

## TiGenix gives business update and announces the full year 2009 financial results

**Leuven (BELGIUM) – March 16, 2010 – TiGenix (NYSE EURONEXT: TIG) gives an update of business activities and announces its financial results for the full year ending December 31, 2009.**

### Business Highlights

- ChondroCelect® approved in Europe and launch started
  - ChondroCelect® approved in EU as the first Advanced Therapy Medicinal Product
  - Commercial roll-out started, first pre-reimbursement patients treated
  - Pricing and reimbursement applications filed in key target markets
  - ChondroCelect trial results published in leading orthopedic journal
  - Post-approval commitments agreed with EMA
- Regulatory path for ChondroCelect in the US clarified
- Organization and infrastructure strengthened
  - Commercial and medical team further strengthened
  - New EU manufacturing facility secured, construction started
  - UK biomaterials company Orthomimetics acquired
- Pipeline and technology development progressing
  - Quality and ease of use of ChondroCelect product further increased
  - Development of proprietary stem cells platform progressing
  - Second approved product added to product portfolio
  - Proprietary biomaterials platform acquired

### Financial Highlights

- Operating loss decreased with 13% compared to 2008
- Cash and cash equivalents of EUR 24.7 million at the end of 2009
- Net proceeds of EUR 25.3 million raised in financing operations in 2009

*“2009 has been a ‘banner year’ for TiGenix. The European approval of ChondroCelect as the ‘First in Class’ in an exciting new area of medicine is a reward for more than 10 years of hard work and commitment of our team. Meanwhile we successfully introduced ChondroCelect in the first target markets. Through the acquisition of Orthomimetics, we added an additional commercial product to our pipeline, allowing us to leverage the European commercial launch and strengthening our leading position in the field of regenerative medicine.” said Gil Beyen, CEO of TiGenix. “In 2010 we will focus on obtaining reimbursement for our products in order to make them broadly available to patients throughout Europe. Further we will take further actions to obtain regulatory approval for ChondroCelect in the US and continue to strengthen our product pipeline with in-house and external programs.”*

## **BUSINESS UPDATE 2009**

### **ChondroCelect® approval and launch started**

#### *ChondroCelect® approved in EU as the first Advanced Therapy Medicinal Product*

Following the positive opinion in June from the Committee for Advanced Therapies (CAT) and the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) on the European Marketing Authorisation Application (MAA), TiGenix received on October 5 the long awaited European marketing authorisation for its lead product, ChondroCelect, from the European Commission.

ChondroCelect is the first cell-based product to obtain a central marketing authorization under the new Advanced-Therapy Medicinal Products (ATMP) legislation. This legislation, which was implemented in 2009, stipulates that all cell-based products need central EMA review and EU approval to be allowed on the market; other products currently on the market will lose their European market approval on 31<sup>st</sup> December 2012 unless they satisfy the clinical and regulatory requirements for EMA approval.

#### *Commercial roll-out started, first pre-reimbursement patients treated*

Shortly after the approval, the first commercial patient was treated (by Dr. Philipp Niemeyer and his team) at the Freiburg University Hospital in Germany. Meanwhile, patients have been treated in centers in all primary target markets, i.e. Germany, Belgium, the Netherlands and the United Kingdom.

These first “pre-reimbursement” commercial ChondroCelect patients have been treated under a variety of payment and reimbursement mechanisms, ranging from self-pay, private insurance, workers compensation, payment from hospital or primary care trust budgets in the UK and reimbursement by one of the German health insurance funds.

#### *Pricing and reimbursement applications filed in key target markets*

Reimbursement dossiers have been submitted in key target markets. Negotiations on pricing and reimbursement with the local health insurance authorities and payers are ongoing and are progressing as planned. We expect a gradual treatment uptake in the second half of the year as reimbursement decisions are confirmed in the target markets.

