

TiGenix Reports Full Year 2013 Financial Results

- ChondroCelect® sales increase to EUR 4.3 million, up 25%
- Cx601 US regulatory and development path confirmed
- EUR 18.5 million secured in private placements, of which EUR 12 million with strategic investor Grifols
- EUR 15.9 million cash at December 31, 2013

Leuven (BELGIUM) – March 11, 2014 –TiGenix NV (Euronext Brussels: TIG), the European leader in cell therapy, gives an update of its business activities and announces financial results for the full year 2013.

Business highlights

- ChondroCelect sales grew 25%, on track to become a cash flow positive asset in 2014
- US regulatory and development path for Cx601 validated in end-of-phase 2 meeting with FDA
- 2/3 of patients enrolled in European Phase III trial of Cx601 in complex perianal fistulas
- Encouraging phase IIa results of Cx611 in rheumatoid arthritis
- Renewal of GMP licence for Dutch manufacturing facility allows completion of sale

Financial highlights

- EUR 18.5 million secured in private placements, of which EUR 12 million with strategic investor Grifols
- Facility loan agreement secured for up to EUR 10 million in December
- EUR 15.9 million in cash & cash equivalents at 31 December, 2013. Average monthly cash burn reduced to EUR 1.1 million
- Net loss of EUR 18.4 million, a 10% reduction from EUR 20.4 million in 2012

“We have made very good progress on all fronts during this year,” said Eduardo Bravo, CEO of TiGenix. “In Grifols, we have added a first-class strategic investor which not only validates our technology platform but strengthens our financial position. ChondroCelect growth remains strong. For Cx601, the regulatory path in the United States has been confirmed and patient recruitment for the phase III trial is progressing well. We will maintain the pace of continuous delivery during 2014, with concrete advances to be announced in the short term”.

Business update

ChondroCelect sales grew 25%, on track to become a cash flow positive asset in 2014

ChondroCelect sales for the year have grown 25% to EUR 4.3 million, compared to EUR 3.4 million in 2012 on a like-for-like basis. ChondroCelect sales for the fourth quarter of 2013 amounted to EUR 1.2 million, up 38% over the same quarter last year, with revenues still mainly fueled by sales in Belgium and the Netherlands.

Growth is expected to accelerate in 2014 with the increasing contribution of sales in the UK and Spain. We reiterate our objective for ChondroCelect to become a cash flow positive asset in the course of 2014.

Patient enrolment in ADMIRE-CD Phase III trial (Cx601) in complex perianal fistulas progressing

Patient enrolment in the ADMIRE-CD trial, the Company's pivotal European Phase III clinical trial for Cx601, is progressing. Recruitment is ongoing at more than 50 centers in 8 countries and should be completed in 2014. Final results are expected in the third quarter of 2015 and, if positive, will allow TiGenix to file for European marketing approval in 2016.

US regulatory and development path validated in end-of-phase 2 meeting with FDA

In December 2013, TiGenix held an end-of-phase 2 meeting with the Food and Drug Administration (FDA) concerning the development of Cx601 in the United States. The objectives of the meeting were to discuss the adequacy of the existing non-clinical package to support an IND for a US-based phase III trial, to obtain guidance on the design of such a trial, and to confirm the acceptability of using the data from the ongoing ADMIRE-CD phase III study in Europe to support a BLA filing. Based on the affirmative feedback received on these three points, TiGenix is starting the technology transfer to a US Contract Manufacturing Organization (CMO) and the preparation of the application for a Special Protocol Assessment (SPA) that will allow the filing of an IND for phase III in 2015.

The Company is also re-opening discussions concerning the partnering of Cx601 in different regions.

Cx611 clinical development plan based on encouraging phase IIa results in RA almost finalised

In October, TiGenix presented the results of its Phase IIa study of Cx611 in refractory rheumatoid arthritis (RA) in a plenary session of the American College of Rheumatology Annual Meeting. Working closely together with an advisory board of international key opinion leaders on the appropriate design of follow-up studies for Cx611 in inflammatory and autoimmune disorders, TiGenix expects to finalise and announce the next steps of the development plan in the coming weeks.

Renewal of GMP licence for Dutch manufacturing facility allows completion of sale

In October, Dutch authorities renewed TiGenix's Good Manufacturing Practice (GMP) licence for its state-of-the-art cell therapy manufacturing facility in Sittard-Geleen, the Netherlands. This renewal allowed the Company to complete negotiations which culminated in the agreement signed in January 2014 to sell the Company's Dutch subsidiary which owns the facility to PharmaCell. On top of the EUR 4.25 million cash to be received (of which EUR 3.5 million will come in 2014), the sale will reduce organisational complexity and eliminate an important part of the Company's fixed costs while maintaining ChondroCelect supply.

