to the shareholders' meeting to the holders of registered shares, holders of registered bonds, holders of registered warrants, holders of registered certificates issued with the cooperation of the Company and to the directors and statutory auditor of the Company. This communication is made by ordinary letter unless the addressees have individually and expressly accepted in writing to receive the notice by another form of communication, without having to give evidence of the fulfilment of such formality.

### ***Formalities to attend the shareholders' meeting***

The formalities to attend the shareholders' meeting are the following:

- A shareholder is only entitled to participate in and vote at the shareholders' meeting, irrespective of the number of shares he owns on the date of the shareholders' meeting, provided that his shares are recorded in his name at midnight (24:00 CET) of the fourteenth (14<sup>th</sup>) day preceding the date of the shareholders' meeting (the "**Record date**"):
  - in case of registered shares, in the register of registered shares of the Company; or
  - in case of dematerialised shares, through book-entry in the accounts of an authorized account holder or clearing organisation.
- In addition, the Company (or the person designated by the Company) must, at the latest on the sixth (6<sup>th</sup>) day preceding the day of the shareholders' meeting, be notified as follows of the intention of the shareholder to participate in the shareholders' meeting:
  - in case of registered shares, the shareholder must, at the latest on the above-mentioned date, notify the Company (or the person designated by the Company) in writing of his intention to participate in the shareholders' meeting and of the number of shares he intends to participate in the shareholders' meeting with by returning a signed paper form, or, if permitted by the convening notice, by sending an electronic form (signed by means of an electronic signature in accordance with the applicable Belgian law) electronically, to the Company on the address indicated in the convening notice; or
  - in case of dematerialised shares or bonds, the shareholder or bondholder must, at the latest on the above-mentioned date, provide the Company (or the person designated by the

Company), or arrange for the Company (or the person designated by the Company) to be provided with, a certificate issued by the authorized account holder or clearing organisation certifying the number of dematerialised shares or bonds recorded in the shareholder's or bondholder's accounts on the Record date in respect of which the shareholder or bondholder has indicated his intention to participate in the shareholders' meeting.

Owners of profit certificates, shares without voting rights, bond holders, warrant holders or holders of other securities issued by the Company, as well as the holders of certificates issued with the cooperation of the Company, can attend the shareholders' meeting, in the instances in which the law grants them this right. In this case, they will have to comply with the same formalities as the shareholders.

### ***Proxy***

Each shareholder has the right to attend a shareholders' meeting and to vote at the shareholders' meeting in person or through a proxy holder. The proxy holder does not need to be a shareholder.

A shareholder may only appoint one person as proxy holder for a particular shareholders' meeting, except in cases provided for in the law.

The Board of Directors may determine the form of the proxies. The appointment of a proxy holder must in any event take place in paper form or electronically, the proxy must be signed by the shareholder (as the case may be, by means of an electronic signature in accordance with the applicable Belgian law) and the Company must receive the proxy at the latest on the sixth (6th) day preceding the day on which the shareholders' meeting is held.

Pursuant to Article 7, §5 of the Belgian Law of May 2, 2007 on the disclosure of major shareholdings, a transparency declaration has to be made if a proxy holder, which is entitled to voting rights above the threshold of 3%, 5%, or any multiple of 5% of the total number of voting rights attached to the outstanding financial instruments of the Company on the date of the relevant shareholders' meeting, would have the right to exercise the voting rights at his discretion.

### ***Right to request items to be added to the agenda and ask questions at the shareholders' meeting***

One or more shareholders holding at least 3% of the capital of the Company may request for items to be added to the agenda of any convened meeting and submit proposed resolutions in relation to existing agenda items or new items to be added to the agenda, provided that (i) they prove ownership of such shareholding as at the date of their request and record their shares representing such shareholding on the Record date and (ii) the additional items on the agenda and/or proposed resolutions have been submitted in writing by these shareholders to the Board of Directors at the latest on the twenty second (22<sup>nd</sup>) day preceding the day on which the relevant shareholders' meeting is held. The shareholding must be proven by a certificate evidencing the registration of the relevant shares in the share register of the Company or by a certificate issued by the authorized account holder or the clearing organisation certifying the book-entry of the relevant number of dematerialised shares in the name of the relevant shareholder(s). As the case may be, the Company shall publish the modified agenda of the shareholders' meeting, at the latest on the fifteenth (15<sup>th</sup>) day preceding the day on which the shareholders' meeting is held. The right to request that items be added to the agenda or that proposed resolutions in relation to existing agenda items be submitted does not apply in case of a second extraordinary shareholders' meeting that must be convened because the quorum was not obtained during the first extraordinary shareholders' meeting.

Within the limits of Article 540 of the Companies Code, the directors and auditors answer, during the shareholders' meeting, the questions raised by shareholders. Shareholders can ask questions either during the meeting or in writing provided that the Company receives the written question at the latest on the sixth (6<sup>th</sup>) day preceding the day on which the shareholders' meeting is held.

### ***Quorum and majorities***

In general, there is no quorum requirement for a shareholders' meeting and decisions are generally passed with a simple majority of the votes of the shares present and represented. Capital increases not decided by the Board of Directors within the framework of the authorized capital, decisions with respect to the Company's dissolution, mergers, de-mergers and certain other reorganisations of the Company, amendments to the Articles of Association (other than an amendment of the corporate purpose), and certain other matters referred to in the Companies Code do not only require the presence or representation of at least 50% of the share capital of the Company but also the approval of at least 75% of the votes cast. An amendment of the Company's corporate purpose, requires the approval of at least 80% of the votes cast at a shareholders' meeting, which in principle can only validly pass such resolution if at least 50% of the share capital of the Company and at least 50% of the profit certificates, if any, are present or represented. In the event where the required quorum is not present or represented at the first meeting, a second meeting needs to be convened through a new notice. The second shareholders' meeting can validly deliberate and decide regardless of the number of shares and profit certificates present or represented.

#### **3.5.4. Preferential subscription right**

In the event of a capital increase in cash with issuance of new shares, or in the event of an issuance of convertible bonds or warrants, the existing shareholders have a preferential right to subscribe for the new shares, convertible bonds or warrants, pro rata of the part of the share capital represented by the shares that they already have. The shareholders' meeting can decide to limit or cancel this preferential subscription right, subject to special reporting requirements. Such decision needs to satisfy the same quorum and majority requirements as the decision to increase the Company's share capital. The above-mentioned preferential right of the shareholders to subscribe for new shares, convertible bonds or warrants has been cancelled or waived in previous transactions.

The shareholders can also decide to authorize the Board of Directors of the Company to limit or cancel the preferential subscription right within the framework of the authorized capital, subject to the terms and conditions set forth in the Companies Code. The extraordinary shareholders' meeting of September 8, 2014 granted this authorization to the Board of Directors.

Normally, the authorization of the Board of Directors of the Company to increase the share capital of the Company through contributions in cash with cancellation or limitation of the preferential right of the existing shareholders is suspended as of the notification to the Company by the FSMA of a public takeover bid on the financial instruments of the Company. The shareholders' meeting can, however, authorize the Board of Directors to increase the share capital by issuing shares in an amount of not more than 10% of the existing shares at the time of such a public takeover bid. Such authorization has not been granted to the Board of Directors of the Company.

#### **3.5.5. Rights regarding dissolution and liquidation**

The Company can only be dissolved by a shareholders' resolution passed with a majority of at least 75% of the votes cast at an extraordinary shareholders' meeting where at least 50% of the share capital is present or represented. In the event the required quorum is not present or represented at the first meeting, a second meeting needs to be convened through a new notice. The second shareholders' meeting can validly deliberate and decide regardless of the number of shares present or represented.

If as a result of losses incurred the ratio of the Company's statutory net-assets (determined in accordance with Belgian legal and accounting rules) to share capital is less than 50%, the Board of Directors must convene a special shareholders' meeting within two months as of the date the Board of Directors discovered or should have discovered this undercapitalisation. At this shareholders' meeting the Board of Directors needs to propose either the dissolution of the Company or the continuation of the Company, in which case the Board of Directors must propose measures to redress the Company's financial situation. Shareholders representing at least 75% of the votes validly cast at this meeting have the right to dissolve



the Company, provided that at least 50% of the Company's share capital is present or represented at the meeting. In the event the required quorum is not present or represented at the first meeting, a second meeting needs to be convened through a new notice. The second shareholders' meeting can validly deliberate and decide regardless of the number of shares present or represented. If as a result of losses incurred the ratio of the Company's net assets to share capital is less than 25%, the same procedure must be followed, it being understood, however, that the dissolution only requires the approval of shareholders representing 25% of the votes cast at the meeting. If the amount of the Company's net assets has dropped below EUR 61,500 (the minimum amount of share capital of a public limited liability company), each interested party is entitled to request the competent court to dissolve the Company. The court can order the dissolution of the Company or grant a grace period within which the Company is to remedy the situation.

If the Company is dissolved for any reason, the liquidation must be carried out by one or more liquidators appointed by the shareholders' meeting and whose appointment has been ratified by the commercial court. In the event the Company is dissolved, the assets or the proceeds of the sale of the remaining assets, after payment of all debts, costs of liquidation and taxes, must be distributed on an equal basis to the shareholders, taking into account possible preferential rights with regard to the liquidation of the Company's shares having such rights, if any. Currently, there are no preferential rights with regard to the liquidation.

### **3.5.6. Redemption and sale of the Company's shares**

In accordance with the Articles of Association and the Companies Code, the Company can only purchase and sell its own shares by virtue of a special shareholders' resolution approved by at least 80% of the votes validly cast at a general shareholders' meeting where at least 50% of the share capital and at least 50% of the profit certificates, if any, are present or represented. In the event the required quorum is not present or represented at the first meeting, a second meeting needs to be convened through a new notice. The second shareholders' meeting can validly deliberate and decide regardless of the number of shares and profit certificates present or represented. The prior approval by the shareholders is not required if the Company purchases the Company's shares to offer them to the Company's personnel.

In accordance with the Companies Code, an offer to purchase the Company's shares must be made to all shareholders under the same conditions. This does not apply to the acquisition of shares via a regulated market or the acquisition of shares that has been unanimously decided by the shareholders at a meeting where all shareholders were present or represented. The Company's shares can only be acquired with funds that would otherwise be available for distribution as a dividend to the shareholders. The total amount of the Company's shares held by the Company can at no time be more than 20% of its share capital. At the date of this Securities Transaction Note, the Board of Directors of the Company does not have any authorization from the shareholders' meeting to redeem shares.

## **3.6. BELGIAN REGULATIONS ON TAKEOVER BIDS, SQUEEZE-OUT AND SELL-OUT RULES**

### **3.6.1. Public takeover bids**

Public takeover bids on the Company's shares and other securities giving access to voting rights (such as warrants or convertible bonds, if any) are subject to the supervision by the FSMA. Public takeover bids must be made for all of the Company's voting securities, as well as for all other securities giving access to voting rights. Prior to making a bid, a bidder must publish a prospectus, which has been approved by the FSMA prior to publication. The bidder must also obtain approval of the relevant competition authorities, where such approval is legally required for the acquisition of the Company.

Belgium has implemented the Thirteenth Company Law Directive (European Directive 2004/25/EC of April 21, 2004) in the Belgian Law on public takeover bids of April 1, 2007 (the "**Takeover Law**") and the Belgian Royal Decree of April 27, 2007 on public takeover bids (the "**Takeover Royal Decree**"). The Takeover Law provides that a mandatory bid will be triggered if a person, as a result of its own acquisition

or the acquisition by persons acting in concert with it or by persons acting on their account, directly or indirectly holds more than 30 per cent of the voting securities in a company that has its registered office in Belgium and of which at least part of the voting securities are traded on a regulated market or on a multilateral trading facility designated by the Takeover Royal Decree. The mere fact of exceeding the relevant threshold through the acquisition of one or more shares of the Company will give rise to a mandatory bid, irrespective of whether or not the price paid in the relevant transaction exceeds the current market price.

There are several provisions of Belgian company law and certain other provisions of Belgian law, such as the obligation to disclose important shareholdings and merger control, that may apply to TiGenix and which may make an unfriendly tender offer, merger, change in management or other change in control, more difficult.

Normally, the authorization of the Board of Directors to increase the share capital of the Company through contributions in kind or in cash with cancellation or limitation of the preferential subscription right of the existing shareholders is suspended as of the notification to the Company by the FSMA of a public takeover bid on the securities of the Company. The general shareholders' meeting can, however, authorize the Board of Directors to increase the share capital by issuing shares in an amount of not more than 10% of the existing shares of the Company at the time of such a public takeover bid. Such authorization has not been granted to the Board of Directors of the Company.

### **3.6.2. Squeeze-out**

Pursuant to Article 513 of the Companies Code, or the regulations promulgated thereunder, a person, acting alone or in concert, who owns 95% of the securities conferring voting power in a company that makes or has made a public call on funds from the public (*vennootschap die een openbaar beroep op het spaarwezen doet of heeft gedaan*), can acquire the totality of the securities conferring voting rights in that company following a squeeze-out offer. The shares that are not voluntarily tendered in response to such offer are deemed to be automatically transferred to the bidder at the end of the procedure. At the end of the offer, the company is no longer deemed a company that makes or has made a public call on funds from the public (*vennootschap die een openbaar beroep op het spaarwezen doet of heeft gedaan*), unless bonds issued by the company are still spread among the public. The consideration for the securities must be in cash and must represent the fair value as to safeguard the interests of the transferring shareholders.

### **3.6.3. Sell-out right**

Holders of voting securities or of securities giving access to voting rights may require the offeror, acting alone or in concert, who owns 95% of the voting capital and 95% of the voting securities in a company that makes or has made a public call on funds from the public (*vennootschap die een openbaar beroep op het spaarwezen doet of heeft gedaan*) following a takeover bid to buy its securities from it at the price of the bid, on the condition that the offeror has acquired, through the acceptance of the bid, securities representing at least 90% of the voting capital subject to the takeover bid.

## **3.7. TAKEOVER BIDS INSTIGATED BY THIRD PARTIES DURING THE PREVIOUS FINANCIAL YEAR AND THE CURRENT FINANCIAL YEAR**

No takeover bid has been instigated by third parties in respect of TiGenix's equity during the previous financial year and the current financial year.

### **3.8. TAXATION IN BELGIUM**

The paragraphs below present a summary of certain material Belgian income tax consequences of the ownership and disposal of shares in the Company (including the New Shares). The summary is based on laws, treaties and regulatory interpretations in effect in Belgium on the date of this Securities Transaction Note, all of which are subject to change, including changes that could have retroactive effect. This summary does not purport to address all tax consequences of the ownership and disposal of the Company's shares, and does not take into account the specific circumstances of particular investors, some of which may be subject to special rules, or the tax laws of any country other than Belgium. This summary does not describe the tax treatment of investors that are subject to special rules, such as banks, insurance companies, collective investment undertakings, dealers in securities or currencies, persons that hold, or will hold, the Company's shares as a position in a straddle, share-repurchase transaction, conversion transactions, synthetic security or other integrated financial transactions.

For purposes of this summary, a Belgian resident is an individual subject to Belgian personal income tax (that is, an individual who is domiciled in Belgium or has his seat of wealth in Belgium or a person assimilated to a resident for purposes of Belgian tax law), a company subject to Belgian corporate income tax (that is, a corporate entity that has its statutory seat, its main establishment, its administrative seat or seat of management in Belgium), an Organization for Financing Pensions subject to Belgian corporate income tax (*i.e.*, a Belgian pension fund incorporated under the form of an Organization for Financing Pensions), or a legal entity subject to Belgian income tax on legal entities (that is, a legal entity other than a company subject to Belgian corporate income tax, that has its statutory seat, its main establishment, its administrative seat or seat of management in Belgium). A Belgian non-resident is any person that is not a Belgian resident.

Please note that on October 16, 2016, the Belgian government announced a reform of the corporate income tax without having disclosed the clear guidelines of such reform which is still subject to discussions within the government. This reform was initially scheduled as from 2017. Due to disagreements within the Belgian government concerning the scope and the content of this reform, we have understood that it was postponed to a later point in the future. This reform will result in changes mainly for Belgian resident companies and Belgian permanent establishments of non-Belgian companies. Further details will be available in the months to come. TiGenix outlines here the tax treatment resulting from the current applicable provisions and the officially announced modifications.

Investors should consult their own advisors regarding the tax consequences of an investment in the Company's shares in the light of their particular circumstances, including the effect of any state, local or other national laws.

#### **3.8.1. Dividends**

For Belgian income tax purposes, the gross amount of all benefits paid on or attributed to the Company's shares is generally treated as a dividend distribution. By way of exception, the repayment of capital carried out in accordance with the Belgian Companies Code is not treated as a dividend distribution to the extent that such repayment is imputed to fiscal capital. In principle, fiscal capital includes the paid-up statutory share capital, and, subject to certain conditions, paid-up share premiums and the amounts subscribed to at the time of the issue of profit-sharing certificates, if treated in the same way as share capital according to the Company's Articles of Association.

A Belgian withholding tax of 27% (this rate will increase to 30% as from January 1, 2017, based on a draft of bill dated December 5, 2016) is normally levied on dividends, subject to such relief as may be available under applicable domestic or tax treaty provisions. In case of a redemption of the Company's shares, the redemption distribution (after deduction of the part of the fiscal capital represented by the redeemed Company's shares) will be treated as a dividend subject to a Belgian withholding tax (current rate of 27%) (this rate will increase to 30% as from January 1, 2017, based on a draft of bill dated December 5, 2016), subject to such relief as may be available under applicable domestic or tax treaty provisions. No

withholding tax will be triggered if this redemption is carried out on a stock exchange and meets certain conditions.

In case of liquidation of the Company, any amounts distributed in excess of the fiscal capital will in principle be subject to a 27% withholding tax (this rate will increase to 30% as from January 1, 2017, based on a draft of bill dated December 5, 2016), subject to such relief as may be available under applicable domestic provisions.