In Germany, ChondroCelect has been awarded “innovative new treatment method” status (“Neue Untersuchungs und Behandlungsmethode” or “NUB”) by the German Institute for the Hospital Remuneration System (InEK GmbH). The NUB status has been approved in thirty hospitals in Germany and gives these hospitals the right to negotiate reimbursement of ChondroCelect with their health insurance funds. Most of these negotiations are expected to take place in the second and third quarter of this year.

#### *ChondroCelect trial results published in leading journal*

In November 2009, the 3-year data of the ChondroCelect trial, entitled "Treatment of Symptomatic Cartilage Defects of the Knee: Characterized Chondrocyte Implantation Results in Better Clinical Outcome at 36 Months in a Randomized Trial Compared to Microfracture" by D. Saris, J. Vanlauwe et al. has been published in the American Journal of Sports Medicine, the official journal of the American Orthopaedic Society for Sports

Medicine (AOSSM), one of the highest ranked, peer-reviewed orthopaedic and sport sciences journals.

In July 2009, the earlier publication entitled “Characterized Chondrocyte Implantation Results in Better Structural Repair When Treating Symptomatic Cartilage Defects of the Knee in a Randomized Controlled Trial Versus Microfracture” by D. Saris, J. Vanlauwe et al. that appeared in the February 2008 issue of the ASJM was awarded with the prestigious Hughston Award.

### *Post-approval commitment agreed with EMA*

The post-approval commitments as specified in the risk management plan have been discussed and further refined in a scientific advice meeting with the EMA. The follow-up study fits in TiGenix’ strive to further support the evidence base and will allow to obtain the requested post-marketing data, including those for large lesions. Enrolment in this confirmatory study will start by the end of 2010.

### **Regulatory path for ChondroCelect in the US clarified**

In 2009 TiGenix had compiled a data package for discussion of the next steps towards the submission of a Biological License Application (BLA) for ChondroCelect in the US with the US Food and Drug Administration (FDA). In a meeting on Monday, March 15, the FDA requested an additional study before the filing of a Biologic License Application (BLA) and invited TiGenix to seek Special Protocol Assessment.

During the meeting, TiGenix has presented the protocol for the European follow-up study, to the FDA. The initial feedback on the proposed protocol has been positive and it is likely that the outline of the study can also be used for the US. The company will interact with the regulatory agencies to assess the possibility for alignment of the protocol for it to fit the combined purpose of the confirmatory trial in Europe and the additional study in the US, and decide on the steps forward.

### **Organization and infrastructure strengthened**

#### *Team strengthened*

The commercial core team to support the launch of ChondroCelect in Germany, the Netherlands, the United Kingdom and Belgium, is fully operational and most of the targeted orthopedic reference centers in these markets have been trained. This team will be reinforced in Scandinavia, Spain and France in order to support the roll-out in about 80 targeted reference centres across Europe.

Philippe Van Wilder joined TiGenix as Director Market Access, Pricing and Reimbursement to lead the pricing and reimbursement activities of the company. Prior to joining TiGenix Philippe was employed at the RIZIV/INAMI, the Belgian national reimbursement authority, where he headed the pharmaceutical reimbursement department. Before joining the RIZIV/INAMI, Philippe worked at Pfizer and GlaxoSmithKline in clinical development and clinical research functions. He holds a degree in industrial pharmacy from the University of Gent.

In September 2009, Koenraad Blot bvba was appointed Chief Medical Officer. In this role Koenraad is in charge of global clinical development of TiGenix pipeline products and medical affairs in support of the launch of the lead products. Prior to this, Koenraad was Chief Medical Officer at elbion, and Head of Clinical Development at Theratechnologies, where he championed the clinical development of tesamorelin, currently under FDA review. Koenraad started his career in the pharmaceutical industry at Pfizer Belgium in 1992 and held positions of increasing responsibility at Pfizer Headquarters (USA) and Pfizer Canada. Koenraad holds an MD from Ghent University and a diploma in tropical medicine from the Prince Leopold Institute for Tropical Medicine, Antwerp.