Board composition

Following the EUR 12 million investment by global healthcare company Grifols through its fully-owned subsidiary Gri-Cel, the Company appointed Dirk Buscher and José Terencio to the Board of Directors, replacing Joel Jean-Mairet (Ysios Capital Partners SGEGR SA) and Nico Vandervelpen (LRM Beheer NV).

In March 2014, co-founder Gil Beyen (Gil Beyen BVBA) resigned from the Board of Directors to assume other responsibilities outside of TiGenix.

Financial results for the full year 2013

Key figures (thousands of Euro, except number of employees and mandate contractors)

	Years ended December 31	
	Thousands of Euro (€)	
	2013	2012*
CONSOLIDATED INCOME STATEMENT		
CONTINUING OPERATIONS		
Sales	4.301	4.084
Gross sales	4.301	4.084
Cost of sales	-1.136	-905
Gross profit	3.165	3.179
Research and development expenses	-10.905	-13.264
Sales and marketing expenses	-3.416	-2.863
General and administrative expenses	-5.796	-5.924
Total operating charges	-21.252	-22.956
Other operating income	939	1.389
Operating Result	-16.013	-17.482
Interest income	11	35
Interest expenses	-45	-60
Foreign exchange differences	-354	-142
Profit/(Loss) before taxes	-16.401	-17.649
Income taxes	59	-1
Profit/(Loss) for the period from continuing operations	-16.342	-17.650
DISCONTINUED OPERATIONS		
Profit/(Loss) for the period from discontinued operations	-2.048	-2.743
Profit/(Loss) for the period	-18.390	-20.393
Basic (diluted) loss per share (EURO)	-0,16	-0,22
Basic (diluted) loss per share from continuing operations (EURO)	-0,14	-0,19
Cash and cash equivalents of continued operations	15.565	11.034
Employees and mandate contractors from continuing operations	56	61

* 2012 figures have been restated to present TiGenix BV as discontinued operations

Gross sales of EUR 4.3 million

ChondroCelect sales for the twelve months to December 31 2013 have grown 25% to EUR 4.3 million, compared to EUR 3.4 million in the same period of last year on a like-for-like basis. Revenues in 2013 have been mainly driven by sales in Belgium and in the Netherlands while additional growth is expected to be fueled by sales in the UK and in Spain where reimbursement was obtained during 2013.

Net loss for the period significantly reduced

The net loss for 2013 amounted to EUR 18.4 million compared to EUR 20.4 million in 2012. The reduced net loss in 2013 is a direct result of the reduced operating loss of the Group's continuing operations as well as of the reduced loss for the period by the wholly-owned subsidiary, TiGenix BV. In line with the decision taken during 2013 to sell this company, this is shown as discontinued operations.

EUR 18.5 million secured in private placements

In 2013, TiGenix raised a total of EUR 18.5 million through two private placements from domestic and international healthcare-specialised investors. The latest equity increase for EUR 12 million took place in November 2013 and was fully subscribed by Grifols through its wholly owned subsidiary Gri-Cel.

In addition to its ability to attract dilutive funding, TiGenix successfully secured in 2013 a total of EUR 2.7 million of non-dilutive funding from grants and soft loans.

Secured facility loan agreement for up to EUR 10 million in December

In December 2013, TiGenix announced the signing of a structured debt financing agreement of up to EUR 10 million with Kreos Capital, Europe's largest and leading provider of debt to high-growth companies. The loan can be drawn down in three tranches at the Company's discretion.

EUR 15.9 million cash & cash equivalents at year-end (including cash from discontinued operations)

At 31 December 2013, the Company had EUR 15.9 million cash in hand, not including the EUR 10 million available from the loan agreement signed with Kreos. Average monthly cash burn for the year has been reduced to EUR 1.1 million.

Outlook for the next 12 months

- The continued uptake of ChondroCelect will make it a cash flow positive asset during 2014
- Cx601: finalise the recruitment of the phase III trial
- Cx601: initiate the technology transfer process with US Contract Manufacturing Organisation (CMO) and submit the application for a Special Protocol Assessment (SPA) in the United States
- Cx611: development plan for new indications to be presented

Complete financial statements

The 2013 financial statements can be found in the investor section of our website www.tigenix.com

Conference call webcast

On March 11, at 14:00 CET/9 a.m. EDT, TiGenix will conduct a conference call webcast:

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+34 91 114 6582	Spain
+31 20 716 8295	Netherlands
+44 20 3427 1907	UK
+1 646 254 3366	USA
Confirmation code	7083606

The live webcast can be followed online via the link:

<http://www.media-server.com/m/p/ts5u7ida>

Following the business activities update and financial results presentation, participants will be able to ask questions. The press release and the slide presentation will be made available in the Newsroom/Events section of our website. A replay of the webcast will be available on our website 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 of clinical stage allogeneic adult stem cell programmes for the treatment of autoimmune and inflammatory diseases. TiGenix is based in 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 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.

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