**(i) Belgian resident individuals**

For Belgian resident individuals who acquire and hold the Company's shares as a private investment, the Belgian dividend withholding tax fully discharges their personal income tax liability. They may nevertheless elect to report the dividends in their personal income tax return. Where the beneficiary opts to report them, dividends will normally be taxable at the lower of the generally applicable 27% withholding tax rate (this rate will increase to 30% as from January 1, 2017, based on a draft of bill dated December 5, 2016) on dividends or at the progressive personal income tax rates applicable to the taxpayer's overall declared income. If the beneficiary reports the dividends, the income tax due on such dividends will not be increased by local surcharges. In addition, if the dividends are reported, the dividend withholding tax levied at source may, in both cases, be credited against the personal income tax due and is reimbursable to the extent that it exceeds the personal income tax due, provided that the dividend distribution does not result in a reduction in value of or a capital loss on the Company's shares. This condition is not applicable if the individual can demonstrate that he has held the Company's shares in full legal ownership for an uninterrupted period of 12 months prior to the payment or attribution of the dividends.

For Belgian resident individuals who acquire and hold the Company's shares for professional purposes, the Belgian withholding tax does not fully discharge their income tax liability. Dividends received must be reported by the investor and will, in such a case, be taxable at the investor's ordinary progressive personal income tax rates (up to 50%, increased with local surcharges). Withholding tax levied at source may be credited against the personal income tax due and is reimbursable to the extent that it exceeds the income tax due, subject to two conditions: (i) the taxpayer must own the Company's shares in full legal ownership at the time the dividends are paid or attributed and (ii) the dividend distribution may not result in a reduction in value of or a capital loss on the Company's shares. The latter condition is not applicable if the investor can demonstrate that he has held the full legal ownership of the Company's shares for an uninterrupted period of 12 months prior to the payment or attribution of the dividends.

**(ii) Belgian resident companies**

For Belgian resident companies subject to corporate income tax, the gross dividend income (including the withholding tax) must be declared in the corporate income tax return and will be subject to a corporate income tax rate of 33.99%. In certain circumstances, reduced corporate income tax rates may apply.

Belgian resident companies can generally (although subject to certain limitations) deduct 95% of the gross dividend received from the taxable income ("**dividend received deduction**"), provided that at the time of a dividend payment or attribution: (i) the Belgian resident company holds the Company's shares representing at least 10% of the share capital of the Company or a participation in the Company with an acquisition value of at least EUR 2,500,000; (ii) the Company's shares have been held or will be held in full ownership for an uninterrupted period of at least one year; and (iii) the conditions relating to the taxation of the underlying distributed income, as described in Article 203 of the Belgian Income Tax Code (the "**Article 203 ITC Taxation Condition**") are met (together, the "**Conditions for the application of the dividend received deduction regime**"). This article 203 of the Belgian Income Tax Code is modified by the Act of December 1, 2016 in order to implement the anti-abuse provision of the Parent-Subsidiary Directive and to prevent double non-taxation situations, applicable as of January 1, 2017.

The Conditions for the application of the dividend received deduction regime depend on a factual analysis and for this reason the availability of this regime should be verified upon each dividend distribution.

Any Belgian dividend withholding tax levied at source may be credited against the corporate income tax due and is reimbursable (except for investment companies) to the extent that it exceeds the corporate income tax due, subject to two conditions: (i) the taxpayer must own the Company's shares in full legal ownership at the time the dividends are paid or attributed and (ii) the dividend distribution may not result in a reduction in value of or a capital loss on the Company's shares. The latter condition is not applicable: (i) if the company can demonstrate that it has held the Company's shares in full legal ownership for an uninterrupted period of 12 months prior to the payment of or attribution on the dividends or (ii) if, during that period, the Company's shares never belonged to a taxpayer other than a resident company or a non-resident company which has, in an uninterrupted manner, invested the Company's shares in a Belgian permanent establishment ("PE") in Belgium.

Dividends distributed to a Belgian resident company will be exempt from Belgian withholding tax provided that the Belgian resident company holds, upon payment or attribution of the dividends, at least 10% of the Company's share capital and such minimum participation is held or will be held during an uninterrupted period of at least one year. Article 266 of the Belgian Income Tax Code is modified by the Act of December 1, 2016 in order to implement the anti-abuse provision of the Parent-Subsidiary Directive and to prevent double non-taxation situations, applicable as of January 1, 2017.

In order to benefit from this exemption, the investor must provide the Company or its paying agent with a certificate confirming its qualifying status and the fact that it meets the two required conditions. If the investor holds a minimum participation for less than one year, at the time the dividends are paid on or attributed to the Company's shares, the Company will temporarily levy the withholding tax but will not transfer it to the Belgian Treasury provided that the investor certifies its qualifying status, the date from which the investor has held such minimum participation, and the investor's commitment to hold the minimum participation for an uninterrupted period of at least one year. The investor must also inform the Company or its paying agent if the one-year period has expired or if its shareholding will drop below 10% of the Company's share capital before the end of the one-year holding period. Upon satisfying the one-year shareholding requirement, the temporarily levied dividend withholding tax will be refunded to the investor.

### **(iii) Belgian non-resident individuals and companies**

For non-resident individuals and companies, the dividend withholding tax will be the only tax on dividends in Belgium, unless the non-resident holds the Company's shares in connection with a business conducted in Belgium through a fixed base in Belgium or a PE in.

If the Company's shares are acquired by a non-resident in connection with a business conducted in Belgium, the investor must report any dividends received, which will be taxable at the applicable non-resident individual or corporate income tax rate, as appropriate. Belgian withholding tax levied at source may then in principle be credited against non-resident individual or corporate income tax and is reimbursable to the extent that it exceeds the income tax due, subject to two conditions: (i) the taxpayer must own the Company's shares in full legal ownership at the time the dividends are paid or attributed and (ii) the dividend distribution may not result in a reduction in value of or a capital loss on the Company's shares. The latter condition is not applicable if (i) the non-resident individual or the non-resident company can demonstrate that the Company's shares were held in full legal ownership for an uninterrupted period of 12 months prior to the payment or attribution of the dividends or (ii) with regard to non-resident companies only, if, during the said period, the Company's shares have not belonged to a taxpayer other than a resident company or a non-resident company which has, in an uninterrupted manner, invested the Company's shares in a Belgian PE.

Non-resident companies whose Company's shares are invested in a Belgian PE may deduct 95% of the gross dividends included in their taxable profits if, at the date dividends are paid or attributed, the Conditions for the application of the dividend received deduction regime (see above) are met. Application of the dividend received deduction regime depends, however, on a factual analysis to be made upon each distribution and its availability should be verified upon each distribution.

Under Belgian tax law, withholding tax is not due on dividends paid to a foreign pension fund which satisfies the following conditions: (i) to be a legal entity with fiscal residence outside of Belgium and without PE in Belgium; (ii) whose corporate purpose consists solely in managing and investing funds collected in order to pay legal or complementary pensions; (iii) whose activity is limited to the investment of funds collected in the exercise of its statutory mission, without any profit making aim; (iv) which is exempt from income tax in its country of residence; and (v) provided, save in certain particular cases as described in Belgian law, that it is not contractually obligated to redistribute the dividends to any ultimate beneficiary of such dividends for whom it would manage the Company's shares, nor obligated to pay a manufactured dividend with respect to the Company's shares under a securities borrowing transaction. The exemption will only apply if the foreign pension fund provides a certificate confirming that it is the full legal owner or *usufruct* holder of the Company's shares and that the above conditions are satisfied. The organization must then forward that certificate to the Company or its paying agent.

Dividends distributed to non-resident companies established in a Member State of the EU or in a country with which Belgium has concluded a double tax treaty that includes a qualifying exchange of information clause and qualifying as a parent company, will be exempt from Belgian withholding tax provided that the Company's shares held by the non-resident company, upon payment or attribution of the dividends, amount to at least 10% of the Company's share capital and such minimum participation is held or will be held during an uninterrupted period of at least one year (the "**parent-subsidiary exemption**"). A company qualifies as a parent company provided that (i) for companies established in a Member State of the EU, it has a legal form as listed in the annex to the EU Parent-Subsidiary Directive of July 23, 1990 (90/435/EC), as amended from time to time, or, for companies established in a country with which Belgium has concluded a qualifying double tax treaty it has a legal form similar to the ones listed in such annex; (ii) it is considered to be a tax resident according to the tax laws of the country where it is established and the double tax treaties concluded between such country and third countries; and (iii) it is subject to corporate income tax or a similar tax without benefiting from a tax regime that derogates from the ordinary tax regime. A reduced Belgian withholding tax of 1.6995% on dividends applies in case the non-resident company, established in the European Economic Area or in a country with which Belgium has concluded a double tax treaty that includes a qualifying exchange of information clause, does not satisfy the 10%-participation threshold but has a participation with an acquisition value of at least EUR 2,500,000 in the relevant company.

In order to benefit from the parent-subsidiary exemption, the investor must provide the Company or its paying agent with a certificate confirming its qualifying status and the fact that it meets the three abovementioned conditions. If the investor holds a minimum participation for less than one year, at the time the dividends are paid on or attributed to the Company's shares, the Company will temporarily levy the withholding tax but will not transfer it to the Belgian Treasury provided that the investor certifies its qualifying status, the date from which the investor has held such minimum participation, and the investor's commitment to hold the minimum participation for an uninterrupted period of at least one year. The investor must also inform the Company or its paying agent if the one-year period has expired or if its shareholding will drop below 10% of the Company's share capital before the end of the one-year holding period. Upon satisfying the one-year shareholding requirement, the temporarily levied dividend withholding tax will be refunded to the investor. In case the investor is a non-resident company established in the European Economic Area or in a country with which Belgium has concluded a double tax treaty that includes a qualifying exchange of information clause, and does not satisfy the 10%-participation threshold but has a participation with an acquisition value of at least EUR 2,500,000 in the Company, the investor must provide the Company or its paying agent with a certificate confirming

its qualifying status, the fact that the acquisition value is at least EUR 2,500,000, the fact that the dividends resulting from the Company's shares are held or will be held during an uninterrupted period of at least one year, and to what extent a tax credit can be obtained by the investor against the Belgian withheld tax.

Belgium has concluded tax treaties with over 93 countries, reducing the dividend withholding tax rate to 20%, 15%, 10%, 5% or 0% for residents of those countries, depending on conditions, among others, related to the size of the shareholding and certain identification formalities.

Prospective holders should consult their own tax advisors as to whether they qualify for reduction in withholding tax upon payment or attribution of dividends, and as to the procedural requirements for obtaining a reduced withholding tax upon the payment of dividends or for making claims for reimbursement.

#### **(iv) Organizations for financing pensions**

For organizations for financing pensions (“**OFPs**”), *i.e.*, Belgian pension funds incorporated under the form of an OFP (*organismes de financement de pensions/organismen voor de financiering van pensioenen*) within the meaning of Article 8 of the Belgian Law of October 27, 2006, the dividend income is generally tax-exempt. Subject to certain limitations, any Belgian dividend withholding tax levied at source may be credited against the corporate income tax due and is reimbursable to the extent that it exceeds the corporate income tax due.

#### **(v) Legal entities**

For taxpayers subject to the Belgium income tax on legal entities, the Belgian dividend withholding tax in principle fully discharges their income tax liability.

### **3.8.2. Capital gains and losses on the Company's shares**

#### **(i) Belgian resident individuals**

In principle, Belgian resident individuals acquiring and holding the Company's shares as a private investment should not be subject to Belgian capital gains tax on the disposal of the Company's shares. The application of a tax of 33% (plus local surcharges) is levied on the gains realized by individuals upon the sale of the Company's shares acquired as of January 1, 2016, provided that such gains are realized within 6 months following the acquisition of the shares. In the case of successive share acquisitions, a last in first out (LIFO) principle is applied in order to determine the shares that are sold and the amount of the capital gains. If the capital gains are realised through a Belgian financial intermediary, a new Belgian capital gain withholding tax applies and fully discharges the individual of reporting the realised capital gain in the annual income tax return. Capital losses are (and remain) not tax deductible, even if realised within 6 months. This "speculation tax" will however be abolished as from January 1, 2017 (based on a draft of bill dated December 5, 2016).

Capital gains realized by a private individual are taxable at 33% (plus local surcharges) if the capital gain is deemed to be realized outside the scope of the normal management of the individual's private estate. Moreover, capital gains realised by Belgian resident individuals on the disposal of the Company's shares for consideration, outside the exercise of a professional activity, to a non-resident company (or a body constituted in a similar legal form), to a foreign State (or one of its political subdivisions or local authorities) or to a non-resident legal entity, are in principle taxable at a rate of 16.5% (plus local surcharges) if, at any time during the five years preceding the sale, the Belgian resident individual has owned directly or indirectly, alone or with his/her spouse or with certain relatives, a substantial shareholding in the Company (*i.e.*, a shareholding of more than 25% in the Company). This capital gains tax does not apply if the Shares are transferred to the above mentioned persons provided that they are established in the European Economic Area (**EEA**). Capital losses are, however, not tax deductible.

Belgian resident individuals who hold the Company's shares for professional purposes are taxable at the ordinary progressive personal income tax rates (plus local surcharges) on any

capital gains realized upon the disposal of the Company's shares, except for the Company's shares held for more than five years, which are taxable at a separate rate of 16.5% (plus local surcharges). Capital losses on the Company's shares incurred by Belgian resident individuals who hold the Company's shares for professional purposes are in principle tax deductible.

Capital gains realized by Belgian resident individuals upon the redemption of the Company's shares or upon the liquidation of the Company will generally be taxable as a dividend (see above, section 3.8.1.(i)).

#### **(ii) Belgian resident companies**

Belgian resident companies (not being Small and Medium sized Enterprises within the meaning of Article 15 of the Belgian Companies Code, hereinafter referred to as "**SMEs**") are subject to Belgian capital gains taxation at a separate rate of 0.412% on gains realized upon the disposal of the Company's shares provided that: (i) the Article 203 ITC Taxation Condition is met and (ii) the Company's shares have been held in full legal ownership for an uninterrupted period of at least one year. The 0.412% separate capital gains tax rate cannot be off-set by any tax assets (such as e.g. tax losses) and can moreover not be off-set by any tax credits.

Belgian resident companies qualifying as SMEs are in principle not subject to Belgian capital gains taxation on gains realized upon the disposal of the Company's shares provided that (i) the Article 203 ITC Taxation Condition is met and (ii) the Company's shares have been held in full legal ownership for an uninterrupted period of at least one year.

If the one-year minimum holding period condition would not be met (but the Article 203 ITC Taxation Condition is met) then the capital gains realized upon the disposal of the Company's shares by Belgian resident companies (both non-SMEs and SMEs) are taxable at a separate corporate income tax rate of 25.75%.

Capital losses on the Company's shares incurred by resident companies (both non-SMEs and SMEs) are as a general rule not tax deductible, save the realized capital losses up to the amount of fiscal capital not reimbursed upon the full distribution of the Company's assets (and capped up to the Company's shares acquisition cost).

Capital gains realized by Belgian resident companies upon the redemption of the Company's shares or upon the liquidation of the Company will in principle be subject to the same taxation regime as dividends (see above).

Company's shares held in the trading portfolios of qualifying credit institutions, investment enterprises and management companies of collective investment undertakings are subject to a different taxation regime. Capital gains realized by these investors will be subject to corporate income tax at the standard rates, and capital losses are tax deductible. Internal transfers to and from trading portfolio are assimilated to a realisation.

#### **(iii) Belgian non-resident individuals and companies**

Capital gains realized on the Company's shares by a non-resident individual that has not acquired the Company's shares in connection with a business conducted through a fixed base in Belgium are in principle not subject to taxation, unless in the following cases:

1. The gains are deemed to be realized outside the scope of the normal management of the individual's private estate. In such case the capital gains have to be reported in a non-resident tax return for the income year during which the gain has been realized and will be taxable in Belgium;
2. The gains originate from the disposal of (part of) a substantial participation in a Belgian company (being a participation representing more than 25% of the share capital of the Company at any time during the last five years prior to the disposal). Then, the realised capital gains may, under certain circumstances, give rise to a 17.66% tax (16.5% plus local surcharge being currently of 7%).
3. The gains are realised by non-resident individuals upon the sale of Company's shares acquired as of January 1, 2016, provided that such gains are realised within 6 months following the



acquisition of the shares. The gains will then be taxable at the rate of 35.31% (33% plus local surcharge being currently of 7%). In the case of successive share acquisitions, a last in first out (LIFO) principle applies in order to determine the shares that are sold and the amount of the capital gains. If the capital gains are realized through a Belgian financial intermediary, a new Belgian capital gain withholding tax applies and fully discharges the individual of reporting the realised capital gain in the annual income tax return. Otherwise, the capital gains have to be reported in a non-resident tax return for the income year during which the gain has been realised. This "speculation tax" will however be abolished as from January 1, 2017 (based on a draft of bill dated December 5, 2016).

However, Belgium has concluded tax treaties with over 93 countries which generally provide for a full exemption from Belgian capital gain taxation on such gains realized by residents of those countries.

Capital losses are generally not tax deductible, even if realised within 6 months.

Capital gains realized by Belgian non-resident individuals upon the redemption of the Company's shares or upon the liquidation of the Company will generally be taxable as a dividend (see above).

Capital gains will be taxable at the ordinary progressive income tax rates and capital losses will be tax deductible, if those gains or losses are realized on the Company's shares by a non-resident individual that holds the Company's shares in connection with a business conducted through a fixed base in Belgium.

Capital gains realized on the Company's shares by non-resident companies or non-resident entities that have not acquired the Company's shares through a Belgian PE are in principle not subject to taxation and losses are not tax deductible.

Capital gains realized by non-resident companies or other non-resident entities that hold the Company's shares through a Belgian PE are generally subject to the same regime as Belgian resident companies (see above).