Following the the acquisition of Orthomimetics, Andrew Lynn assumed lead business development responsibilities at TiGenix in the role of Chief Business Officer. Andrew was founder and CEO of Orthomimetics Limited, leading the company to successful closure of Series A financing, European approval of the company's flagship product, and a successful sale to TiGenix in 2009. He was the recipient of the 2008 ACES Award for European entrepreneurship and was listed as a member of the 2009 MIT Technology Review TR35, an annual list of innovators in business and technology.

#### *New EU manufacturing facility secured, construction started*

In anticipation of the growing demand for ChondroCelect and the further expansion of the product pipeline, TiGenix has selected a building on the Chemelot Campus in Sittard-Geleen, the Netherlands, to locate its new cell expansion facility. The site is located close to TiGenix' headquarters in Leuven and centrally in its key European markets, in a region that is strong in distribution and (bio)logistics and that is highly committed to develop as a transnational centre of excellence for life sciences and regenerative medicine. The refurbishing of the building has started and is progressing according to plan to become operational by mid 2011.

The company secured the necessary funding to set-up the new GMP manufacturing facility through a private placement for a total amount of EUR 5.4 million, subscribed by NV Industriebank LIOF, Particon BV, Limburg Ventures BV and LRM NV.

#### *UK biomaterials company Orthomimetics acquired*

In December 2009, TiGenix acquired UK-based Orthomimetics. Through the acquisition of Orthomimetics, TiGenix added a second commercial product to its pipeline, acquired a leading biomaterials platform and strengthened the talent pool of the company by adding 9 highly qualified people to the team.

### **Product pipeline and technology development progressing**

#### *Quality and ease of use of ChondroCelect product further increased*

A further step in improving the ease of use and quality of ChondroCelect was the development of a proprietary biopsy tool, the ChondroCelect Harvester™, allowing the surgeon to harvest a cartilage biopsy in an easy and consistent manner. This device was developed in close collaboration with Dr. Yves Fortems and the medical device company MedInvents. The ChondroCelect Harvester™ has received CE Mark approval.

ChondroCelect has been approved for use with a biodegradable collagen membrane to seal the defect. The use of the collagen membrane significantly facilitates the implantation procedure and opens the perspective to further improvements. In collaboration with its clinical advisors, TiGenix is assessing the use of different scaffolds, including the Orthomimetics' collagen scaffolds for the implantation of ChondroCelect.

### *Development of proprietary stem cells platform progressing*

The company is continuing the development work on a stem cells based product for meniscus repair, as part of an IWT grant. The development of a proprietary stem cell platform aims at broadening the product offering to other musculoskeletal tissues and to move to allogeneic approaches. The researchers are also investigating new targeted therapies that can be used to modulate certain biological pathways with the objective to prevent or delay the progression of osteoarthritis.

### *Second approved product added to product portfolio*

Orthomimetics' lead product ChondroMimetic is an off-the-shelf, resorbable implant for the minimally invasive repair of small osteochondral (cartilage and underlying bone) defects. Small osteochondral defects represent an important medical need that is currently not covered by TiGenix' products. ChondroMimetic forms an excellent fit with ChondroCelect, since both products target the same customer base in complementary indications. The product has received European market approval (CE-Mark) and will be launched on the European market in the second half of this year.

### *Proprietary biomaterials platform acquired*

The acquisition of Orthomimetics also broadens TiGenix biomaterials expertise and allows the company to broaden its development focus towards regenerative medicine products for meniscus, tendon, and ligaments. Orthomimetics' technological advantage lies in the patent-protected ability to combine three natural biomaterials, collagen, glycosaminoglycans and calcium phosphate, into bioresorbable tissue regeneration scaffolds. The combination of Orthomimetics' biomaterials know-how with TiGenix' expertise in developing cell-based therapeutic products creates a unique platform from which innovative future combination products can be developed.

## **FINANCIAL RESULTS FOR 2009**

### **The operating loss decreased with 13% compared to 2008**

Although the first commercial sales of ChondroCelect were realized at the end of 2009, the revenues of EUR 1.0 million mainly consist of grant funding for meniscus and osteoarthritis research.

