

TiGenix Business Update & Financial Highlights for the First Half of 2012

- **Commercial roll-out of ChondroCelect Continues to Gain Momentum**
- **All Clinical Stem Cell Programs on Track**
- **Sufficient Cash to Bring the Company to the Next Value Inflection Point**

Leuven (BELGIUM) – August 23, 2012 –TiGenix NV (NYSE Euronext: TIG), the European leader in cell therapy, gives an update of its business activities and provides the financial highlights for the half year ending June 30, 2012.

Business highlights

- ChondroCelect:
 - ChondroCelect sales EUR 2.1 million, including EUR 0.7 million of 2011 deferred sales
 - ChondroCelect obtains national reimbursement in the Netherlands
 - Large follow-up study in leading journal confirms efficacy and safety of ChondroCelect
- Progress development pipeline
 - ADMIRE-CD Phase III trial (Cx601) in complex perianal fistula enrolls first patient
 - Cx611 Phase IIa in rheumatoid arthritis (RA) completes enrollment
 - Cx621 Phase I clinical trial successfully concluded, confirming safety of proprietary intra-lymphatic route of administration of stem cells
- Corporate:
 - European production facility obtains manufacturing license

Financial highlights

- Group revenues of EUR 2.9 million
- Net loss reduced by 23%
- EUR 11.7 million cash on hand

“The significant progress in all our clinical programs and the commercial ramp up of ChondroCelect in the first half year of 2012 reinforce our position as the European leader in cell therapy,” says Eduardo Bravo, CEO of TiGenix. “We continue to consistently deliver on the objectives we set more than a year ago, keeping all key programs on plan, meeting our aggressive targets, and keeping costs under control. In addition, we are in discussions with a number of companies in connection with the US rights to Cx601.”

Business update

Commercial roll-out of ChondroCelect continues to gain momentum

ChondroCelect sales for the first half of 2012 amounted to EUR 2.1 million, comprising EUR 1.5 million from 2012 sales, up 115% compared to the same period of last year, and EUR 0.7 million of deferred sales from 2011 as a result of the retroactive reimbursement in the Netherland per January 1, 2011.

Discussions to obtain full national reimbursement keep advancing in Spain, France, and Germany. In addition to the recent important reimbursement success, the Company has obtained a positive decision in the Netherlands by one of the leading private healthcare insurance companies to make treatment with ChondroCelect compulsory for its insured, no longer reimbursing non-ATMP cartilage products. Similarly, two of the large private insurers in the UK expressed their intention to routinely reimburse ChondroCelect going forward.

Positive outcome of ChondroCelect compassionate use program published in leading journal

Positive outcome data from the ChondroCelect® compassionate use program (CUP), involving 43 orthopedic centers in 7 European countries, treating 370 patients with ChondroCelect over the span of four years, were published in the June, 2012 issue of *Cartilage*, the official journal of the International Cartilage Repair Society. The data show that the implantation of ChondroCelect results in a positive benefit/risk ratio when used in an unselected, heterogeneous population, irrespective of the follow-up period, lesion size and type of lesion treated. The study provides TiGenix with a large and unique data set to support the long-term safety and efficacy of ChondroCelect.

ADMIRE-CD Phase III trial (Cx601) in complex perianal fistula enrolls first patient

TiGenix has enrolled the first patient in the ADMIRE-CD trial, its pivotal Phase III clinical trial with Cx601, an adipose derived allogeneic stem cell suspension for the treatment of complex perianal fistulas in Crohn's disease patients. This multicenter, randomized, double-blind, placebo-controlled Phase III trial will enroll approximately 278 patients at 46 centers across 7 European countries and Israel. The main objectives of the study are to demonstrate safety and superior efficacy over placebo in perianal fistulas in Crohn's disease patients who failed to respond to previous treatment(s), in most cases biologicals, and to confirm the strong safety and efficacy results from the Phase II trial completed in 2011. Final results of the trial are expected in H2 2014, and, if positive, will allow the Company to file for marketing authorization with the European Medicines Agency.

TiGenix is in discussions with a number of companies in connection with the US rights to Cx601.

Cx611 Phase IIa in rheumatoid arthritis completes enrollment

On August 8 the Company completed the enrollment in this trial. This is the most advanced clinical trial in the world with stem cells in RA and the final results are expected no later than April 2013. Although the primary objective is to demonstrate safety, feasibility, tolerance and optimal dosing, this 53-subject, randomized, placebo controlled, multicenter study will follow the patients for 6 months after three injections of Cx611. It will therefore provide a strong first indication of the duration of the efficacy of Cx611 in this very difficult patient population – the enrolled patients have previously failed to respond to at least two biologicals – and will set the stage not only for the further development of Cx611 in RA, but also in a wide range of other autoimmune disorders.

Cx621 Phase I clinical trial successfully completed

TiGenix has successfully completed the company's Phase I clinical trial to assess the safety of intra-lymphatic administration of its expanded adipose stem cell product Cx621. Cx621 aims to capitalize on the benefits of TiGenix's proprietary approach of intra-lymphatic administration to treat autoimmune disorders. The confirmation of the safety of intra-lymphatic administration of our expanded adipose stem cells (eASCs) has potentially important clinical and commercial implications. It opens up the possibility of achieving efficacy at lower dosage, which would further increase the safety profile of TiGenix's eASCs, while it would simultaneously reduce the cost of goods and improve margins. An additional benefit is that the subcutaneous lymph nodes are superficial and readily visible by ultrasound, and thus allow for a rapid and easy injection.