#### **(iv) Organizations for financing pensions**

OFPs are, in principle, not subject to Belgian capital gains taxation realized upon the disposal of the Company's shares, and capital losses are not tax deductible.

#### **(v) Belgian legal entities**

Belgian resident legal entities subject to the legal entities income tax are, in principle, not subject to Belgian capital gains taxation on the disposal of the Company's shares. However, capital gains realized upon disposal of (part of) a substantial participation in a Belgian company (being a participation representing more than 25% of the share capital of the Company at any time during the last five years prior to the disposal) may under certain circumstances give rise to a 16.995% tax.

Capital gains realized by Belgian resident legal entities upon the redemption of the Company's shares or upon the liquidation of the Company will in principle be taxed as dividends.

Capital losses on the Company's shares incurred by Belgian resident legal entities are not tax deductible.

#### **(vi) Potential Application of Article 228, §3 ITC**

Under a strict reading of Article 228, §3 of the Belgian Income Tax Code 1992 ("ITC"), capital gains realized on shares by non-residents could be subject to Belgian taxation, levied in the form of a professional withholding tax, if the following three conditions are cumulatively met: (i) the capital gain would have been taxable if the non-resident were a Belgian tax resident, (ii) the income is "borne by" a Belgian resident or by a Belgian establishment of a foreign entity (which would, in such a context, mean that the capital gain is realized upon a transfer of shares to a Belgian resident or to a Belgian establishment of a foreign entity, together a "**Belgian Purchaser**"), and (iii) Belgium has the right to tax such capital gain pursuant to the applicable

double tax treaty, or, if no such tax treaty applies, the non-resident does not demonstrate that the capital gain is effectively taxed in its state of residence. However, a draft of bill dated October 5, 2016 explicitly limits the scope of Article 228, §3 ITC in such a way that expenses made by a resident to acquire securities from a non-resident does not fall in the scope of Article 228, §3 ITC anymore. Before the vote of this bill, it remains unclear whether a capital gain included in the purchase price of an asset can be considered to be “borne by” the purchaser of the asset within the meaning of the second condition mentioned above. The parliamentary documents of the law that introduced Article 228, §3 ITC support the view that the legislator did not intend for Article 228, §3 ITC to apply to a capital gain included in the purchase price of an asset, but only to payments for services. On 23 July 2014, formal guidance on the interpretation of Article 228, §3 ITC has been issued by the Belgian tax authorities (in the Belgian Official Gazette). The Belgian tax authorities state therein that Article 228, §3 ITC only covers payments for services, as a result of which no professional withholding tax should apply to capital gains realized by non-residents in the situations described above.

### **3.8.3. Tax on stock exchange transactions**

No tax on stock exchange transactions is due upon subscription to the Company's shares (primary market transactions). The purchase and the sale and any other acquisition or transfer for consideration of the Company's shares (secondary market) in Belgium through a professional intermediary is subject to the tax on stock exchange transactions (*taks op de beursverrichtingen*) of 0.27% of the purchase price, capped at EUR 800 per transaction and per party. According to a draft of bill dated December 5, 2016 this cap of EUR 800 will be doubled (to EUR 1,600) as from January 1, 2017.

No tax on stock exchange transactions is due on transactions entered into by the following parties, provided they are acting for their own account: (i) professional intermediaries described in Article 2, 9° and 10° of the Belgian Law of August 2, 2002; (ii) insurance companies described in Article 2, §1 of the Belgian Law of July 9, 1975; (iii) professional retirement institutions referred to in Article 2, 1° of the Belgian Law of October 27, 2006 concerning the supervision on institutions for occupational pension; (iv) collective investment institutions; and (v) Belgian non-residents provided they deliver a certificate to its financial intermediary in Belgium confirming their non-resident status.

As stated above in the section “Risk Factors”, the EU Commission adopted on February 14, 2013 the Draft Directive on an FTT. The Draft Directive currently stipulates that once the FTT enters into force, the Participating Member States shall not maintain or introduce taxes on financial transactions other than the FTT (or VAT as provided in the Council Directive 2006/112/EC of November 28, 2006 on the common system of value added tax). For Belgium, the tax on stock exchange transactions should thus be abolished once the FTT enters into force. The Draft Directive is still subject to negotiation between the Participating Member States and therefore may be changed at any time. A Eurogroup session held in October 2016 agreed to push ahead with the project having agreed that the European Commission will present an updated proposal in the weeks to come.

## 4. ADMISSION TO TRADING AND DEALING ARRANGEMENTS

### 4.1. ADMISSION TO TRADING

The Prospectus has been prepared for the purpose of the admission to trading of up to 52,900,000 shares, consisting of the New Shares and the Over-Allotted Shares (if any), on Euronext Brussels pursuant to and in accordance with Article 20 and following of the Act of June 16, 2006. No public offering of the New Shares or the Over-Allotted Shares (if any) will be made and no one has taken any action that would, or is intended to, permit a public offering in any country or jurisdiction where any such action for such purpose is required, including in Belgium.

An application has been made for the admission to trading of the New Shares on Euronext Brussels. It is expected that the admission to trading will become effective and that dealings in the New Shares on Euronext Brussels will commence on or around December 20, 2016. If the over-allotment option is exercised by the Underwriters, an application will also be made for the admission to trading of the Over-Allotted Shares on Euronext Brussels.

The New Shares and, as the case may be, the Over-Allotted Shares will be traded as are the existing shares of the Company under international code number ISIN BE0003864817 and symbol "TIG" on Euronext Brussels.

### 4.2. DEALING ARRANGEMENTS

To facilitate the initial public offering of ADSs representing the New Shares to retail and institutional investors in the United States and to other unspecified institutional and professional investors, the Underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the ADSs during and after the offering on the NASDAQ Global Select Market. Any such transactions will be undertaken in compliance with Regulation M as promulgated by the Securities and Exchange Commission (the "**SEC**") in the United States. Such stabilization activities may be undertaken as of December 15, 2016 until January 13, 2017. Save as required under Regulation M, the Underwriters do not intend to disclose the extent of any over-allocations or stabilisation transactions. If the Underwriters commence any stabilization activities in relation to the ADSs on the NASDAQ Global Select Market, they may discontinue them at any time. No stabilization activities will be undertaken by the Underwriters on Euronext Brussels.

In connection with this offering, some Underwriters (and selling group members) may also engage in passive market making transactions in the ADSs on the NASDAQ Global Select Market. Passive market making consists of displaying bids on the NASDAQ Global Select Market limited by the prices of independent market makers and effecting purchases limited by those prices in response to order flow. Rule 103 of Regulation M promulgated by the SEC limits the amount of net purchases that each passive market maker may make and the displayed size of each bid. Passive market, if commenced, may be discontinued at any time.

These activities may have the effect of raising or maintaining the market price of the ADSs or preventing or retarding a decline in the market price of the ADSs. As a result, the price of the ADSs may be higher than the price that would otherwise prevail in the open market, and, as a result, the price of the shares (including the New Shares) may be higher than the price that would otherwise prevail in the open market.

In the framework of the Transaction, the Underwriters have been granted an option to subscribe for up to 6,900,000 additional new shares to cover over-allotments or short positions of ADSs, if any. This option may be exercised at any time until January 13, 2017.

## 5. EXPENSES RELATED TO THE ISSUANCE OF THE NEW SHARES

The total net proceeds of the issue of the New Shares at the occasion of the Transaction amount to approximately USD 31.55 million, after deducting underwriting discounts and commissions and estimated outstanding offering expenses payable by TiGenix.

The costs and expenses incurred by the Company in relation to the Transaction (including the offering of the ADSs and the issue and the admission to trading of the New Shares on Euronext Brussels) consist of mainly underwriting fees and of other fees, including accounting, legal and printing fees. The Company agreed to pay underwriting discounts and commissions of 7% of the gross proceeds of the Transaction. The following table sets forth the main expenses the Company will be required to pay in connection with the Transaction, other than the aforementioned underwriting discounts and commissions. TiGenix has already paid and accounted for approximately USD 4.6 million of the estimated USD 6.2 million aggregate expenses, as reflected in its financial statements for 2014 and 2015 and for the six-month period ended June 30, 2016. All amounts are estimated, except the SEC registration fee, the FINRA filing fee, the NASDAQ listing fee and the FSMA filing fee:

<b>Expenses</b>	<b>Amount (in USD)</b>
SEC registration fee .....	6,163
FINRA filing fee .....	9,608
NASDAQ listing fee .....	75,000
FSMA filing fee .....	15,277
Euronext listing fee .....	21,072
Legal fees and expenses .....	3,137,689
Accounting fees and expenses .....	2,538,494
Printing fees.....	423,805
<b>Total</b> .....	<b>6,227,108</b>

## 6. DILUTION

The financial consequences of the issuance of the New Shares for the existing shareholders immediately prior to such issuance are summarized below. The admission to trading of the New Shares does, as such, not cause any additional dilution nor has it any other direct financial consequences for the shareholders of the Company.

### 6.1. EVOLUTION OF THE SHARE CAPITAL AND THE SHARE IN THE PROFITS

#### 6.1.1. Evolution of the share capital since December 31, 2015

The share capital of the Company as per December 31, 2015 amounted to EUR 17,730,458.70, represented by 177,304,587 shares. No capital increases or reductions have effectively taken place since December 31, 2015 except for (i) the capital increase of EUR 2,500,000 completed on March 14, 2016 as a result of the closing of the private placement of 25 million new shares announced on March 9, 2016 and (ii) the conditional capital increases in relation to the issuance of the New Shares and the Over-Allotted Shares approved on December 5, 2016.

#### 6.1.2. Financial consequences for the existing shareholders of the Transaction

Immediately prior to the Transaction the share capital of the Company amounted to EUR 20,230,458.70 represented by 202,304,587 shares, without nominal value, each representing 1/202,304,587th of the share capital.

Upon the First Closing of the Capital Increase, the share capital of the Company will be increased by the Board of Directors, acting within the framework of the authorized capital with cancellation of the preferential subscription rights of the existing shareholders, with EUR 4.6 million (excluding issuance premium) through the issuance of 46,000,000 New Shares. Therefore, immediately following the issue of the New Shares at the occasion of the Transaction, the share capital of the Company will amount to EUR 24,830,458.70, represented by 248,304,587 shares.

In addition, as per June 30, 2016:

- there are 9,898,500 granted and outstanding warrants (i.e. warrants that have been granted and that have not yet become null and void for any reason as per June 30, 2016) (the "**Outstanding Warrants**"). In accordance with the conditions of the warrants plans under which they were issued, upon exercise, the Outstanding Warrants entitle the warrant holders to one new share in the Company per exercised warrant, being a total of 9,898,500 new shares in the Company in case all 9,898,500 Outstanding Warrants are exercised.
- there are 250 outstanding convertible bonds due 2018 ("**Convertible Bonds**") which, at their current conversion price of EUR 0.9263, can be converted into 26,989,096 new shares in the Company in case all 250 Convertible Bonds are converted.

On July 4, 2016, TiGenix SAU entered into a licensing agreement with Takeda Pharmaceuticals International AG ("**Takeda**") pursuant to which Takeda agreed to invest EUR 10 million in new ordinary shares of TiGenix within one year of the effective date of the licensing agreement. The subscription price per share shall be equal to the average of the closing share prices of the Company on Euronext Brussels during the period of 30 calendar days immediately preceding the date on which the issuance of such new ordinary shares commenced (the "**Takeda Shares**").

Leaving the 9,898,500 Outstanding Warrants, the 250 Convertible Bonds and the Takeda Shares aside and only taking into account the number of shares that were outstanding immediately prior to the Transaction, the issue of 46,000,000 New Shares at the occasion of the Transaction will result in a

dilution of the share of the existing shares in the Company in the profits of the Company of (rounded-off) 18.53%.

In case, in addition to the number of shares that were outstanding immediately prior to the Transaction, also the maximum number of shares that can be issued upon exercise of all Outstanding Warrants, conversion of all 250 Convertible Bonds and issuance of the Takeda Shares<sup>3</sup> is taken into account, the issue of 46,000,000 million New Shares at the occasion of the Transaction will result in a dilution of up to (rounded-off) 15.51%.

The dilution relating to the share in the Company's profits also applies, *mutatis mutandis*, to the voting and other rights attached to the shares of the Company, as well as to the share in the liquidation proceeds, if any, and the preferential subscription rights.

## 6.2. COMPUTATION OF THE EFFECT ON THE NUMBER OF SECURITIES, THE SHARE CAPITAL AND THE NET EQUITY OF THE COMPANY

A computation of the evolution of the number of securities with voting rights attached, the share capital and the net equity of the Company as a result of the issuance of the New Shares is set forth in the table below. In the table a distinction is made between a hypothesis where it is assumed that none of the Outstanding Warrants, Convertible Bonds and Takeda Shares have been exercised/converted/issued, and a hypothesis where it is assumed that all Outstanding Warrants, Convertible Bonds and Takeda Shares have been exercised/converted/issued.

	Not diluted for Outstanding Warrants, Convertible Bonds and Takeda Shares <sup>(1)</sup>		Fully diluted for Outstanding Warrants, Convertible Bonds and Takeda Shares <sup>(2)</sup>	
	Prior to the Transaction	Upon completion of the Transaction <sup>(3)</sup>	Prior to the Transaction	Upon completion of the Transaction <sup>(3)</sup>
<b>Number of securities with voting rights attached</b>				
<b>A</b>	<b>Existing shares prior to the Transaction</b>			
	202,304,587	202,304,587	250,549,366	250,549,366
<b>B</b>	<b>New Shares</b>			
	0	46,000,000	0	46,000,000
<b>C</b>	<b>Total (A + B)</b>			
	202,304,587	248,304,587	250,549,366	296,549,366
<b>D</b>	<b>Dilution as a result of the Transaction (B : C)</b>			
		18.53%		15.51%

<sup>3</sup> Assuming a price per Takeda Share of EUR 0.8805, being the average of the closing share prices of the Company on Euronext Brussels during the period of 30 calendar days immediately preceding December 15, 2016.

		Not diluted for Outstanding Warrants, Convertible Bonds and Takeda Shares <sup>(1)</sup>		Fully diluted for Outstanding Warrants, Convertible Bonds and Takeda Shares <sup>(2)</sup>	
		Prior to the Transaction	Upon completion of the Transaction <sup>(3)</sup>	Prior to the Transaction	Upon completion of the Transaction <sup>(3)</sup>
<b>Share capital (statutory basis) (EUR) <sup>(4)</sup></b>					
<b>E</b>	<b>Share capital prior to the Transaction</b>	20,230,458.70	20,230,458.70	26,024,967.76	26,024,967.76
<b>F</b>	<b>Capital increase as a result of the issue of New Shares</b>	0	4,600,000	0	4,600,000
<b>G</b>	<b>Total (E + F)</b>	20,230,458.70	24,830,458.70	26,024,967.76	30,624,967.76
<b>H</b>	<b>Per share (G : C)</b>	0.100	0.100	0.104	0.103
<b>Net equity (consolidated basis) (EUR) <sup>(6), (7)</sup></b>					
<b>I</b>	<b>Net equity prior to the Transaction</b>	26,496,892.83	26,496,892.83	74,386,937.98	74,386,937.98
<b>J</b>	<b>Increase of net equity as a result of the Transaction</b>	0	33,836,370.54	0	33,836,370.54
<b>K</b>	<b>Total (I + J)</b>	26,496,892.83	60,333,263.37	74,386,937.98	108,223,308.52
<b>L</b>	<b>Per share (K : C)</b>	0.131	0.243	0.297	0.365

Remarks:

- (1) Assuming that none of the 9,898,500 Outstanding Warrants are exercised, that none of the 250 outstanding Convertible Bonds are converted and that the Takeda Shares are not issued.
- (2) Assuming that all 9,898,500 Outstanding Warrants are exercised, all 250 outstanding Convertible Bonds are converted at the current conversion price and the Takeda Shares are issued at EUR 0.8805 per share (being the average of the closing share prices of the Company on Euronext Brussels during the period of 30 calendar days immediately preceding December 15, 2016). For the warrants issued on February 26, 2007, EUR 0.997 (par value at that time) of the exercise price per warrant shall be recorded as capital and the excess shall be recorded as issuance premium. For the warrants issued on March 20, 2008, EUR 0.977 (par value at that time) of the exercise price per warrant shall be recorded as capital and the excess shall be recorded as issuance premium. For the warrants issued on June 19, 2009 and March 12, 2010, EUR 0.978 (par value at that time) of the exercise price per warrant shall be recorded as capital and the excess shall be recorded as issuance premium. For the warrants issued on July 6, 2012, March 20, 2013, December 16, 2013, April 22, 2014, and December 7, 2015, EUR 0.10 (par value at that time) of the exercise price per warrant shall be recorded as capital and the excess shall be recorded as issuance premium.
- (3) Excluding the issue of Over-Allotted Shares (if any).
- (4) As starting point for the calculation of the share capital (on a statutory basis), the registered capital of TiGenix NV as per June 30, 2016 was taken.
- (5) Excluding issuance premium or any capital increase resulting from the issue of Over-Allotted Shares (if any).
- (6) As starting point for the calculation of the net assets (on a consolidated basis), the audited net assets of TiGenix NV on a consolidated basis under IFRS per June 30, 2016 were taken. The results of the TiGenix group after June 30, 2016 have

not been taken into account.

- (7) The computation of the increase of the net equity as a result of the Transaction is based on a USD/EUR exchange rate of 1.0536 USD per EUR, as applicable on December 14, 2016, to calculate the EUR equivalent of USD 0.775. This USD/EUR exchange rate may be lower or higher than the actual exchange rate that will be used to calculate the EUR equivalent of USD 0.775 on December 20, 2016 for the purpose of the First Closing of the Capital Increase.

The above table demonstrates that the issue of the New Shares at the occasion of the Transaction leads to an increase of the amount represented by each share in the net equity of the Company on a consolidated basis under IFRS.

