



H1 2014 Business and Financial Update

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26 August 2014



Forward-Looking Statements

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Multiple product candidates in clinical development

Cx601 and Cx611 are our two key products in clinical development

Product ¹	Cell Type	Indication	Preclinical	Phase I	Phase II	Phase III	Market	
Cx601 (local)	allogeneic adipose-derived stem cells	complex perianal fistulas in Crohn's patients	Orphan Drug (EU)					
			Orphan Drug Filed (US)					
Cx611 (intravenous)	allogeneic adipose- derived stem cells	rheumatoid arthritis						
		severe sepsis						
Cx621 (intralymphatic)	allogeneic adipose- derived stem cells	autoimmune disorders						
ChondroCelect	characterised autologous chondrocytes	cartilage lesions of the knee	Partnered²					

¹ Covered by 24 patent families

² Distributed through Swedish Orphan Biovitrum (Sobi) and Finnish Red Cross Blood Systems

Business highlights H1 2014

- eASC¹ technology platform

- Cx601: patient recruitment in European Phase III study in complex perianal fistulas in Crohn's disease is 95% complete. Trial results expected in Q3 2015, allowing for filing in Europe for marketing authorisation in H1 2016
- Strategy for developing Cx601 for the US market confirmed
- Cx611: clinical development plan communicated and now in implementation

- ChondroSelect

- Strategic re-positioning of product completed through licensing of marketing and distribution rights, and sale of Dutch manufacturing facility
- Marketing authorisation renewed by European Medicines Agency (EMA)

¹expanded adipose-derived stem cells

Clinical development of Cx601

Progress with Phase III ADMIRE-CD² study

- Patient recruitment 95% complete
- Trial results expected earlier in Q3 2015, allowing for filing in Europe for marketing authorisation in H1 2016

Clear US strategy defined for Cx601

- **Positive Type B meeting held with FDA**
 - Confirmed adequacy of the existing non-clinical package to support an IND¹ filing for a US-based pivotal Phase III trial
 - Confirmed acceptability of using data from the ongoing ADMIRE-CD² Phase III study in Europe to support a biologic license application (BLA)
 - Reached agreement on key parameters of future US pivotal Phase III trial
- **Development plan for the US being implemented**
 - Selection of contract manufacturing organisation for technology transfer expected in Q3 2014
 - Application for special protocol assessment, submission expected Q4 2014
 - IND¹ application expected to be filed as soon as technology transfer finalised

¹ Investigational New Drug

² Adipose-Derived Mesenchymal stem cells for Induction of Remission in perianal fistulising Crohn's Disease

Clinical development of Cx611

Selecting the right indication

Key criteria

- Mechanism of action of eASCs
- Medical need
- Current and future treatment options
- Scientific Advisory Board

Early Rheumatoid Arthritis

- Induce and maintain low disease activity
- Target acute & inflammatory disease state
- Indication of activity evidenced in refractory patients in phase II clinical trial

Severe Sepsis

- Reduce high mortality despite current treatments
- Focus on both pro- and anti-inflammatory response
- Robust evidence of therapeutic efficacy in experimental animal models

ChondroCelect

Strategic re-positioning completed

Marketing and distribution rights licensed to Sobi

- Leading European specialty pharmaceutical company focused on niche disease areas
- Sobi will continue to market and distribute the product where it is currently available and has the rights to expand the product's availability in multiple additional territories
- 20% royalty on CC net sales (22% in year 1) and reimbursement of almost all CC expenses => CC becomes a cash-flow positive asset for TiGenix

Dutch manufacturing facility sold to PharmaCell

- Upfront payment of Euro 3.5 million, and final payment of Euro 0.75 million in 2017
- ChondroCelect will continue to be manufactured at the facility under a long-term manufacturing agreement

Financial highlights H1 2014

- Sales of ChondroCelect increased 16% to Euro 2.6 million compared to H1 2013, and are booked in Discontinued Operations
- Grants increased by 12%, showing the success of the Company in obtaining non-dilutive financing
- Loss for the period relating to continuing operations in line with same period last year
- Liquidity position of Euro 19.2 million at 30 June 2014

<i>Thousands of euros (€), except for share data (in euros)</i>	Period ended June 30	
	2014	2013
CONSOLIDATED INCOME STATEMENT		
CONTINUING OPERATIONS		
Revenues		
Royalties	-	-
Grants	821	736
Total revenues	821	736
Research and development expenses	-5.097	-5.314
General and administrative expenses	-2.859	-2.735
Total operating charges	-7.956	-8.049
Operating Loss	-7.135	-7.313
Financial income	25	5
Financial expenses	-369	-28
Foreign exchange differences	170	-38
Loss before taxes	-7.309	-7.374
Income taxes	-	42
Loss for the period from continuing operations	-7.309	-7.332
DISCONTINUED OPERATIONS		
Loss for the period from discontinued operations	-1.842	-1.505
Loss for the period	-9.151	-8.837
<i>Attributable to equity holders of TiGenix NV</i>	<i>-9.151</i>	<i>-8.837</i>
Basic (diluted) loss per share (EURO)	-0,06	-0,09
Basic (diluted) loss per share from continuing operations (EURO)	-0,05	-0,07
Basic (diluted) loss per share from discontinuing operations (EURO)	-0,01	-0,02

2013 figures have been restated for comparative purposes to present ChondroCelect as a discontinued operation

Outlook

Expectations for the next 12-18 months

- Complete patient recruitment in the Phase III study of Cx601 in complex perianal fistulas in Crohn's disease before the end of the year, and communicate trial results in Q3 2015
- Select contract manufacturing organisation (CMO) for the production of Cx601 in the US, after which TiGenix will begin technology transfer during H2 2014
- File for a Special Protocol Assessment (SPA) for Cx601 with the Food and Drug Administration (FDA) in the US by the end of 2014
- Start a mechanism of action trial of Cx611 in severe sepsis in early 2015, and complete it in Q3 2015
- Start patient recruitment for a Phase IIb study of Cx611 in early rheumatoid arthritis in Q3 2015

Q&A