European production facility obtains manufacturing license

On April 24, further to the cGMP inspection by the Dutch authorities, TiGenix obtained the manufacturing authorization for human medicinal products for its European manufacturing plant in Sittard-Geleen in the Netherlands. The state-of-the-art manufacturing site is unique in Europe as it is 100% geared towards the production of innovative cell therapy products. The plant provides TiGenix

with crucial manufacturing capabilities to support the anticipated growth in demand for ChondroCelect for cartilage repair, and has sufficient capacity for the production of the Company's advanced stem cell therapy products.

Financial results for the first half of 2012

Key figures (Thousands of Euro, except number of employees)

	Period ended June 30	
	2012	2011
	<i>Thousands of Euro (€)</i>	
CONSOLIDATED INCOME STATEMENT		
CONTINUING OPERATIONS		
Sales	2.129	370
<i>Gross sales</i>	1.471	781
<i>Deferred sales</i>	658	-411
Cost of sales	-391	-182
Gross profit	1.738	188
Research and development expenses	-7.396	-5.296
Sales and marketing expenses	-1.153	-1.248
General and administrative expenses	-3.143	-3.676
Other operating expenses	0	-2.779
Total operating charges	-11.691	-12.999
Other operating income	787	103
Operating Result	-9.166	-12.707
Interest income	50	82
Interest expenses	-33	-93
Foreign exchange differences	-358	-664
Profit/(Loss) before taxes	-9.507	-13.383
Income taxes	0	380
Profit/(Loss) for the period from continuing operations	-9.507	-13.003
DISCONTINUED OPERATIONS		
Profit/(Loss) for the period from discontinued operations	-461	0
Profit/(Loss) for the period	-9.968	-13.003
<i>Attributable to equity holders of TiGenix NV</i>	<i>-9.968</i>	<i>-13.003</i>
Cash and cash equivalents	11.727	24.881
Number of employees and mandate contractors	69	80

Group sales⁽¹⁾ for the first 6 months of EUR 2.1 million

Group sales for the first six months of 2012 amounted to EUR 2.1 million, a substantial increase from EUR 0.4 million in the same period of last year. Gross sales for ChondroCelect for the first six months of 2012 were EUR 1.5 million, a 115% increase compared with the same period last year, reflecting the continued uptake in Belgium and the Netherlands. As a result of the retroactive reimbursement in the Netherlands per January 1, 2011, an additional EUR 0.7 million in deferred 2011 sales bring the total sales of ChondroCelect for H1 2012 to EUR 2.1 million.

(1) Sales of ChondroMimetic are not included in 2012 figures as TiGenix Ltd is considered as an asset to be held for sale.

Net loss reduced by 23%

Net loss for the first six months of 2012 decreased by 23% compared with the same period last year as a direct result of sales growth during the period, and strict cost controls, which offset continued investments in the commercialization effort to support ChondroCelect and increased R&D expenses to keep advancing our clinical programs. At the end of June 2012, the total number of employees and mandate contractors was equal to 69 people, compared with 80 at the end of June 2011.

Cash position of EUR 11.7 million on June 30, 2012

On June 30, the Company had a cash position of EUR 11.7 million. Net cash used during the first six months of 2012 was EUR 8.1 million in line with management's guidance. Based on its current cash position, anticipated commercial revenues from ChondroCelect sales, partnering of Cx601, and the sale of TiGenix Ltd, the company believes it is sufficiently financed to keep executing on its business plan.

Outlook next 12 months

- National reimbursement decisions in major European countries for ChondroCelect
- ChondroCelect distribution agreements in selected countries
- First commercial batches of ChondroCelect produced at Sittard-Geleen manufacturing facility
- US partnering agreement for Cx601
- Final results of Cx611 in Rheumatoid Arthritis
- Additional non dilutive funding through R&D grants and soft loan programs

Auditor's limited review

The statutory auditors BDO Bedrijfsrevisoren BCV's limited review can be found in the H1 2012 Condensed Consolidated Financial Statements in the investor section on our website at www.tigenix.com

Financial Half Year Results

The H1 2012 financial interim statements can be found in the investor section on our website www.tigenix.com

Conference call webcast

On August 23, at 14:00 Central European Time (CET), TiGenix will conduct a conference call webcast.

To participate in the conference call, please dial:

+32 2 400 6864 (Belgium)
+44 207 136 2056 (UK)
+1 718 354 1359 (US)
+34 91 791 1292 (Spain)

The online live webcast can be followed via the link:

<http://www.media-server.com/m/p/99ja5i5>

Following an update of the business activities and presentation of the financial results, the participants will be able to ask questions.

The press release and the presentation will be made available in the Investor and Newsroom sections on our website.

A replay of the webcast will be available shortly after the conference call.



For more information:

Eduardo Bravo
Chief Executive Officer

eduardo.bravo@tigenix.com

Claudia D'Augusta
Chief Financial Officer

claudia.daugusta@tigenix.com

Hans Herklots
Director Investor & Media Relations

hans.herklots@tigenix.com

+32 16 39 60 97

About TiGenix

TiGenix NV (NYSE Euronext: TIG) is a leading European cell therapy company with a marketed cell therapy product for cartilage repair, ChondroCelect®, and a strong pipeline with clinical stage allogeneic adult stem cell programs for the treatment of autoimmune and inflammatory diseases. TiGenix is based out of Leuven (Belgium) and has operations in Madrid (Spain), and Sittard-Geleen (the Netherlands). For more information please visit www.tigenix.com.

Forward-looking information

This document may contain forward-looking statements and estimates 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” 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 TiGenix’ 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. 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 only speak as of the date of the publication of this document. TiGenix disclaims any obligation to update any such forward-looking statement, forecast or estimates to reflect any change in TiGenix’ 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.