The table below provides an overview of the effect of the Transaction on the major shareholders:

<b>Shareholder</b>	<b>Number of shares declared in transparency declaration<sup>(1)</sup></b>	<b>% of shares (simulation) as per September 30, 2016<sup>(2)</sup></b>	<b>% of shares (simulation) as per First Closing of the Capital Increase<sup>(3)</sup></b>
Grifols S.A. / Gri-CEL S.A.	34,188,034	16.90%	13.77%
Cormorant Asset Management LLC	11,756,894	5.81%	4.73%
BNP Paribas Investments Partners SA <sup>(4)</sup>	6,650,503	3.29%	2.68%

Remarks:

- (1) Information based on the transparency notifications received by the Company.
- (2) Percentages based on number of shares at time of transparency declaration, but denominator as per September 30, 2016.
- (3) Percentages based on number of shares at time of transparency declaration (in the assumption that none of the major shareholders will buy any ADSs or ordinary shares in the Transaction), but denominator as per First Closing of the Capital Increase and excluding Over-Allotment Shares.
- (4) BNP Paribas Investments Partners SA holds its participation through its subsidiaries investment companies BNP Paribas Investments Partners UK Ltd and BNP Paribas Investments Partners Belgium SA, and is controlled by BNP Paribas SA which benefits from an exemption to aggregate its participations with the participations of its subsidiaries investment companies pursuant to Article 21 of the Royal Decree of February 14, 2008 regarding the publication of major holdings.



## 7. ADDITIONAL INFORMATION

### 7.1. LEGAL ADVISORS

The Company was advised by Osborne Clarke BV CVBA, Marnixlaan 23, 1000 Brussels, Belgium, with respect to certain specific legal matters in connection with the issuance and the admission to trading of the New Shares.

### 7.2. STATUTORY AUDITOR

The Company's statutory auditor is BDO Bedrijfsrevisoren - BDO Réviseurs d'Entreprises CVBA/SCRL, a civil company, having the form of a cooperative company with limited liability (*coöperatieve vennootschap met beperkte aansprakelijkheid / société coopérative à responsabilité limitée*) organised and existing under the laws of Belgium, with registered office at The Corporate Village, Da Vincilaan 9 – Box E.6, Elsinore Building, 1935 Zaventem, Belgium (registered with the Institute of Statutory Auditors (*Instituut van de Bedrijfsrevisoren / Institut des Réviseurs d'Entreprises*) under number B00023), represented by Veerle Catry. The annual shareholders' meeting of June 2, 2016 reappointed BDO Bedrijfsrevisoren – BDO Réviseurs d'Entreprises CVBA/SCRL as statutory auditor of the Company for a term of 3 years, ending immediately after the closing of the shareholders' meeting to be held in 2019, that will have deliberated and resolved on the financial statements for the financial year ended on December 31, 2018.

In connection with the Transaction, the statutory auditor has, on December 5, 2016, issued a report pursuant to and in accordance with Articles 596 of the Companies Code. The conclusions of this report are as follows (free translation from Dutch):

*“In the framework of the issuance of maximum 83,000,000 new shares without nominal value and restriction of the subscription right of shareholders, in connection with a capital increase in NV TIGENIX whereby the issuance price per share amounts to minimum 0.10 EUR, we are of the opinion, following our review:*

*a) that the financial and accounting data included in the special report of the Board of Directors, relating to the issuance price and financial consequences, are fair (getrouw) and*

*b) sufficient to inform the existing shareholders who have to decide on the subscription.”*

This report is available for inspection on the Company's website.

### 7.3. DOCUMENTS INCORPORATED BY REFERENCE, OVERVIEW OF PRESS RELEASES AND CERTAIN OTHER DEVELOPMENTS SINCE APRIL 12, 2016

The information incorporated by reference herein shall form an integral part of this Securities Transaction Note, save that any statement contained in a document which is incorporated by reference herein, shall be modified or superseded for the purpose of this Securities Transaction Note to the extent that a statement contained in this Securities Transaction Note modifies or supersedes such earlier statement (whether expressly, by implication or otherwise). Any statement so modified or superseded shall not, except as so modified or superseded, constitute a part of this Securities Transaction Note.

This section contains an overview of the press releases issued by the Company since April 12, 2016, the date on which the Registration Document was approved by the FSMA. For a more detailed review of the contents of the press releases that are incorporated by reference only, reference is made to the Company's website, where these press releases are publicly available.

These press releases shall be incorporated in, and form part of, the Prospectus, save that any statement contained in a document which is incorporated by reference shall be modified or superseded for the purpose of the Prospectus to the extent that a statement contained herein modifies or supersedes such earlier statement (whether expressly, by implication or otherwise). Any statement so modified or superseded shall not, except as so modified or superseded, constitute a part of this Prospectus.

Finally, this section contains an overview of certain other developments since April 12, 2016.

**7.3.1. May 3, 2016 press release: TiGenix publishes the convening notice to the annual shareholders' meeting to be held on 2 June 2016**

On May 3, 2016 TiGenix published its convening notice to the annual shareholders' meeting to be held on June 2, 2016.

**7.3.2. May 18, 2016 press release: TiGenix Cx601 positive Phase III results to be presented at Digestive Disease Week in the USA**

On May 18, 2016 the Company presented the week 24 positive results from its Phase III ADMIRE-CD pivotal study of Cx601 at the 2016 Digestive Disease Week (DDW) in San Diego, California (USA).

**7.3.3. June 16, 2016 press release: TiGenix CEO Eduardo Bravo assumes leadership of European Biopharmaceutical Enterprises (EBE)**

On June 16, 2016 the Company announced that its CEO, Eduardo Bravo, has been named President of the EBE Board of Directors.

**7.3.4. June 17, 2016 press release: TiGenix announces six-month Phase I/II results of AlloCSC-01 in Acute Myocardial Infarction**

On June 17, 2016 the Company announced the preliminary six-month results from the CAREMI clinical trial, an exploratory Phase I/II study of AlloCSC-01, TiGenix's expanded cardiac stem cell treatment for acute myocardial infarction.

**Copy of the press release:**

CAREMI is the "first-in-human" clinical trial to evaluate the safety and efficacy over twelve months intracoronary infusion of AlloCSC-01, a suspension of allogeneic human expanded cardiac stemcells (CSCs), in patients with acute myocardial infarction (AMI) and left ventricular dysfunction. Enrolment was completed in November 2015 with 49 patients randomized (AlloCSC-01: placebo; 2:1). The preliminary interim data is comprised of the six-month follow up of the 49 randomized patients plus two patients from the escalation phase who received similar target doses of 35 million cells (51 in total). Eight centers are participating in the CAREMI trial led by Prof. Fernández-Avilés, Head of the Department of Cardiology at the Hospital General Universitario Gregorio Marañón in Madrid (Spain), and Prof. Janssens, Head of the Department of Cardiovascular Diseases, University Hospital, Leuven (Belgium), as principal investigators.

"We are happy to report the preliminary interim results from our exploratory study of AlloCSC-01 in AMI that broadens our clinical development pipeline in a large area of unmet need", said Dr. Marie Paule Richard, Chief Medical Officer at TiGenix. "The safety results confirm that intracoronary delivery of AlloCSC-01 is well tolerated during the acute and sub-acute phases of the infarct, fulfilling the principal goal of the study at six months."

As per the protocol design, the primary objective of this study is to provide evidence of the acute and long-term safety profile of AlloCSC-01. On the primary acute safety endpoint, no mortality of any cause within one month was recorded for both placebo and AlloCSC-01 groups. Similarly, no major adverse cardiac event (MACE) was recorded within one month in either group. Importantly for the long-term safety evaluation, no MACE was recorded in either two group at six months. Preliminary secondary efficacy data

at six months was limited to infarct size evolution, defined as a percent of the left ventricular mass measured by magnetic resonance imaging. The mean absolute change in infarct size from baseline to six months was similar in both groups. The final full set of safety and efficacy study results at twelve months will be reported in first half of 2017.

“The positive data reported today shows the safety of early intracoronary delivery of AlloCSC-01 postAMI” said Prof. Fernández-Avilés. “We are encouraged by the safety outcome and are optimistic that this first-in-human trial with a novel cell population will be an important milestone in our quest to find a better treatment for patients at high risk of cardiac remodelling and heart failure.”

“A key question of the CAREMI study was the safety of a relatively early administration of allogeneic cardiac stem cells. This has now been addressed. We now look forward to the final safety and efficacy analysis” concluded Prof. Janssens.

#### **7.3.5. July 5, 2016 press release: TiGenix reconfirms its strategic focus on its allogeneic stem cell platforms**

On July 5, 2016 the Company announced the initiation of the withdrawal of the Marketing Authorization for ChondroCelect® due to commercial reasons. This decision is in line with TiGenix’s strategy to concentrate its resources and capabilities on its allogeneic stem cell platforms, its upcoming Cx601 Phase III US trial and its other clinical stage assets.

##### **Copy of the press release:**

Due to the regulatory environment around autologous chondrocyte-based cell therapy products in Europe leading to a difficult competitive landscape for ChondroCelect, together with the lack of reimbursement in key European countries, TiGenix has been prompted to initiate the withdrawal process of the Marketing Authorization for ChondroCelect® for commercial reasons. Consequently, TiGenix has come to an agreement with Sobi for the early termination of their existing commercial relationship and will also terminate its manufacturing agreement with PharmaCell.

“TiGenix continues to be committed to bring novel therapeutics based on our proprietary allogeneic stem cell platforms to patients with high unmet medical need, as was evidenced by the recently announced licensing agreement with Takeda Pharmaceutical for the ex-US rights to commercialize Cx601 for the treatment of perianal fistula in Crohn’s disease,” said Eduardo Bravo, CEO of TiGenix. “To deliver shareholder value we need to focus all our efforts and internal resources on the upcoming Cx601 Phase III US trial while advancing with our other clinical stage assets, namely AlloCSC-01 in acute myocardial infarction and Cx611 in severe sepsis.”

TiGenix will be working with the regulatory agencies on this withdrawal, and is in the process of notifying healthcare professionals and remind them of the availability of therapeutic alternatives for patients with cartilage lesions of the knee.

#### **7.3.6. July 5, 2016 press release: Takeda and TiGenix Enter into Licensing Agreement for Ex-U.S. rights to Cx601 for the Treatment of Complex Perianal Fistulas in Patients with Crohn’s Disease**

On July 5, 2016 the Company and Takeda Pharmaceutical Company Limited announced that the companies have entered into an exclusive ex-U.S. license, development and commercialization agreement for Cx601, a suspension of allogeneic adipose-derived stem cells (eASC) injected intra-lesionally for the treatment of complex perianal fistulas in patients with Crohn’s disease. TiGenix will receive an upfront cash payment of €25 million. TiGenix will be eligible to receive additional regulatory and sales milestone payments for up to a potential total of €355 million and double digit royalties on net sales by Takeda. The first anticipated milestone payment is €15 million upon obtaining the Marketing Authorization of Cx601 in the European Economic Area (EEA). In addition, Takeda will make an equity investment of €10 million in the share capital of TiGenix within the next 12 months.

##### **Copy of the press release:**

Crohn's disease is a chronic inflammatory disease of the gastrointestinal tract. People living with Crohn's disease often experience complex perianal fistulas for which there are limited treatment options. Recognizing the debilitating nature of the disorder and the lack of treatment options, in 2009 the European Commission granted Cx601 orphan designation for the treatment of complex perianal fistulas. In March 2016, TiGenix announced that it submitted the Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for Cx601. The filing was based on the 24 week results of the ADMIRE-CD Phase 3 clinical trial. The company also recently announced top-line 52 week data confirming the efficacy and safety of a single injection of Cx601.

Following Marketing Authorization in the European Union, Takeda will become the marketing authorization holder and will be responsible for all commercialization and regulatory activities. Takeda will also be responsible for additional development activities of Cx601 for the indication of complex perianal fistulas in Crohn's disease. TiGenix will retain the rights to develop Cx601 in new indications.

"In Europe approximately one million people suffer from Crohn's disease, with rising incidence. As a leader in gastroenterology, Takeda aspires to bring innovative treatments to patients where unmet medical needs exist," said Marc Princen, President of Europe and Canada, Takeda. "This collaboration and the addition of Cx601 to our portfolio highlights Takeda's commitment to the development of treatments to improve the health of people living with gastroenterological disorders, leveraging our expertise in Inflammatory Bowel Disease and Crohn's specifically."

"TiGenix is pleased to partner with Takeda, a global pharmaceutical company with a strong track record and strong leadership position in gastroenterology. This agreement reduces the investment risks associated with building a pan-European marketing and selling infrastructure, and helps get this much-needed treatment option to patients and gives to Cx601 the best partner with the needed capabilities and resources to secure its commercial success" said Eduardo Bravo, CEO, TiGenix. "This agreement further provides TiGenix with the financial strength to move forward with the clinical development of Cx601 in the U.S., which represents approximately 50 percent of the world's Crohn's market."

#### **Additional information in relation to the Takeda licensing agreement**

The agreement excludes clinical development and commercialization rights in the United States, where TiGenix will continue to develop Cx601 for complex perianal fistulas. TiGenix also retains the right to develop Cx601 in any indications outside the indication of complex perianal fistulas. Canada and Japan will be included in the scope of the agreement if Takeda notifies TiGenix of their intent to cover either or both of these countries by December 31, 2016. However, if Takeda has not presented TiGenix with a plan accepted by the regulatory authorities of either Canada or Japan to access the market in those countries by the second anniversary of the receipt of marketing authorization from the EMA, TiGenix has the option of unilaterally excluding those territories from the scope of the agreement. If either or both of Canada or Japan are included in the scope of the agreement, Takeda will pay TiGenix EUR 1.5 million upon receipt of regulatory approval for the sale of Cx601 to patients in either country. In addition, if Cx601 is approved for reimbursement in either or both of Canada or Japan at a price equivalent to EUR 30,000 per patient or more, Takeda will pay TiGenix a further EUR 1 million per country.

In Europe, TiGenix will transfer the marketing authorization to Takeda once it is granted by the EMA. Takeda will also make milestone payments for positive pricing and market access decisions from regulators in France, Germany, Italy, Spain and the United Kingdom of EUR 2 million per country, if Cx601 is approved at a price of EUR 30,000 or equivalent per patient or more, or EUR 1 million per country, if Cx601 is approved at a price between EUR 26,000 and EUR 30,000 or equivalent per patient.

Under the agreement, TiGenix will receive tiered quarterly royalty payments on net sales of Cx601 on a country-by-country basis, ranging from 10% to 18%, and calculated based on the price of Cx601 in each country during that quarter. TiGenix will also receive one-time sales milestone payments ranging from EUR 15 million, if net sales in the territory reach EUR 150 million, to EUR 100 million, if net sales reach EUR 1 billion. The potential sales and reimbursement milestones could total up to EUR 340 million, and are in addition to any royalty payments TiGenix receives under the agreement.

Takeda has also agreed to invest EUR 10 million in equity within one year of the effective date of the agreement. The shares will be subject to a one-year lock-up, subject to certain exceptions.

Under the agreement, TiGenix will cooperate closely with Takeda and will set up a number of joint committees to oversee the overall commercialization process; operational matters including product development, intellectual property and regulatory matters; and manufacturing. While TiGenix will initially continue to manufacture Cx601 at its facility in Madrid, and Takeda will share the cost of expanding the facility to increase the manufacturing capacity up to 1,200 doses of Cx601 per year, TiGenix intends to transfer manufacturing responsibilities to Takeda once the technology transfer process is complete, which is expected to be by January 1, 2021 at the latest.

The agreement will expire on a country-by-country basis at the occurrence of the latest any of the following:

- the twentieth anniversary of the date of the first commercial sale of Cx601 in such country
- the expiration of the last valid patent claim covering Cx601 or its use in such country
- the expiration of market exclusivity in such country granted under the marketing authorization of the product as an orphan drug
- the expiration of any data exclusivity with respect to Cx601.

Either party may terminate the agreement with thirty days' written notice in case of insolvency of the other party. Either party may terminate the agreement upon a change of control of the other party with sixty days' written notice. Either party may terminate the agreement in case of a material breach or non-performance by the other party with immediate effect or, in case of a curable material breach, if such breach should not be cured within sixty days after receipt of such notice.

TiGenix also has a right to terminate the agreement on a region-by-region basis with thirty days' written notice if expected royalties from a key market within the region are at least 25% lower than expected based on the commercialization plan provided by Takeda for at least three consecutive years and TiGenix reasonably determines that Takeda did not use commercially reasonable efforts to meet the established sales target. If TiGenix cannot mutually resolve any dispute related to such a claim either within the established committees or through negotiations between senior management or the board of directors within thirty days, the dispute shall be referred to a third party expert for adjudication. In addition, TiGenix can terminate the agreement with thirty days' notice if Takeda or one of its affiliates challenges or takes any material steps to assist a third party in challenging the validity of TiGenix's intellectual property rights.

Takeda has a right to terminate the agreement with thirty days' written notice if TiGenix does not obtain marketing authorization from the EMA within four years of the entry into the agreement. Takeda can also terminate the agreement with thirty days' written notice on a country-by-country basis if there is a third party claim of infringement of intellectual property rights provided that external counsel confirms that there is a greater than 50% probability of a finding of infringement, or in the case of a final court decision confirming such infringement.

In addition, TiGenix remains solely responsible for certain third party obligations arising from sales of the product, including with respect to the rights licensed from the Universidad Autónoma de Madrid or the Consejo Superior de Investigaciones Científicas. In case TiGenix decides to terminate any such existing license and Takeda disagrees with that decision, Takeda may request that TiGenix assigns them the license or terminate the agreement on a country-by-country basis.

Finally, Takeda has the right to terminate the agreement with thirty days' written notice in case any changes to the production or quality control process required by regulatory authorities lead to the production costs increasing by more than 15%.

