

TiGenix Reports Full Year 2012 Financial Results

- ChondroCelect[®] sales increase to EUR 4.1 million, up 101%
- Cx611 RA program reported positive interim safety results
- Cx601 ADMIRE-CD trial ongoing in 8 countries
- EUR 11.1 million cash at December 31, 2012

Leuven (BELGIUM) – March 12, 2013 –TiGenix NV (Euronext Brussels: TIG), the European leader in cell therapy, today gave a business update and announced financial results for the full year 2012.

Business highlights

- ChondroCelect:
 - ChondroCelect sales substantially increased following second national reimbursement in the Netherlands
- Development pipeline progress:
 - Cx601: ADMIRE-CD Phase III trial in complex perianal fistula in Crohn's disease patients fully on track & partnering discussions on-going
 - Cx611 Phase IIa in rheumatoid arthritis (RA) reported positive interim safety data – final results expected in April 2013
 - Cx621 Phase I successfully confirmed safety profile of intralymphatic administration of eASCs

Corporate

- Jean Stéphane appointed chairman & Russell Greig appointed member of the Board of Directors
- Key approvals for manufacturing facilities in the Netherlands and Spain

Financial highlights

- ChondroCelect gross sales for 2012 amounted to EUR 4.1 million, an increase of 101% over the previous year on a like-for-like basis
- In December, TiGenix raised EUR 6.7 million through a private placement from a wide range of domestic and international investors
- EUR 11.1 million cash & cash equivalents at year-end

“In 2012 we have made great operational, clinical and commercial progress,” says Eduardo Bravo, CEO of TiGenix. “We have significantly advanced in all our clinical programs, which are fully on schedule; we have obtained national reimbursement for ChondroCelect in the Netherlands, and we have continued to build our presence in other European markets and across the Middle-East. And in December, we raised funds from specialized healthcare investors, both domestic and international

ones. We are on the cusp of a number of key milestones that should further strengthen TiGenix's position as the European leader in cell therapy."

Business Update

ChondroCelect® sales up substantially

ChondroCelect gross sales for 2012 amounted to EUR 4.1 million, comprising of EUR 3.4 million in 2012 sales and EUR 0.7 million from deferred sales in 2011. Adjusting for these deferred sales, 2012 numbers represent a 101% growth over 2011 on a like-for-like basis.

This excellent result in the commercial roll out of ChondroCelect reflects the continued sales growth in Belgium and in the Netherlands after the reimbursement obtained in both countries respectively in May 2011 and in June 2012.

In addition, in 2012 TiGenix has put in place a broad market access strategy to further grow sales. Aside from Belgium and the Netherlands, ChondroCelect is reimbursed on a case-by-case basis in Germany (NUB4 status), and by selected primary care trusts in the UK. Additionally, two leading private insurance companies in the UK have started to reimburse ChondroCelect on a routine basis. Private insurance groups in Spain have reimbursed a limited number of patients. TiGenix is pursuing national reimbursement in Spain and France and expanded reimbursement in Germany and the UK.

Outside TiGenix's core commercial countries, the Company closed a distribution agreement for the Middle-East, with Genpharm. An agreement with the Finnish Red Cross Blood Service for Finland has been in place since the end of 2011.

Cx601: ADMIRE-CD Phase III trial in complex perianal fistula in Crohn's disease patients on track & partnering discussions on-going

Cx601 is TiGenix's most advanced clinical stage product and has completed a Phase II study, published in October 2012 in the *International Journal of Colorectal Disease*. Cx601 is an adipose derived allogeneic stem cell suspension (eASC) for the treatment of complex perianal fistulas in Crohn's disease patients. Cx601 has been granted orphan designation by the EMA. Ethics committees and regulatory agencies in all of the eight participating countries have approved the protocol of the phase III study, and patient recruitment is progressing on plan. 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 of the Phase II trial. Final results of the trial are expected in 2H 2014, and, if positive, should allow the Company to file for marketing authorisation with the EMA in the first half of 2015.

Partnership discussions are ongoing for co-development and commercialization of Cx601 in different regions.

Cx611 Phase IIa in rheumatoid arthritis (RA) reported positive interim safety results

Cx611 is an allogeneic eASC product candidate for the treatment of RA. This is the most advanced trial in the world with stem cells in RA and the Company expects to report final results in April 2013. Positive interim safety results were reported in December 2012. This multicenter (20 centers), placebo-controlled study enrolled 53 patients, divided in 3 cohorts with different dosing regimens. The objective of the trial is to determine safety, feasibility, tolerance, and optimal dosing, and obtain a first indication of efficacy in this very difficult to treat patient population that has previously failed to

respond to at least two biologicals. TiGenix expects that the phase IIa results will set the stage for the further development of Cx611 in RA, and potentially in a wide range of other autoimmune disorders.

Phase I successfully concluded for Cx621 to assess intra-lymphatic administration of eASCs

Cx621 is an allogeneic eASC product candidate for the treatment of autoimmune diseases via a proprietary technique of intra-lymphatic administration. In July 2012, TiGenix successfully concluded a phase I study to assess safety, tolerability and pharmacodynamics of intra-lymphatic administration of Cx621 in healthy volunteers. The Company filed a patent for this novel route of administration and is currently evaluating in which autoimmune indication eventually move the product forward into the next clinical stage of development.