#### **7.3.7. July 20, 2016 press release: Cormorant Asset Management, LLC notifies 5.81% shareholding in TiGenix**

On July 20, 2016 the Company published the transparency notification pursuant to Article 14 of the Belgian Law of May 2, 2007 regarding the publication of major holdings in issuers whose securities are admitted to trading on a regulated market and including various provisions.

**Copy of the press release:**

**Summary of the notification**

On July 19, 2016, TiGenix NV received a transparency notification from Cormorant Asset Management, LLC, following the acquisition of shares on March 14, 2016 by two entities controlled by it (i.e., Cormorant Global Healthcare Master Fund, LP and CRMA SPV, LP) after which Cormorant Asset Management, LLC has the discretionary power to exercise 11,756,894 voting rights in TiGenix NV (5.81% of the voting rights). As a result the 5% threshold was crossed.

**Content of the notification by Cormorant Asset Management, LLC**

Date of the notification: July 19, 2016.

Reason of the notification: acquisition of shares.

Person subject to the notification requirement: Cormorant Asset Management, LLC, who is a person that notifies alone.

Date on which the threshold was crossed: March 14, 2016.

Threshold that was crossed: 5%.

Denominator: 202,304,587.

Details of the notification: following the acquisition of shares, the number of voting rights was as follows:  
- Cormorant Asset Management, LLC holds 11,756,894 voting rights in TiGenix NV (5.81% of voting rights).

Chain of controlled undertakings through which the holdings are effectively held: Cormorant Asset Management, LLC is not a controlled entity. Cormorant Asset Management, LLC has received the discretionary power to exercise the voting rights of 11,756,894 TiGenix shares from the following two entities, which are both controlled by it: Cormorant Global Healthcare Master Fund, LP and CRMA SPV, LP.

**7.3.8. August 2, 2016 press release: Takeda and TiGenix Announce Publication in *The Lancet* of 24-Week Results of the Phase 3 ADMIRE-CD Trial Investigating Cx601 in the Treatment of Complex Perianal Fistulas in Patients with Crohn's Disease**

On August 2, 2016 Takeda Pharmaceutical Company Limited and TiGenix NV announced that the 24-week results of the Phase 3 ADMIRE-CD trial investigating Cx601 have been published in *The Lancet*.

**7.3.9. September 20, 2016 press release: TiGenix Business and Financial Update for the First Half 2016**

On September 20, 2016 TiGenix NV reported its business and financial highlights for the first half of 2016.

**Copy of the press release:**

Below are the key business and financial highlights for the first half of 2016, ending June 30, 2016, as well as other post period events:

- **Cx601 continued to reach significant major value inflection points**
  - Cx601 delivered positive follow-up results at 52 weeks, confirming its sustained efficacy and safety profile. Cx601's positive Phase III 24-week results were presented at the European

Crohn's and Colitis Organization (ECCO), at the Digestive Disease Week (DDW) in the US and published in *The Lancet*

- Significant progress was also made on the regulatory front. Based on the data from the pivotal Phase III trial in Europe, TiGenix submitted a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA). Cx601's marketing authorization is expected to be granted in the second half of 2017
  - Licensing agreement for the ex-US rights of Cx601 signed in July with Takeda for up to EUR 380 million in regulatory and sales milestones, of which EUR 25 million at signing, and double digit royalties on net sales. Takeda committed to a EUR 10 million equity investment within the 12 months following the signing TiGenix retains 100% of the US rights, estimated to be 50% of the global market as well as the right to further develop Cx601 in new indications
  - TiGenix retains 100% of the US rights, estimated to be 50% of the global market as well as the right to further develop Cx601 in new indications
- **Significant progress with the pipeline and strategic focus reconfirmed**
  - **Broadening of the shareholder base with European and US marquee investors**
  - **Cash position at June 30, 2016 of EUR 24.1 million, further strengthened in July by the upfront cash payment of EUR 25 million received from Takeda**

"It has been an extremely positive first half of the year for us. We have made solid progress both on the operations and in the financial front," said Eduardo Bravo, CEO of TiGenix. "With our recent licensing agreement with Takeda, with their solid track record and strong leadership position in gastroenterology, we have the best partner with the needed capabilities and resources to secure the commercial success of Cx601. We have also gained the financial strength to move forward with the clinical development of Cx601 in the US and continue to make progress with the rest of the assets in development such as AlloCSC-01 in Acute Myocardial Infarction and Cx611 for Severe Sepsis. TiGenix is in an excellent position with clear value-creation catalysts in the medium-to-short term."

## **Business Highlights for the first half 2016 and post June 30, 2016**

### **Cx601 continued to reach significant major value inflection points**

In February TiGenix secured the license for the commercial production of cell therapy products, a relevant achievement to secure the needed commercial manufacturing capacity for the forthcoming launch of Cx601 as well as for the fulfilment of the final requirements to file a Marketing Authorization Application (MAA) for Cx601 with the European Medicines Agency (EMA).

In March TiGenix announced positive follow-up results at 52 weeks for Cx601, reporting sustained efficacy and safety profile. Top line follow-up data showed that in the ITT<sup>4</sup> population (n=212), Cx601 achieved statistical superiority (p=0.012) with 54% combined remission at week 52 compared to 37% in the placebo arm. The 52-week data also showed a higher rate of sustained closure in those patients treated with Cx601 and in combined remission at week 24 (75.0%) compared to patients in the placebo group (55.9%). In terms of safety, treatment-emergent adverse events (non-serious and serious) and discontinuations due to adverse events were comparable between Cx601 and placebo groups.

In March TiGenix submitted a centralized European MAA for Cx601. The centralized procedure offers a substantial benefit for the marketing authorization holder as it allows to market the medicine and make it available to patients and healthcare professionals throughout the European Union on the basis of a single

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<sup>4</sup> ITT: Intention to treat i.e. all patients randomized in the trial.

marketing authorization. Once granted, the centralized marketing authorization is valid in all European Union member states as well as in the European Economic Area (EEA) countries, as well as Iceland, Liechtenstein and Norway. TiGenix is currently preparing the responses to the Day 120 List of Questions received from the Committee of Human Medicinal Products (CHMP within EMA). We expect a marketing authorization by the European Commission could be forthcoming by the second half 2017.

The relevance of the 24-week results of Cx601 and its potential as a truly innovative treatment for complex perianal fistulas in Crohn's disease patients was further confirmed by their selection for oral presentation at the two most important medical congresses in this field: in March in Europe at the ECCO, the main European congress for Crohn's and Colitis specialists, with more than 6,000 delegates registered this year; in May in the US at the Digestive Disease Week, the largest congress with international attendees and organized in the US for the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Furthermore, in July, the 24-week results were published by *The Lancet*<sup>5</sup>, one of the most highly regarded and well-known medical journals in the world. This publication will increase awareness of Cx601 results ahead of the initiation of the pivotal Phase III trial for registration of Cx601 in the US.

In July TiGenix entered into a licensing agreement with Takeda, a global pharmaceutical company active in gastroenterology, under which Takeda acquired the exclusive right to develop and commercialize Cx601 for complex perianal fistulas outside the US. Under the terms of the licensing agreement, TiGenix received a cash payment of EUR 25 million after signing. In addition TiGenix is eligible to receive additional regulatory and sales milestone payments for up to a potential total of EUR 355 million plus double-digit royalties on net sales. The first anticipated milestone payment will be EUR 15 million upon obtaining the marketing authorization of Cx601 in Europe. Takeda has also committed to an equity investment of EUR 10 million within 12 months from signing the agreement. This agreement increases the probability of commercial success of Cx601 by drawing on the reimbursement and commercial expertise of one of the leaders in the field. Finally, this agreement provides TiGenix with the financial strength necessary to move forward with the development of Cx601 for registration in the US and advance with the other assets in its allogeneic stem cell platforms.

TiGenix retains 100% of the US rights, estimated to be 50% of Cx601 global market, as well as the right to further develop Cx601 in new indications. The US Food and Drug Administration, or FDA, agreed through a special protocol assessment procedure (SPA) in 2015 that the pivotal Phase III trial, if successful, could, together with the European Phase III data, serve as supportive evidence for filing a biologics license application, or BLA, for regulatory approval of Cx601 with the FDA. TiGenix expects to initiate such trial in the first half of 2017. TiGenix is currently exploring different expedited pathways, which could facilitate and accelerate Cx601 development and the review of its future BLA.

### **Progress with Pipeline and strategic focus reconfirmed**

In June, TiGenix announced the preliminary interim six-month Phase I/II results of AlloCSC-01 in Acute Myocardial Infarction. As per the protocol design, the primary objective of this study is to provide evidence of the acute and long-term safety profile of AlloCSC-01. On the primary acute safety endpoint, no mortality from any cause within one month was recorded for both placebo and AlloCSC-01 groups, as was reported at six months. Similarly, no major adverse cardiac event (MACE) was recorded within one month in either group. Importantly for the long-term safety evaluation, no MACE was recorded in either of the two groups at six months. The safety results confirm that the intracoronary delivery of AlloCSC-01 is well tolerated during the acute and sub-acute phases of the infarct, fulfilling the principal goal of the study at six months. Preliminary secondary efficacy data at six months was limited to infarct size evolution, defined as a percent of the left ventricular mass measured by magnetic resonance imaging. The mean absolute change in infarct size from baseline to six months was similar in both groups. The final full set of safety and efficacy study results at twelve months will be reported in the first half of 2017.

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<sup>5</sup> Panés P, et al. Expanded allogeneic adipose-derived mesenchymal stem cells (Cx601) for complex perianal fistulas in Crohn's disease: a phase 3 randomized, double-blind controlled trial. *The Lancet* [online]. Published online July 28, 2016, available at [http://dx.doi.org/10.1016/S0140-6736\(16\)31203-X](http://dx.doi.org/10.1016/S0140-6736(16)31203-X).



With respect to Cx611, TiGenix' second allogeneic expanded adipose-derived stem cell based (eASCs)-product candidate intravenously-administered, TiGenix has made solid progress in the preparation activities for the Phase Ib/IIa clinical trial in severe sepsis secondary to severe community-acquired pneumonia (sCAP). The study is a randomized, double blind, placebo controlled multicenter trial expecting to enrol 180 patients across Europe (the SEPCELL study). TiGenix expects to enrol the first patient of this study in the second half of 2016. SEPCELL has been awarded a EUR 5.4 million grant by the European Union under the Horizon 2020 Research and Innovation Programme.

In July TiGenix announced the initiation of the withdrawal of the marketing authorization for ChondroCelect for commercial reasons. This decision is in line with TiGenix's strategy to concentrate its resources and capabilities on its allogeneic stem cell platforms.

#### Financial Highlights for the first half 2016

	SIX-MONTH PERIOD ENDED JUNE 30	
<i>Thousands of euros (€), except for share data (in euros)</i>	2016	2015
<b>CONSOLIDATED INCOME STATEMENTS</b>		
<b>CONTINUING OPERATIONS</b>		
<b>Revenues</b>		
Royalties	293	333
Grants and other operating income	650	605
<b>Total revenues</b>	<b>943</b>	<b>938</b>
Research and development expenses	(9,702)	(7,656)
General and administrative expenses	(4,322)	(2,833)
<b>Total operating charges</b>	<b>(14,024)</b>	<b>(10,489)</b>
<b>Operating Loss</b>	<b>(13,081)</b>	<b>(9,551)</b>
Financial income	57	34
Interest on borrowings and other financial costs	(3,766)	(3,080)
Fair value gains	7,750	1,285
Foreign exchange differences	(292)	747
<b>Loss before taxes</b>	<b>(9,332)</b>	<b>(10,565)</b>
Income taxes	(48)	-
<b>Loss for the period</b>	<b>(9,380)</b>	<b>(10,565)</b>
<i>Attributable to equity holders of TiGenix NV</i>	<i>(9,380)</i>	<i>(10,565)</i>
<b>Basic (diluted) loss per share</b>	<b>(0.05)</b>	<b>(0.07)</b>
<b>Basic (diluted) loss per share from continuing operations</b>	<b>(0.05)</b>	<b>(0.07)</b>

During the first half 2016, total revenues remained stable at EUR 0.9 million when compared to the same period of 2015. Revenues mainly represented royalties and other operating income received from Sobi.

Research and development expenses for the first half 2016 amounted to EUR 9.7 million, compared to EUR 7.7 million for the same period in 2015, a 26% increase which is mainly attributable to clinical activities in connection with the ongoing Phase I/II clinical trial for AlloCSC-01 in acute myocardial infarction, the preparation activities for the launching of the pivotal Phase III trial for the registration of

Cx601 in the US and the Phase Ib/IIa clinical trial for Cx611 in severe sepsis as well as other key activities related to the filing of Cx601 MAA in Europe.

General and administrative expenses in the first half of 2016 increased by 54% and amounted to EUR 4.3 million. This increase was mainly attributable to non-recurrent expenses related to advisory fees for the preparation of the US IPO and the Takeda licensing agreement.

As a result of the above, the operating loss amounted to EUR 13.1 million compared to EUR 9.6 million during the same period of 2015.

The net financial income of the first six months of 2016 amounted to EUR 3.8 million compared to the net financial loss of EUR 1.0 million during the same period of 2015. Net financial income/(loss) comprised of financial income, interest on borrowings and other financial costs, fair value gains/(losses) and foreign exchange differences. The main driver that explains the evolution during the first half of 2016 is the change in the fair value (mainly non-cash) of the embedded derivative on the convertible bonds issued in March 2015.

As a result, the loss for the first half 2016 amounted to EUR 9.4 million, compared to EUR 10.6 million for the same period in 2015, which represents a decrease of 11%.

At the end of June 2016, the Company had cash and cash equivalents of EUR 24.1 million, compared to EUR 18.0 million at the beginning of the year. This increase is mainly due to gross proceeds of EUR 23.8 million raised through the March private placement via an accelerated book-building procedure with specialist investors in Europe and in the US. Net cash used in operating activities in the first half of 2016 amounted to EUR 12.6 million. Additionally in July TiGenix obtained a cash payment of EUR 25.0 million after the signing of the licensing agreement with Takeda.

## **Outlook**

TiGenix anticipates announcing the following key milestones over the next 18 months:

- 2H 2016: initiate enrolment of Cx611 Phase Ib/IIa trial in severe sepsis
- 1H 2017: announce final results of the Phase II trial of AlloSCS-01 (CAREMI) in acute myocardial infarction
- 1H 2017: start of Cx601 pivotal Phase III trial for registration in the US
- 2H 2017: grant of Market Authorisation in the European Economic Area (EEA) to Cx601 for the treatment of complex perianal fistulas in Crohn's disease patients. If granted, Takeda will become the marketing authorization holder and will be responsible for all commercialization and regulatory activities of Cx601 in the EEA

## **Auditor's limited review**

The review of the statutory auditor of the Company, BDO Bedrijfsrevisoren Burg. Ven. CBVA, can be found in the Condensed Consolidated Interim Financial Information for the first half of 2016 in the investor section of the TiGenix website at <http://www.tigenix.com>.

## **Interim financial statements**

The interim financial information for the first half of 2016 can be found in the investor section of the TiGenix website at <http://www.tigenix.com>.

**7.3.10. September 22, 2016 press release: TiGenix appoints Dr. June Almenoff to its Board of Directors**

On September 22, 2016 TiGenix announced that it has appointed June Almenoff, M.D., Ph.D., as a member of its Board of Directors in replacement of R&S Consulting BVBA (permanently represented by Dirk Reyn).

**7.3.11. October 17, 2016 press release: TiGenix announces orphan drug designation (OCC) for Cx601 in Switzerland**

On October 17, 2016 TiGenix announced that Cx601, its lead product candidate being developed for the treatment of complex perianal fistulas in Crohn's disease patients, has been granted Orphan Drug Designation status in Switzerland. This is the second orphan drug designation granted to Cx601.

**7.3.12. October 26, 2016 press release: TiGenix publishes transparency notifications pursuant to Article 14 of the Law of May 2, 2007**

On October 26, 2016 TiGenix announced that it received two transparency notifications pursuant to Article 14, first paragraph of the Belgian Law of May 2, 2007 regarding the publication of major holdings in issuers whose securities are admitted to trading on a regulated market and including various provisions.

**Copy of the press release:**

**Summary of the notifications**

On October 21, 2016, TiGenix NV received two transparency notifications from RA Capital Management, LLC. In the first transparency notification RA Capital Management, LLC notifies the acquisition of 7,500,000 voting rights linked to securities in TiGenix NV (3.71% of the total voting rights) on March 14, 2016. As a result, the 3% threshold was crossed upwards. In the second transparency notification, RA Capital Management, LLC notifies the subsequent disposal of voting rights linked to securities on September 29, 2016, after which it held 6,039,076 voting rights in TiGenix NV (2.99% of the total voting rights) as of September 29, 2016 and consequently crossed downwards the 3% threshold.

**Content of the first notification**

*Date of the notification:* October 14, 2016.

*Reason of the notification:* acquisition of voting securities or voting rights.

*Person subject to the notification requirement:* RA Capital Management, LLC (a person that notifies alone).

*Date on which the threshold was crossed:* March 14, 2016.

*Threshold that was crossed:* 3%.

*Denominator:* 202,304,587.

*Details of the notification:*

Following the acquisition of voting rights linked to securities, the number of voting rights is as follows:

- RA Capital Management, LLC holds 7,500,000 voting securities in TiGenix NV (3.71% of the total voting rights).

*Chain of controlled undertakings through which the holdings are effectively held:* RA Capital Management, LLC is not a controlled entity.

*Additional information:* RA Capital Management, LLC is the discretionary investment manager who exercises the voting rights.

**Content of the second notification**

Date of the notification: October 14, 2016.

Reason of the notification: disposal of voting securities or voting rights; downward crossing of the lowest threshold.

Person subject to the notification requirement: RA Capital Management, LLC (a person who notifies alone).

Date on which the threshold was crossed: September 29, 2016.

Threshold that was crossed: 3%.

Denominator: 202,304,587.

Details of the notification:

Following the disposal of voting securities, the number of voting rights is as follows:

- RA Capital Management, LLC holds 6,039,076 voting securities in TiGenix NV (2.99% of the total voting rights).

Chain of controlled undertakings through which the holdings are effectively held: RA Capital Management, LLC is not a controlled entity.

Additional information: RA Capital Management, LLC is the discretionary investment manager who exercises the voting rights.

#### **7.3.13. October 26, 2016 press release: TiGenix provides update on proposed initial public offering in the United States**

On October 26, 2016 TiGenix announced the filing of an amendment to its registration statement on Form F-1 with the U.S. Securities and Exchange Commission for the proposed initial public offering in the United States of its American Depositary Shares ("ADSs"), initially filed on December 22, 2015. The amendment includes a revised syndicate of underwriters for the proposed offering. The number and price of the ADSs to be offered will be determined if and when the initial public offering is launched.

#### **7.3.14. December 5, 2016 press release: TiGenix announces launch of proposed initial public offering in the United States**

On December 5, 2016 TiGenix announced that it intends to offer and sell, subject to market and other conditions, 2.75 million American Depositary Shares ("ADSs") representing 55 million ordinary shares in an initial public offering in the United States (the "Offering").

##### **Copy of the press release:**

In connection with the Offering, TiGenix intends to grant the underwriters a 30-day option to purchase additional ordinary shares in the form of ADSs, provided that the number of such additional ADSs shall not exceed 15% of the ADSs sold in the Offering.

Each of the ADSs offered represents the right to receive twenty (20) ordinary shares.

The final issuance price per ADS (in USD) sold in the Offering will be determined following the bookbuilding process.

TiGenix's ordinary shares are currently listed on Euronext Brussels. An application has been made to list the ADSs on the NASDAQ Global Market under the symbol "TIG". Application will also be made to admit the ordinary shares, underlying the ADSs, issued pursuant to the Offering to trading on Euronext Brussels.

BofA Merrill Lynch and Cowen and Company, LLC are acting as joint book-running managers, Canaccord Genuity is acting as lead manager and BTIG is acting as co-manager for the proposed Offering.

A registration statement has been filed with the U.S. Securities and Exchange Commission but has not yet become effective. The ADSs may not be sold nor may offers to buy be accepted prior to the time the registration statement becomes effective.

The proposed offering of ADSs will be made only by means of a prospectus. A copy of the preliminary prospectus, when available, can be obtained from BofA Merrill Lynch, NC1-004-03-43, 200 North College Street, 3rd floor, Charlotte, NC 28255-0001, Attn: Prospectus Department, Email: dg.prospectus\_requests@baml.com and from Cowen and Company LLC, c/o Broadridge Financial Services, 1155 Long Island Avenue, Edgewood, NY 11717, Attn: Prospectus Department, by telephone at (631) 274-2806 or by fax at (631) 254-7140.

This press release is for information purposes only and does not constitute, and should not be construed as, an offer to sell or the solicitation of an offer to buy or subscribe to any securities of TiGenix NV, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale is not permitted or to any person or entity to whom it is unlawful to make such offer, solicitation or sale. This press release is not for publication or distribution, directly or indirectly, in or into any state or jurisdiction into which doing so would be unlawful.

### **7.3.15. TiGenix Financial Half Year Results 2016**

#### **Financial Highlights for the first half 2016**

During the first half 2016, total revenues remained stable at EUR 0.9 million when compared to the same period of 2015. Revenues mainly represented royalties and other operating income received from Sobi.

Research and development expenses for the first half 2016 amounted to EUR 9.7 million, compared to EUR 7.7 million for the same period in 2015, representing a 26% increase which is mainly attributable to clinical activities in connection with the ongoing Phase I/II clinical trial for AlloCSC-01 in acute myocardial infarction, the preparation activities for the launching of the pivotal Phase III trial for registration of Cx601 in the US and the Phase Ib/IIa clinical trial for Cx611 in severe sepsis as well as other key activities related to the filing of Cx601 MAA in Europe.

General and administrative expenses in the first half of 2016 increased by 54% and amounted to EUR 4.3 million, from EUR 2.8 million for the same period of 2015. This increase was mainly attributable to non-recurrent expenses related advisory expenses for the preparation of the US IPO and the Takeda licensing agreement.

As a result of the above, the operating loss amounted to EUR 13.1 million compared to EUR 9.6 million during the same period of 2015.

The net financial income of the first six months of 2016, amounted to EUR 3.8 million compared to EUR 1.0 million loss during the same period of 2015. Net financial income/(loss) comprises financial income, interest on borrowings and other financial costs, fair value gains/(losses) and foreign exchange differences, evolution of which is mainly explained as follows:

- Fair value gains of the period amounted to EUR 7.8 million compared to EUR 1.3 million for the same period of 2015. The main driver that explains the evolution during the first half 2016 is the change in the fair value (mainly non-cash) of the embedded derivative on the convertible bonds issued in March 2015 (in line with the lower share price at 30 June 2016 as compared to 31 December 2015)
- Interests on borrowings and other financial costs of the period amounted to EUR 3.8 million compared to EUR 3.1 million for the same period of 2015. This increase is mostly driven by the financial interests of the convertible bonds. As the bonds were issued on March 6, 2015 they were not fully impacting the six-month period ended in June 2015. By contrast they generated financial interest during the entire six-month period ended in June 2016
- Negative foreign exchange differences of the period amounted to EUR 0.3 million compared to positive foreign exchange differences of EUR 0.7 million for the same period of 2015. The decrease is mainly due to the translation into euros of the US dollar denominated intercompany

balance existing between the Company and its subsidiary, TiGenix Inc. The EUR 0.3 million at June 30, 2016 is due to the negative evolution of the US dollar against euro during the six month-period ended 30 June 2016

As a result, the loss for the first half 2016 amounted to EUR 9.4 million, compared to EUR 10.6 million for the same period in 2015, which represents a decrease of 11%.

At the end of June 2016, the Company had cash and cash equivalents of EUR 24.1 million, compared to EUR 18.0 million at the beginning of the year. This increase is mainly due to gross proceeds of EUR 23.8 million raised through the March private placement via an accelerated book-building procedure with specialist investors in Europe and in the US. Net cash used in operating activities in the first half 2016 amounted to EUR 12.6 million. Additionally in July TiGenix obtained a cash-payment of EUR 25.0 million at the signing of the licensing agreement with Takeda.

#### Important events after 30 June 2016

On July 5, 2016, Takeda and TiGenix entered into an exclusive ex-U.S. license, development and commercialization agreement for Cx601. On July 11, 2016 TiGenix received a non-refundable up-front payment of EUR 25.0 million.

In July TiGenix announced the initiation of the withdrawal of the marketing authorization for ChondroSelect for commercial reasons. This decision is in line with TiGenix's strategy to concentrate its resources and capabilities on its allogeneic stem cell platforms.

#### CONDENSED CONSOLIDATED INCOME STATEMENTS (UNAUDITED)

<i>Thousands of euros (€), except for share data (in euros)</i>	SIX-MONTH PERIOD ENDED JUNE 30,	
	2016	2015
<b>CONSOLIDATED INCOME STATEMENTS</b>		
<b>CONTINUING OPERATIONS</b>		
<b>Revenues</b>		
Royalties	293	333
Grants and other operating income	650	605
<b>Total revenues</b>	<b>943</b>	<b>938</b>
Research and development expenses	(9,702)	(7,656)
General and administrative expenses	(4,322)	(2,833)
<b>Total operating charges</b>	<b>(14,024)</b>	<b>(10,489)</b>
<b>Operating Loss</b>	<b>(13,081)</b>	<b>(9,551)</b>
Financial income	57	34
Interest on borrowings and other financial costs	(3,766)	(3,080)
Fair value gains	7,750	1,285
Foreign exchange differences	(292)	747
<b>Loss before taxes</b>	<b>(9,332)</b>	<b>(10,565)</b>
Income taxes	(48)	-
<b>Loss for the period</b>	<b>(9,380)</b>	<b>(10,565)</b>
<i>Attributable to equity holders of TiGenix NV</i>	(9,380)	(10,565)
<b>Basic (diluted) loss per share</b>	<b>(0.05)</b>	<b>(0.07)</b>
<b>Basic (diluted) loss per share from continuing operations</b>	<b>(0.05)</b>	<b>(0.07)</b>

The accompanying notes form an integral part of these unaudited condensed consolidated interim financial statements.

**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (UNAUDITED)**

	Six month period ended June 30,	
	2016	2015
<b>Loss for the period</b>	(9,380)	(10,565)
<i>Items of other comprehensive income that may be reclassified subsequently to the income statement</i>		
Currency translation differences	212	(726)
<b>Other comprehensive income (loss)</b>	<b>212</b>	<b>(726)</b>
<b>Total comprehensive loss</b>	<b>(9,168)</b>	<b>(11,291)</b>
<i>Attributable to equity holders of TiGenix NV</i>	(9,168)	(11,291)

The accompanying notes form an integral part of these unaudited condensed consolidated interim financial statements.

**CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION (UNAUDITED)**

<i>Thousands of euros (€)</i>	Notes	As at June 30, 2016	As at December 31, 2015
<b>ASSETS</b>			
Intangible assets		47,772	48,993
Property, plant and equipment		987	484
Other non-current assets	4	1,519	4,764
<b>Non-current assets</b>		<b>50,278</b>	<b>54,241</b>
Inventories		244	365
Trade and other receivables		2,753	3,033
Current tax assets		1,561	1,147
Other current financial assets		3,120	2,403
Cash and cash equivalents	5	24,113	17,982
<b>Current assets</b>		<b>31,791</b>	<b>24,930</b>
<b>TOTAL ASSETS</b>		<b>82,069</b>	<b>79,171</b>
<b>EQUITY AND LIABILITIES</b>			
Share capital	5	20,230	17,730
Share premium	5	132,364	112,750
Accumulated deficit		(129,382)	(120,002)
Other reserves		3,285	2,667
<b>Equity attributable to equity holders</b>		<b>26,497</b>	<b>13,145</b>
<b>Total equity</b>		<b>26,497</b>	<b>13,145</b>
Financial loans and other payables	6	31,421	40,084
Deferred tax liability		6	24
Other non-current liabilities contingent consideration		12,900	12,029
<b>Non-current liabilities</b>		<b>44,327</b>	<b>52,137</b>
Current portion of financial loans	6	4,956	4,611
Other financial liabilities		522	985
Trade and other payables		1,896	3,349
Other current liabilities		3,871	4,944
<b>Current liabilities</b>		<b>11,245</b>	<b>13,889</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>82,069</b>	<b>79,171</b>

The accompanying notes form an integral part of these unaudited condensed consolidated interim financial statements.



**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)**

	Six month period ended June 30,	
	Thousands of euros (€)	2016
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
<b>Operating loss</b>	<b>(13,081)</b>	<b>(9,551)</b>
Adjustments for:		
Depreciation and amortisation expense	1,595	1,659
Share-based compensation	405	86
Grants income	(179)	(201)
(Gain) Loss on sale / writte-off of PP&E & Intangible	178	-
Other	(32)	55
	<u>(11,114)</u>	<u>(7,952)</u>
Movements in working capital:		
(Increase)/ decrease in inventories	121	(3)
(Increase)/ decrease in trade and other receivables	280	(467)
Increase/(decrease) in trade and other payables	(1,453)	102
Increase/(decrease) in other financial liabilities	-	(201)
Increase/(decrease) in other current liabilities	(1,598)	(516)
	<u>(13,765)</u>	<u>(9,037)</u>
<b>Cash used in operations</b>	<b>(13,765)</b>	<b>(9,037)</b>
Income taxes received	1,147	-
<b>Net cash used in operating activities</b>	<b>(12,618)</b>	<b>(9,037)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Acquisition of property, plant and equipment	(563)	(9)
Acquisition of intangible assets	(306)	(208)
Proceeds from disposal of property, plant and equipment	33	-
(Increase)/Decrease of other non-current assets	1,041	(2,163)
(Increase)/Decrease of other current financial assets	(40)	(2,196)
<b>Net cash (used in) provided by investing activities</b>	<b>165</b>	<b>(4,576)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Gross proceeds from issue of equity instruments of the Company	23,750	-
Transaction costs equity instruments	(1,636)	-
Proceeds from issue of convertible notes	-	25,000
Issuance costs convertible notes	-	(1,127)
Reimbursements of financial loans	(2,244)	(1,164)
Reimbursements of other financial liabilities	-	(163)
Proceeds from financial loans	257	-
Proceeds from government grants	79	888
Interest paid	(1,621)	(560)
<b>Net cash provided by financing activities</b>	<b>18,585</b>	<b>22,874</b>
<b>Net increase/(decrease) in cash and cash equivalents</b>	<b>6,132</b>	<b>9,261</b>
Cash and cash equivalents at beginning of the period	17,981	13,471
<b>Cash and cash equivalents at end of period</b>	<b>24,113</b>	<b>22,732</b>

The accompanying notes form an integral part of these unaudited condensed consolidated interim financial statements.

### CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY (UNAUDITED)

Thousands of euros (€), except for share data (in euros)	Attributable to equity holders of the Company						Total Equity
	Numbers of shares	Share capital	Share premium	Accumulated deficits	Other reserves		
					Equity-settled employee benefits reserve	Translation reserves	
At January 1, 2015	160,476,620	16,048	100,118	(87,041)	6,744	(1,110)	34,759
Loss for the period	-	-	-	(10,565)	-	-	(10,565)
Other comprehensive income	-	-	-	-	-	(726)	(726)
Total comprehensive income	-	-	-	(10,565)	-	(726)	(11,291)
Issuance of shares	-	-	-	-	-	-	-
Share-based compensation	-	-	-	-	86	-	86
Other	-	-	-	-	-	(2)	(2)
At June 30, 2015	160,476,620	16,048	100,118	(97,606)	6,830	(1,838)	23,552
At January 1, 2016	177,304,587	17,730	112,750	(120,002)	4,784	(2,117)	13,145
Loss for the period	-	-	-	(9,380)	-	-	(9,380)
Other comprehensive income	-	-	-	-	-	212	212
Total comprehensive income	-	-	-	(9,380)	-	212	(9,168)
Issuance of shares	25,000,000	2,500	21,250	-	-	-	23,750
Transaction costs	-	-	(1,636)	-	-	-	(1,636)
Share-based compensation	-	-	-	-	405	-	405
Other	-	-	-	-	-	1	1
At June 30, 2016	202,304,587	20,230	132,364	(129,382)	5,189	(1,903)	26,497

The accompanying notes form an integral part of these unaudited condensed consolidated interim financial statements.

### NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

#### 1. General information

TiGenix NV, the parent company, (hereafter "TiGenix", the "Company" or the "Group") is a limited liability company incorporated and domiciled in Belgium. These condensed consolidated interim financial statements of the Company as at June 30, 2016 and for the six-month periods ended June 30, 2016 and 2015 (hereafter the interim period) comprise the financial statements of TiGenix NV (Belgium legal entity) and its subsidiaries TiGenix S.A.U. (Spanish legal entity), Coretherapix, S.L.U. (Spanish legal entity) and TiGenix Inc. (United States legal entity).

#### 2. Summary of significant accounting policies and estimates

##### Basis of preparation

The condensed consolidated interim financial statements have been prepared in accordance with International Accounting Standard (IAS) 34 (Interim Financial Reporting) as issued by the International Accounting Standards Board and endorsed by the European Union. These condensed consolidated interim financial statements do not include all the information required for full annual financial statements and should be read in conjunction with the consolidated financial statements of the Group as at and for the year ended December 31, 2015.

In the opinion of the Group's management, the unaudited condensed consolidated interim financial statements have been prepared on the same basis as the audited financial statements and include all adjustments, which include only normal recurring adjustments necessary to present fairly the Group's statement of financial position as at June 30, 2016 and its results of operations, its cash flows and changes in equity for the six-month periods ended June 30, 2016 and 2015 respectively. The results for the six-month period ended June 30, 2016 are not necessarily indicative of the results expected for the full year.

### *Liquidity*

*The Company is subject to a number of risks similar to those of other pre-commercial stage companies, including its dependence on key individuals, uncertainty of product development and generation of revenues, dependence on outside sources of capital, risks associated with research, development, testing, and obtaining related regulatory approvals of its pipeline products, dependence on third party manufacturers, suppliers and collaborators, successful protection of intellectual property, competition with larger, better-capitalized companies, successful completion of the Company's development programs and, ultimately, the attainment of profitable operations are dependent on future events, including obtaining adequate financing to fulfill its development activities and generating a level of revenues adequate to support the Company's cost structure.*

The Company has experienced net losses and significant cash outflows from cash used in operating activities over the past years, and as at June 30, 2016, had an accumulated deficit of approximately EUR 129.4 million, a net loss for the period of EUR 9.4 million and net cash used in operating activities of EUR 12.6 million for the six-month period ended June 30, 2016.

These conditions, among others, raise substantial doubt about the Company's ability to continue as a going concern. The accompanying unaudited condensed consolidated interim financial statements have been prepared assuming that the Company will continue as a going concern. This basis of accounting contemplates the recovery of the Company's assets and the satisfaction of liabilities in the normal course of business. The unaudited condensed consolidated interim financial statements do not include any adjustments due to this uncertainty relating to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company be forced to take any actions.

The future viability of the Company is dependent on its ability to generate cash from operating activities, to raise additional capital to finance its operations or to successfully obtain regulatory approval to allow marketing of the Company's products. The Company's failure to raise capital as and when needed could have a negative impact on its financial condition and ability to pursue its business strategies.

As at June 30, 2016, the Company had cash and cash equivalents of EUR 24.1 million. In addition on July 11, 2016 the EUR 25.0 million upfront payment from Cx601 licensing deal was received (see note 10). The board of directors is of the opinion that this cash position is sufficient to continue operating at least for the next 12 months but will require significant additional cash resources to launch new development phases of existing projects in the pipeline.