Appointments of Jean Stéphane as chairman & Russell Greig as member of Board of Directors

On September 19, TiGenix appointed Jean Stéphane chairman and Russell Greig member of the Board of Directors. Both are former members of the Corporate Executive Team of GlaxoSmithKline, and have a sterling track record that will be of immense value as TiGenix enters into a pivotal phase of its growth with the commercial roll-out of ChondroCelect and the advanced clinical development of its cell therapy programs.

Key approvals for manufacturing facilities in the Netherlands and Spain

In September 2012, TiGenix obtained the approval from the EMA for the production of ChondroCelect in its new state-of-the-art manufacturing facility in Sittard-Geleen, the Netherlands. The new site is unique in Europe as it is 100% geared towards the production of innovative cell therapy products. It provides crucial manufacturing capabilities to support the expected growth in demand for ChondroCelect for cartilage repair, and has sufficient capacity for the production of other advanced stem cell therapy products.

In addition, in January 2013, TiGenix successfully renewed its manufacturing authorization for stem cell products at its manufacturing facility in Madrid, Spain. The GMP facility in Madrid performs a vital function by manufacturing high-quality, clinical grade allogeneic stem cell products to fuel TiGenix's key clinical programs.

Financial results for the full year 2012

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

	Years ended December 31	
	2012	2011*
<i>Thousands of Euro (€)</i>		
CONSOLIDATED INCOME STATEMENT		
CONTINUING OPERATIONS		
Sales	4,084	1,146
<i>Gross sales</i>	4,084	1,804**
<i>Deferred sales and discounts</i>	0	-657
Cost of sales	-905	-455
Gross profit	3,179	691
Research and development expenses	-13,936	-10,595
Sales and marketing expenses	-2,881	-2,726
General and administrative expenses	-6,026	-6,593
Other operating expenses	0	-2,974
Total operating charges	-23,749	-23,344
Other operating income	1,389	393
Operating Result	-18,276	-21,805
Interest income	35	708
Interest expenses	-61	-408
Foreign exchange differences	-142	434
Profit/(Loss) before taxes	-18,443	-21,071
Income taxes	-1	0
Profit/(Loss) for the period from continuing operations	-18,444	-21,071
DISCONTINUED OPERATIONS		
Profit/(Loss) for the period from discontinued operations	-1,949	-16,234
Profit/(Loss) for the period	-20,393	-37,305
Cash and cash equivalents	11,072	19,771
Number of employees and mandate contractors	67	75

*The 2011 consolidated financial statements have been adjusted to reflect the capitalization of the expenses incurred that were essential to bring the Dutch manufacturing facility into operations;

** 2011 gross sales include EUR 0.1 million in ChondroMimetic sales.

Gross sales of EUR 4.1 million

Gross sales in 2012 amounted to EUR 4.1 million, comprising of EUR 3.4 million of sales from 2012 and EUR 0.7 million of deferred sales from 2011, an increase of 101% over last year on a like-for-like basis.

Operational expenses firmly under control

In 2012, the Company's cost basis has been kept at the same level as in 2011. At the end of 2012, total staff and mandate contractors of the group numbered 67 employees, compared to 75 employees at the end of 2011.

Operating loss for the period amounted to EUR 18.3 million compared to EUR 21.8 million in 2011, or a 16% decrease, as a result of the increase in sales and an important increase in "other operating income" related to grants.

Net loss significantly reduced

The net loss for 2012 amounted to EUR 20.4 million compared to EUR 37.3 million in 2011. Net loss in 2011 was significantly impacted by an extraordinary non-cash charge for EUR 16.2 million for impairments related to discontinued operations (TiGenix Ltd).

EUR 6.7 million secured in private placement

TiGenix raised EUR 6.7 million in financing activities through a private placement from domestic and international specialized investors. The placement was priced at a 9% discount on the average closing price of the previous 30 days, and the offering was twice oversubscribed, demonstrating a clear interest of healthcare investors in the Company.

EUR 11.1 million cash & cash equivalents at year-end

At December 31, 2012, the Company had EUR 11.1 million cash at hand. The net cash used in operating activities during the period amounted to EUR 17.7 million, slightly below the operating cash burn in 2011, and in line with the Company's effort to increase efficiency and to carefully manage its operational cash flow.

In addition to its ability to attract dilutive funding, TiGenix has successfully secured EUR 2.1 million in 2012 in non-dilutive funding from grants and soft loans.

Outlook for the next 12 months

- Phase IIa study results for Cx611 in RA
- ChondroCelect continued uptake & reimbursement in additional countries
- Cx601: partnering & finalize recruitment of phase III
- Additional non-dilutive funding, such as grants and soft loans

Complete financial statements

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

Conference call webcast

On March 12, at 14:00 CET/9am DST, TiGenix will conduct a conference call webcast:

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+34 91 791 7146	Spain
+31 20 713 2998	Netherlands
+44 20 3140 8286	UK
+1 212 444 0481	USA
Confirmation code	54 38 572

The online live webcast can be followed via the link:

<http://www.tigenix.com/en/page/165/webcast>

Following the 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 newsroom section on our website. A replay of the webcast will be available shortly after the conference call.

For more information

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About TiGenix

TiGenix NV (Euronext Brussels: TIG) is a leading European cell therapy company with a marketed 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 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. 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

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