### *Accounting estimates and judgements*

The Company analyses, at each Reporting date, any executory contract that could be onerous to account for the corresponding provision. This estimation is based on the unavoidable expected costs and expected incomes derived from the executory contract, its remaining duration and the potential exit compensation that could be included in those contracts. The above mentioned calculation also considers past performance evidences and future expected developments based on the most reliable information existing at each reporting period.

At June 30, 2016, the Company has calculated an onerous provision for the service that is being rendered, acting as an agent, in the Pharmacell- Sobi contracts, considering expected income and expenses based on the last performance results, and the most likely scenario of duration of the contract with the information existing at the date. It does not include any exit compensation or penalty.

The following International Standards and Interpretations have been adopted during the period:

- Annual Improvements to IFRSs 2010-2012 Cycle (issued by the IASB in December 2013)
- Annual Improvements to IFRSs 2012-2014 Cycle (issued by the IASB in September 2014)
- IFRS 11 Joint Arrangements — Amendments regarding the accounting for acquisitions of an interest in a joint operation (May 2014)

- IAS 1 Presentation of Financial Statements — Amendments resulting from the disclosure initiative (December 2014)
- IAS 16 Property, Plant and Equipment — Amendments regarding the clarification of acceptable methods of depreciation and amortization (May 2014)
- IAS 16 Property, Plant and Equipment — Amendments bringing bearer plants into the scope of IAS 16 (June 2014)
- IAS 19 Employee Benefits — Amendments relating to Defined Benefit Plans: Employee Contributions (November 2013)
- IAS 27 Consolidated and Separate Financial Statements — Amendments reinstating the equity method as an accounting option for investments in subsidiaries, joint ventures and associates in an entity's separate financial statements (August 2014)
- IAS 38 Intangible Assets — Amendments regarding the clarification of acceptable methods of depreciation and amortization (May 2014)
- IAS 41 Agriculture — Amendments bringing bearer plants into the scope of IAS 16 (June 2014)

The application of these standards did not have a material effect on the condensed consolidated interim financial statements prepared on June 30, 2016.

The Company elected not to early adopt the following new Standards, Interpretations and Amendments, which have been issued by the IASB, but are not yet mandatory as per June 30, 2016:

- IFRS 9 *Financial Instruments* and subsequent amendments

On July 24, 2014 the IASB published the complete version of IFRS 9, financial instruments, which replaces most of the guidance in IAS 39. This includes amended guidance for the classification and measurement of financial assets by introducing a fair value through other comprehensive income category for certain debt instruments. It also contains a new impairment model which will result in earlier recognition of losses. No changes were introduced for the classification and measurement of financial liabilities, except for the recognition of changes in own credit risk in other comprehensive income for liabilities designated at fair value through profit or loss. IFRS 9 also includes a new hedging guidance. It will be effective for annual periods beginning on or after January 1, 2018, subject to endorsement by the European Union.

- IFRS 15 *Revenue from Contracts with Customers*

IFRS 15 specifies how and when a company will recognize revenue as well as requiring such entities to provide users of financial statements with more informative, relevant disclosures. The standard provides a single, principles-based five-step model to be applied to all contracts with customers as follows:

- Identify the contract(s) with a customer
- Identify the performance obligations in the contract
- Determine the transaction price
- Allocate the transaction price to the performance obligations in the contract
- Recognize revenue when (or as) the entity satisfies a performance obligation.

IFRS 15 was issued in May 2014 and replaces IAS 11—Construction Contracts, IAS 18—Revenue, IFRIC 13—Customer Loyalty Programmes, IFRIC 15—Agreements for the Construction of Real Estate, IFRIC 18—Transfers of Assets from Customers and SIC 31—Revenue—Barter Transactions involving Advertising Services. The IASB has voted to publish an Exposure Draft proposing a one-year deferral of the effective date of the revenue Standard to January 1, 2018. The reason for deferring the effective date is that the IASB is planning to issue an Exposure Draft with proposed clarifications to the Standard, stemming from the joint Transition Resource Group (TRG) meetings, as well as the desire to keep the

effective date of the IASB's and the FASB's revenue Standards aligned. Earlier adoption is permitted. IFRS 15 is subject to endorsement by the European Union.

- IFRS 16, Leases

On January 13, 2016, the IASB issued IFRS 16, Leases, which provides lease accounting guidance. Under the new guidance, lessees will be required to present right-of-use assets and lease liabilities on the statement of financial position. At the lease commencement date, a lessee is required to recognize a lease liability, which is the lessee's discounted obligation to make lease payments arising from a lease, as well as a right of use asset, representing the lessee's right to use, or control the use of, a specified asset for the lease term. IFRS 16 is effective for annual reporting periods beginning on or after January 1, 2019, subject to endorsement by the European Union.

Earlier application is permitted for entities that apply IFRS 15, Revenue from Contracts with Customers, at or before the initial application of IFRS 16.

The directors are currently reviewing the impact of the above-mentioned Standards and Interpretations and are yet to conclude on whether any such standards will have a significant impact on the financial statements of the Group in the period of initial application.

The other standards, interpretations and amendments issued by the IASB (of which some still subject to endorsement by the European Union), but not yet effective are not expected to have a material impact on the Group's future consolidated financial statements.

### **3. Segment information**

TiGenix is managed and operated as one business unit, which is reflected in the organizational structure and internal reporting. No separate lines of business or separate business entities have been identified with respect to any of the product candidates or geographical markets and no segment information is currently disclosed in the internal reporting.

Accordingly, it has been concluded that it is not relevant to include segment disclosures as the group business activities are not organized on the basis of differences in related product.

### **4. Other non-current assets**

The evolution of the other non-current assets during 2016 is mainly due to the senior, unsecured convertible bonds issued by the Company on March 6, 2015 for a total principal amount of EUR 25.0 million. One of the conditions related to the convertible bonds was a coupon escrow for the aggregate amount of the interests to be paid on the bonds on the first four interest payment dates, up to and including March 6, 2017. The corresponding amount was transferred to a restricted account, for the purpose of paying those four interest amounts. The interest payment of EUR 1.1 million to be executed in March 2017 that had been recognized at the end of 2015 as a non-current asset, has been classified to short term on June 30, 2016.

Furthermore the tax deductions at the level of TiGenix SAU and Coretherapix for R&D activities performed in 2014 have been classified from non-current assets to current tax assets as it is expected they will be collected before the end of the second quarter of 2017.

The fair value, of EUR 639 thousand, corresponding to the receivable in relation the consideration received for the sale of TiGenix BV to Pharmacell in 2014, has been reclassified to other current financial assets as the payment is expected to be received in May 2017.

### **5. Capital increase through private placement**

On March 14, 2016 TiGenix NV raised EUR 23.8 million in gross proceeds through a private placement of 25,000,000 new shares at a subscription price of EUR 0.95 per share.

The New Shares were placed through an accelerated book building with institutional investors in Belgium and abroad at a price of EUR 0.95 per share. The New Shares represent 12.4% of the total number of 202,304,587 shares outstanding after the issue of the New Shares.

TiGenix intends to use the net proceeds of the private placement to advance in the Cx601 marketing authorization approval process in Europe and the technology transfer of Cx601 to Lonza, a U.S.-based contract manufacturer, to enable the launch of the future phase III study of Cx601 in the U.S.

The Company will keep searching for additional funding to further strengthen its working capital and to fund its operations, which may include additional private placement transactions or public offerings of securities.

## 6. Financial loans and other payables

	As at June 30, 2016	As at December 31, 2015
<i>Thousands of euros (€)</i>		
<b>Non-current</b>		
Financial loans	6,743	7,879
Convertible notes (Ordinary note)	19,383	18,127
Convertible notes (Warrant)	5,193	13,337
Other payables	102	741
<b>Non-current borrowings</b>	<b>31,421</b>	<b>40,084</b>
<b>Current</b>		
Current portion of financial loans	4,243	3,898
Convertible notes (Ordinary note)	713	713
Other financial liabilities	522	985
<b>Current borrowings</b>	<b>5,478</b>	<b>5,596</b>
<b>Total</b>	<b>36,899</b>	<b>45,680</b>

The company's current and non-current borrowings can be detailed as follows:

- Two loans received in different tranches over 2011 and 2013 from Madrid Network, presented within financial loans, for an original amount of EUR 5.9 million to finance the TiGenix SAU Phase III study for complex perianal fistulas in Crohn's disease patients and to develop the potential of stem cells in autoimmune inflammatory diseases. The loans will be reimbursed over a period of ten years starting in 2015 with an annual fixed interest rate of 1.46%. Outstanding amount for this facility at June 30, 2016 was EUR 2.7 million of which EUR 2.1 million are long term. During the six-month period ended at June 30, 2016 EUR 0.3 million were repaid.
- Interest-free loans, presented within financial loans, maturing in 2025 received from the Spanish Government. These loans have an original amount of EUR 3.2 million. Outstanding amount for this facility at June 30, 2016 was EUR 1.2 million of which EUR 0.9 million are long term. During the six-month period ended at June 30, 2016 EUR 0.3 million were repaid.
- Kreos loan, presented within financial loans, received in 3 tranches over 2014 of EUR 5.0 million, EUR 2.5 million and EUR 2.5 million respectively. The loan will be repaid as from the first anniversary over a period of four years and has a fixed interest rate of 12.5%. The fair value of this loan measured at amortized cost in the statement of financial position at June 30, 2016 has been determined in accordance with generally accepted pricing models based on discounted cash flow. The loan is amortized using the effective interest method on a discounted rate of 20.16%. Outstanding amount for this facility at June 30, 2016 was EUR 6.2 million of which EUR 3.1 million are long term.
- Convertible notes issued by TiGenix NV in March 2015 due 2018 for a total principal amount of EUR 25.0 million and with a nominal value of EUR 100,000 per convertible bond. The bonds meet the definition of hybrid instrument under IAS 39 and are accounted as two instruments, the host contract and the embedded derivative. At issuance, the instrument had a nominal value of

EUR 25.0 million, being the fair value of the embedded derivative EUR 7.9 million and the amortized cost of the Ordinary Note EUR 16.4 million. As at June 30, 2016 the fair value of the embedded derivative amounts to EUR 5.2 million and the amortized cost of the Ordinary Note to EUR 20.1 million. The financial income due to the changes in the fair value of the derivative during the six-month period ended June 30, 2016 (EUR 8.1 million) has been recorded in the "fair value gains" caption in the condensed consolidated interim financial statements. The Ordinary note is amortized using the effective interest method on a discounted rate of 28.06%.

- Interest-free loan from the Innpacto Program, presented within the financial loans has a term of 10 years, with a grace period of three years. In January 2012, the Company received the first annual installment of the Innpacto loan amounting to EUR 548 thousand. In 2013, the Company received two annual payments of the Innpacto loan, one of EUR 457 thousand and another of EUR 142 thousand. Outstanding amount for this facility at June 30, 2016 was EUR 532 thousand of which EUR 389 thousand are long term.
- In January 2016, the Company received a loan of EUR 337 thousand from the Retos Program. The loan will be reimbursed over a period of six years starting in 2019 with a grace period of three years and with an annual fixed interest rate of 0.329%. Outstanding amount for this facility at June 30, 2016 was EUR 0.3 million of which EUR 0.3 million are long term.

The borrowings were granted subject to the condition of maintaining specific covenants. As at June 30, 2016, the Group was not in breach of any of the covenants.

Other payables include:

As at December 31, 2015, other payables consisted of deferred grants on soft loans and were related to government grants received in the form of loans obtained at below market rate interest in which the period to be audited had not yet expired and grants received from European Commission Horizon 2020 (the European Union framework program for research and innovation) program to conduct a clinical Phase Ib/IIa trial of Cx611 in patients with severe sepsis secondary to severe community-acquired pneumonia (sCAP). During 2016, EUR 639 thousand of these grants have been reclassified to Other current liabilities as for this grant amount it is expected that the conditions to be recognized will be met within the next twelve months.

Other financial liabilities include:

- Warrants issued as a consideration for the Kreos loan for an amount of EUR 0.5 million. The warrant plan consisted of 1,994,302 warrants that were issued with an exercise price of EUR 0.75 exercisable immediately and which expire in April 2019. The warrants also included a put option that authorized Kreos Capital IV (Expert Fund) to return the warrants to the Company and to settle the warrants in cash under certain circumstances. In May 2015, Kreos Capital exercised this put option and executed one third of the warrants (EUR 163.333). As from January 2016, the remaining two thirds of the warrants put option have lapsed due to the increase in the price of the share which makes this amount no longer exercisable by Kreos Capital.

## 7. Fair value of financial instruments

	As at June 30, 2016			
	Thousands of euros (€)	Carrying amount	Fair value	Fair value hierarchy
<b>Financial assets</b>				
Loans and receivables		1,519	1,519	
<i>Other non-current assets</i>		1,519	1,519	Level 2
<b>Financial liabilities</b>				
Amortised cost				
Financial loans and other payables		31,083	41,495	
<i>Financial loans</i>		10,987	14,131	
<i>Convertible notes (Ordinary note)</i>		20,096	27,364	Level 2
Fair value through profit or loss		18,615	18,615	
<i>Convertible notes (Warrant)</i>		5,193	5,193	Level 3
<i>Other financial liabilities</i>		522	522	Level 2
<i>Other liabilities contingent consideration</i>		12,900	12,900	Level 3

The fair values of the financial assets and financial liabilities measured at amortized cost in the statement of financial position have been determined in accordance with generally accepted pricing models based on discounted cash flow analysis, with the most significant inputs being the discount rate that reflects the credit risk. The fair value of the Financial loans has been determined based on a discount rate of 4.97% reflecting the market credit risk for a company such as TiGenix.

The fair value of Convertibles notes (warrant) and Other financial liabilities at fair value through profit or loss is measured using generally accepted pricing models (Black-Scholes valuation model for the warrants issued during 2014 as a consideration for the Kreos loan and Monte Carlo valuation model for an embedded derivative issued related to the convertible bonds issued on March 2015).

The inputs with the most significant effect on the fair value calculation of the Kreos warrants are the value and volatility of TiGenix's shares. The potential effect of using reasonable assumptions (Black-Scholes formula) for these inputs are the following: i) share price (10% increase/decrease would have an impact of 86/83 thousand of euros) ii) volatility of the shares (10% increase/decrease would have an impact of 40/-41 thousand of euros).

Pursuant to the terms and conditions of the convertible bonds issued on March 6, 2015, the measurement of the warrant at fair value shall be reflected at any time at its fair value determined by direct observation.

The inputs with the most significant effect on the fair value calculation are the value and volatility of TiGenix's shares. The potential effect of using reasonable assumptions (Black-Scholes formula) for these inputs are the following: i) share price (10% increase/decrease would have an impact of 1.6/-1.1 million euros) ii) volatility of the shares (10% increase/decrease would have an impact of 0.6/-0.6 million euros).

On July 31, 2015 the Group acquired 100% of the issued share capital of Coretherapix, SLU ("Coretherapix") from its sole shareholder, Genetrix, S.L. The fair value of the contingent deferred elements of the purchase price of 11.3 million euros on the date of the acquisition was computed as the sum of the probability-weighted values of the fair values of the purchase prices associated with each of the nine product development routes.

Management modelled these routes as a succession of decision points at which the Company decides to pursue internal development or licensing at different times, and in different circumstances such as whether the product enters into a pivotal trial or otherwise. In addition to the license/not to license decision, the decision tree was subject to results of the ongoing phase I/IIa trial. Two different options were considered: i) a fast development process under which the current Phase I/IIa phase ends at YE



2017 with a significant success and is followed by a three-year Phase II Pivotal trial that ends at December 31, 2020 and a two-year market approval process that ends at December 31, 2022, with commercialization commencing in 2023 and ii) slow development process in which the current Phase I/IIa phase ends at December 31, 2017 and is followed by a three-year Phase IIb trial that ends at December 31, 2020, a three-year Phase III trial that ends at December 31, 2023 and a two-year market approval process that ends at December 31, 2025, commercialization commences in 2026.

The fair value of each route was in turn computed as the sum of the survival probability discounted present values of the contingent payments in each such route including the Milestone and Commercialization Payments. Significant increase (decrease) in the market penetration and price of the product would result in higher (lower) fair value of the contingent consideration liability, while significant increase (decrease) in the discount rate would result in lower (higher) fair value of the liability.

The fair value of Other liabilities contingent consideration amounting to EUR 12.9 million was computed as the sum of the probability-weighted values of the fair values of the purchase prices associated with each of the nine product development routes. As of June 30, 2016 the fair value of the contingent consideration increased by EUR 0.9 million from December 31, 2015 due to the update of discounting future cash flows to June 30, 2016.

Except for the current portion of financial loans and the other financial liabilities, the current financial assets and liabilities are not included in the table above as their carrying amounts approximate their fair values.

## **8. Fair value gains**

Fair value gains, included in the Consolidated Income Statement have increased by EUR 6.5 million for the six-month period ended in 2016 compared to the same period of 2015 due to the following:

- Derivative financial liability related to Kreos warrants: as of June 30, 2016 Kreos warrants valuation (Black-Scholes option pricing model) amounted to EUR 523 thousand, in comparison with the EUR 985 thousand valuation at the end of 2015, therefore EUR 462 thousand has been included as fair value gains. This difference is mainly explained due to the decrease in TiGenix price share and the elimination of a no longer exercisable put option included in the Kreos warrants for a total amount of EUR 85 thousand. The fair value gain at June 30, 2016 represents a positive deviation of EUR 605 thousand when comparing to the fair value loss registered at June 30, 2015.
- Derivative financial liability related to the convertible bonds warrants: as of June 30, 2016 convertible bonds warrants amounted to EUR 5,193 thousand, in comparison with EUR 13,337 thousand at the end of 2015, therefore EUR 8,144 thousand has been recorded as fair value gain. This difference is mainly due to the changes in volatility and TiGenix share price. The fair value gain at June 30, 2016 represents a positive deviation of EUR 6.8 million when comparing to the fair value gain for the same period in 2015.
- Coretherapix contingent consideration: includes the fair value at June 30, 2016 of the contingent deferred elements of the purchase price of Coretherapix (EUR 12.9 million). As of June 30, 2015 the Coretherapix acquisition did not take place yet and therefore no effect was shown in this respect. The fair value of contingent consideration increased with EUR 0.9 million for the first six months of 2016 due to the update of discounted future cash flows to June 30, 2016 and resulted in a financial expense of EUR 0.9 million.

## **9. Related party transaction**

Transactions between the Group and its employees, consultants or directors are disclosed below:

### ***Compensation of Key management personnel***

Key management personnel are identified as being the CEO, CFO, CTO and CMO.

The combined remuneration package of the key management for the six months period of 2016 was as follows:

<i>Thousands of euros</i>	Six month period ended	
	June 30,	
	2016	2015
Short-term benefits	1,141	926
Post-employment benefits	65	43
Share-based payments	-	52
<b>Total</b>	<b>1,206</b>	<b>1,021</b>

No loan, quasi loan or other guarantee is outstanding with members of the management team.

## 10. Significant events after balance sheet date June 30, 2016

### Takeda and TiGenix enter into Licensing Agreement for EX-US rights to Cx601

On July 5, 2016, Takeda and TiGenix entered into an exclusive ex-U.S. license, development and commercialization agreement for Cx601, a suspension of allogeneic adipose-derived stem cells (eASC) injected intra-lesionally for the treatment of complex perianal fistulas in patients with Crohn's disease.

Following Marketing Authorization in the European Union, Takeda will become the marketing authorization holder and will be responsible for all commercialization and regulatory activities. Takeda will also be responsible for additional development activities of Cx601 for the indication of complex perianal fistulas in Crohn's disease. TiGenix will retain the rights to develop Cx601 in new indications

During July 2016, TiGenix received a non-refundable upfront cash payment of EUR 25.0 million in execution of this agreement. In addition, the Company is eligible to receive regulatory and sales milestone payments for up to a potential total of EUR 355 million and double digit royalties on net sales by Takeda.

The first anticipated milestone payment is EUR 15 million upon obtaining the Marketing Authorization of Cx601 in the European Economic Area (EEA). In addition, Takeda will make an equity investment of EUR 10 million in the share capital of TiGenix within the next 12 months after the agreement.

### TiGenix reconfirms its strategic focus on its allogenic stem cell platforms

Due to the regulatory environment around autologous chondrocyte-based cell therapy products in Europe leading to a difficult competitive landscape for ChondroCelect, together with the lack of reimbursement in key European countries, TiGenix has been prompted to initiate the withdrawal process of the Marketing Authorization for ChondroCelect® for commercial reasons.

Consequently, on July 4, 2016, TiGenix has come to an agreement with Sobi for the early termination of their existing commercial relationship. The original agreement was effective as of June 1, 2014, for the exclusive marketing and distribution rights with respect to ChondroCelect within the European Union (excluding Finland, where there was a pre-existing distribution agreement with Finnish Red Cross Blood Service), Switzerland, Norway, Russia, Turkey and the Middle East and North Africa region. Within the context of the agreement, Sobi marketed and distributed the product in the reimbursed countries Spain, Belgium and Netherlands and TiGenix received a royalty of 20% of the net sales. As part of the termination agreement the parties agreed that the distribution agreement shall expire on November 30, 2016.

In addition to the Sobi termination, TiGenix has also sent a termination notice to Pharmacell with respect to the manufacturing agreement of ChondroCelect. This agreement was in place since May 30, 2014 and its termination, is expected to be effective on May 30, 2017.

Both the distribution agreement with Sobi and the manufacturing agreement with Pharmacell include commitments for minimum binding quantities of ChondroCelect that are required to be purchased by us and from us under the respective agreements. As such, we have estimated a contingent asset and liability for an undiscounted amount of EUR 1.9 million.

As of June 30, 2016 a provision of EUR 245 thousand was included in the income statement to reflect the excess of the expected expenses over the expected incomes from these contracts.

I, the undersigned, Eduardo Bravo, Chief Executive Officer and member of the board of directors, declare to the best of my knowledge, that:

- 1) The set of condensed financial statements prepared in accordance with the applicable accounting standards gives a true and fair view of the assets, liabilities, financial position and results of TiGenix NV and the undertakings included in the consolidation;
- 2) The interim report is giving a true overview of the important events and the most important transactions with related parties that have occurred during the first six months of the accounting year, and the effect thereof on the condensed financial overviews, as well as a description of the most important risks and uncertainties for the remaining months of the accounting year.

Done on September 16, 2016

## **Statutory auditor's report to the Board of Directors of TiGenix NV on the review of the condensed consolidated interim financial information as of and for the six-month period ended 30 June 2016**

### **Introduction**

We have reviewed the accompanying condensed consolidated statement of financial position of TiGenix NV and its subsidiaries as of 30 June 2016 and the related condensed consolidated statements of comprehensive income, cash flows and changes in equity for the six-month period then ended, as well as the condensed explanatory notes. The Board of Directors is responsible for the preparation and presentation of this condensed consolidated interim financial information in accordance with IAS 34 as adopted by the European Union. Our responsibility is to express a conclusion on this condensed consolidated interim financial information based on our review.

### **Scope of review**

We conducted our review in accordance with the International Standard on Review Engagements 2410, "Review of Interim Financial Information Performed by the Independent Auditor of the Entity". Our review was limited primarily to analyzing, comparing and discussing the condensed consolidated interim financial information and thus was substantially less in scope than an audit of that information. We have not performed an audit and, accordingly, we do not express an audit opinion.

### **Conclusion**

Based on our review, nothing has come to our attention that causes us to believe that the accompanying condensed consolidated interim financial information is not prepared, in all material respects, in accordance with IAS 34 as adopted by the European Union.

The Company has suffered recurring losses from operations and has a liquidity position that raises uncertainty about its ability to continue as a going concern. Without modifying our conclusion, we draw your attention to note 2 of the condensed consolidated interim financial information, in which the Board of Directors justifies the application of the valuation rules in going concern. The condensed consolidated interim financial information does not include any adjustments due to this uncertainty relating to the recoverability and classification of recorded assets amounts and classification of liabilities that might be necessary should the Company no longer be in a going concern position.

Zaventem, 16 September 2016

BDO Bedrijfsrevisoren Burg. Ven. CBVA / BDO Réviseurs d'Entreprises Soc. Civ. SCRL  
Statutory auditor  
Represented by Veerle Catry

### 7.3.16. Additional information about the financial loans and other payables of the Company

As at June 30, 2016, the Company was not in breach of any of the covenants applicable to the Company's borrowings. As at the date of this Prospectus, and to the Company's best estimates, the Company is not close to a breach of the covenants.

### 7.3.17. Marketing authorization application for Cx601 with EMA

#### Status update

Based on the data from its pivotal Phase III trial in Europe, TiGenix submitted a marketing authorization application for Cx601 to the EMA in March 2016. In July 2016, the EMA sent TiGenix the day 120 list of questions, their initial response to TiGenix' application for marketing authorization. In this response, the EMA informed TiGenix of certain major objections and, following its standard protocol for review at day 120, stated that TiGenix' application was not approvable at that time. These objections would preclude a recommendation for marketing authorization unless TiGenix is able to address them adequately. The major objections identified by the EMA in the day 120 day list of questions – and elaborated upon by EMA during an August 2016 clarification meeting, during which TiGenix discussed its strategy to address the major objections – relate to the following principal deficiencies:

- The EMA questioned whether the stability data available to date adequately supports the stability of the intermediate master cell stock and also questioned the relevance of the potency test for stability of the master cell stock. TiGenix expects to update the stability data in its application based on data that has been generated as part of the stability protocols currently in place. At the time of the submission of TiGenix' replies to the day 120 list of questions, it will have additional one-year stability data for older batches, while more recent batches of the master cell stock will have completed their first year of stability. TiGenix believes that based on this data, it will be able to provide additional information about the behavior of the master cell stock while in storage.
- The EMA noted that the information provided on the starting material with respect to details on the donor selection and testing is incomplete. TiGenix acknowledges that the information about donor testing included in its initial submission was limited and it is prepared to provide additional information. TiGenix intends to respond fully to the EMA's request, which includes, among other things, providing information about the tests performed on the donors, including the list of the viral markers that were tested and the names and addresses of the centers where the lipoaspirates, or the material removed through a liposuction procedure that it uses to produce its eASCs, are collected along with information about the inspection status of these centers.
- The EMA deemed the viral safety risk assessment of TiGenix to be insufficient. Although TiGenix performed a safety risk assessment prior to submission of its application for marketing authorization, it did not believe such assessment was relevant and, therefore, did not include it in its application materials. TiGenix is updating this risk assessment following the requirements outlined in the relevant directives of the European Commission and the general text of the European Pharmacopeia on viral safety, as directed by the EMA, and will provide this updated risk assessment as part of its replies to the day 120 list of questions.
- The EMA questioned the clinical relevance of the observed treatment effect as defined by the primary endpoint used. Specifically, the EMA raised three key questions related to the primary endpoint definition and results:
  - *Question on MRI-based endpoint as representative of complete closure of fistulas:* The EMA requested justification of the imaging portion of the primary endpoint. TiGenix anticipates providing additional clarifications and two expert opinions on the justification of the primary endpoint in its replies to the day 120 list of questions, including justification of the greater than two centimeter cutoff and re-reading of the data using different cutoffs. During the August 2016 clarification meeting, the reviewers acknowledged the clinical relevance of the selection of absence of collections for the imaging part of the primary

endpoint and they also acknowledged the clinical justification provided for the selected cut-off.

- *Question on whether the primary endpoint is adequately sensitive as a measurement of change given the exclusion criterion of collections greater than two centimeters:* In light of this question, the EMA requested to see data based on absence of collections as assessed by MRI. TiGenix anticipates generating the requested data by December 2016, which is when it expects to submit its replies to the day 120 list of questions to the EMA.
- *Question on long-term efficacy:* The EMA requested to see data on development of new fistulas at a time point later than twenty-four weeks. TiGenix believes that the data from the follow-up analysis at fifty-two weeks, which was not available as part of its initial submission, and which demonstrates, among other findings, that 75% of patients treated with Cx601 who achieved combined remission at twenty-four weeks did not relapse by week fifty-two, is of clinical relevance. This data will be submitted as part of TiGenix' replies to the day 120 list of questions. During the August 2016 clarification meeting, the reviewers acknowledged the clinical relevance of this data.

Based on the August 2016 clarification meeting and the results of the follow-up analysis after fifty-two weeks, TiGenix believes it has reasonable replies to each of the major objections identified by the EMA.

The day 120 list of questions also included a number of technical questions and comments that do not rise to the level of major objections. TiGenix believes that it has adequate replies to all of these questions and comments.

TiGenix expects to submit its replies to the day 120 list of questions in December 2016, and it expects the EMA to send it their day 180 list of outstanding issues in February 2017. The day 120 list of questions and the day 180 list of outstanding issues are part of the EMA's official review timetable.

In addition, as part of the marketing authorization approval process, TiGenix had a Good Clinical Practice inspection in September 2016. The EMA indicated that this was a routine inspection and that no specific concerns had been identified by the reviewers during their evaluation of TiGenix' application. The inspectors identified certain critical and major deviations from GCP.

The Company submitted its initial replies to the report from this inspection, including the corresponding planned "corrective and preventive actions" on October 21, 2016. The Company received the inspector's report to the EMA's Committee for Human Medicinal Products, or the Integrated Inspection Report, in November 2016, which indicated that the inspectors continue to be concerned about potential critical GCP deviations, in particular a potential violation of patient privacy due to the presence of a company sponsored healthcare professional during the administration of Cx601.

This healthcare professional was trained or had previous experience in the administration of Advanced Therapy Medicinal Products. This professional was present at the time of administration of Cx601 or placebo by the surgeon in the initial administrations at each trial site to ensure proper understanding and therefore compliance with the surgical protocol. This enabled TiGenix to standardize the surgical procedure to administer Cx601 and placebo to help ensure the quality of the safety and efficacy data generated. The presence of this additional healthcare professional was not disclosed to patients prior to the procedure when they gave informed consent or included in the clinical protocol that was evaluated by an ethics committee. In their Integrated Inspection Report, the inspectors recommend that the data from the trial should be disregarded as part of the marketing authorization application. In making their recommendation, the inspectors focused on the infringement of the patient's right to consent to the presence of a company sponsored healthcare professional irrespective of mitigating factors. Due to the nature of this finding, the inspectors deemed the trial not to be conducted in accordance with ethical principles, including GCP and applicable regulatory requirements.

TiGenix believes that it has reasonable replies to the inspectors' concerns, including an evaluation of the impact of the potential privacy violation on the patients and its proposed preventive actions, each of which the Company will include in its replies to the issues raised in the Integrated Inspection Report, which the Company will submit as part of its replies to the day 120 list of questions. TiGenix believes that any potential violation of patient privacy due to the presence of an additional individual would be limited, since

this individual was a healthcare professional subject to a duty of confidentiality, did not have access to any patient information and was only present during the surgical procedure, usually entering the room after the patient was anesthetized and covered.

In addition, TiGenix believes that given the lack of treatment alternatives and the heavy commitment of the patients for invasive procedures under the treatment protocol, it is unlikely that the patients would not have given specific consent for the presence of an additional specifically trained healthcare professional to ensure the safety and efficacy of the intervention. Moreover, it is TiGenix' view that the presence of this professional does not affect the integrity of the trial data.

Although TiGenix expects a decision from the EMA on its marketing authorization application during the second half of 2017, its replies might not be satisfactory and its marketing authorization application might not be approved by the EMA. If marketing authorization were to be approved by the second half of 2017, Takeda could begin to commercialize Cx601 in Europe thereafter.

While TiGenix believes that the data it has announced to date is sufficient for TiGenix to receive marketing authorization in Europe, the data it is continuing to collect and analyze, and the interpretation of such data by the regulatory authorities, prescribing physicians and others, including potential partners, could have a significant impact on the value of the asset and TiGenix' ability to realize its full value.

### **Centralized Authorization Procedure**

The EMA is responsible for the centralized procedure, resulting in centralized marketing authorization, the single marketing authorization that is valid across the European Economic Area.

The centralized authorization procedure is required for the following types of products:

- Medicinal products developed by using recombinant DNA technology, the controlled expression of genes coded for biologically active proteins in prokaryotes and eukaryotes, including transformed mammalian cells, or hybridoma or monoclonal antibody methods.
- Advanced therapy medicinal products, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines.
- Medicinal products for human use containing a new active substance that did not receive community marketing authorization when the community authorization procedure was first implemented, for which the therapeutic indication is the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, autoimmune diseases and other immune dysfunctions or viral diseases.
- Officially designated orphan medicines.

The Pediatric Regulation places some obligations for the applicant when developing a new medicinal product, in order to ensure that medicines to treat children are subject to ethical research of high quality and are appropriately authorized for use in children, and to improve collection of information on the use of medicines in the various subsets of the pediatric population. The application will have to include the pediatric investigation plan decision but also the results in accordance with the agreed pediatric investigation plan.

The Pediatric Committee of the EMA issued a positive opinion on the pediatric investigation plan for Cx601 in September 2014.

Applications through the centralized authorization procedure are submitted directly to the EMA. The centralized procedure enables applicants to obtain a marketing authorization that is valid in all European Union member states based on a single application. Under the centralized procedure, the EMA's Committee for Human Medicinal Products, or CHMP, is required to adopt an opinion on a valid application within 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions. More specifically, on day 120 of the procedure, once the CHMP has received the preliminary assessment reports and opinions from the rapporteur and co-rapporteur, it prepares a list of potential outstanding issues, referred to as "other concerns" or "major objections", as part of its day 120 list of questions. These are sent to the applicant together with the CHMP's recommendation. The CHMP generally makes one of two recommendations: (1) the marketing

authorization application for the product could be approvable provided that satisfactory answers are given to the “other concerns” identified and that all other conditions outlined are implemented and complied with; or (2) the marketing authorization application for the product is not approvable at that time since “major objections” have been identified. Applicants have three months from the date of receiving the day 120 list of questions to respond to the CHMP, and can request a three-month extension if necessary. The rapporteur and co-rapporteur assess the applicant’s replies, revise the assessment report as necessary and may prepare a list of outstanding issues. The revised assessment report and list of outstanding issues are sent to the applicant together with the CHMP’s recommendation by day 180 of the procedure. Applicants then have one month to respond to the CHMP (and can request a one or two-month extension). The granting of marketing authorization will depend on the recommendations and potential major objections identified by the CHMP as well as the ability of the applicant to respond adequately to these findings. According to a presentation published by the EMA, for the period from December 2005 to December 2010, of the eighteen marketing authorization applications that received a positive opinion from the EMA, the number of major objections received during the EMA review period ranged from zero to ten, with an average of four major objections, and of the twenty marketing authorization applications that either received a negative opinion from the EMA or were otherwise withdrawn by the applicant, the number of major objections received during the EMA review period ranged from one to thirty-four, with an average of ten major objections. After the adoption of the CHMP’s opinion, a decision on the marketing authorization application must be adopted by the European Commission, after consulting the European Union member states, which in total can take more than sixty days. An applicant for a marketing authorization may request a re-examination in the event of a negative opinion, at which time the CHMP appoints new rapporteurs. Within sixty days of receipt of the negative opinion, the applicant must submit a document explaining the basis for its request for re-examination. The CHMP has sixty days to consider the applicant’s request for re-examination. The applicant may request an oral explanation before the CHMP, which is routinely granted, following which CHMP will adopt a final opinion. The final opinion, whether positive or negative, is published by the CHMP shortly following the CHMP meeting at which the oral explanation takes place.

Once centralized marketing authorization has been granted for a medicinal product, the holder of that authorization can make the medicinal product available to patients and healthcare professionals in all European Economic Area countries.