Total research and development costs for 2009 were EUR (8.1) million compared with EUR (10.0) million for 2008. The decrease of 19% is mainly attributable to the capitalization of the development cost for ChondroCelect as of July 2009 – after obtaining a positive CHMP opinion – and a decrease in subcontracting research and development activities.

Selling, general and administrative costs increased by 7% to EUR (7.3) million. This increase is fully related to an increase of the selling cost in anticipation of the commercial launch of ChondroCelect and Chondromimetic in 2010.

This resulted in a net operating loss of EUR (14.4) million, a decrease of 13% compared to 2008.

### **Cash and cash equivalents of EUR 24.7 million at the end of 2009**

The operating loss of EUR (14.4) million, adjusted for the non-cash item of EUR 2.0 million, the capitalized development costs for ChondroCelect of EUR (0.8) million and other adjustments of EUR (0.1) million resulted in a net cash used in operating activities of EUR (13.3) million.

Net cash used in investing activities amounted to EUR (12.4) million. TiGenix acquired Orthomimetics Ltd. (currently TiGenix Ltd.) and started the construction and refurbishment of the new cell expansion facility in the Netherlands for a total amount of EUR (13.0) million. These investments were partially compensated by the EUR 0.7 million net interests received on the cash and cash equivalents.

The net cash used in operating and investing activities was almost completely compensated with the EUR 25.3 million of additional cash raised by share issues.

This resulted in a net decrease in cash and cash equivalents of EUR 0.5 million in 2009.

### **Net proceeds of EUR 25.3 million raised in financing operations in 2009**

In 2009, TiGenix completed two financing rounds raising a total amount of EUR 13.1 million. The proceeds of the June financing operation are dedicated to the construction and refurbishment of the new cell expansion facility in the Netherlands while the proceeds of the December financing operation will be used to support the launch of ChondroCelect and Chondromimetic.

At the end of November 2009, the acquisition of Orthomimetics Ltd. was closed in an all share deal. The initial consideration was EUR 12.9 million and the outstanding balance of EUR 3.4 million will be settled in 2010 and 2012.

These financing operations were associated with issue costs totaling EUR (0.7) million.

At December 31, 2009, TiGenix had a sound balance sheet structure with cash and cash equivalents of EUR 24.7 million.

## OUTLOOK

- ChondroCelect pricing and reimbursement agreements in key target countries
- European Launch of Chondromimetic
- Publication of 5 year follow-up data from TIGACT01 study
- Start of patient enrollment for ChondroCelect confirmatory study
- Start of clinical development of MeniscoCelect

**CONSOLIDATED INCOME STATEMENT**  
**FOR 12 MONTHS ENDED DECEMBER 31, 2009 AND 2008**

Thousands of Euro (€)	Years ended December 31	
	2009	2008
<b>CONSOLIDATED INCOME STATEMENT</b>		
Sales	46	0
Other revenues	986	321
<b>Revenues</b>	<b>1,032</b>	<b>321</b>
Research and development expenses	8,114	9,975
Selling, general and administrative expenses	7,316	6,851
Other operating income	0	0
Other operating expenses	0	0
<b>Total operating charges</b>	<b>15,430</b>	<b>16,825</b>
<b>Operating Result (EBIT*)</b>	<b>(14,398)</b>	<b>(16,505)</b>
Financial result	300	1,340
<b>Profit/(Loss) before taxes</b>	<b>(14,098)</b>	<b>(15,165)</b>
Income taxes	0	0
<b>Net Profit/(Loss)</b>	<b>(14,098)</b>	<b>(15,165)</b>
<b>Basic loss per share</b>	<b>(0.55)</b>	<b>(0.62)</b>

**STATEMENT OF COMPREHENSIVE INCOME**  
**FOR 12 MONTHS ENDED DECEMBER 31, 2009 AND 2008**

Thousands of Euro (€)	Years ended December 31	
	2009	2008
<b>CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME</b>		
Net Profit/(Loss)	(14,098)	(15,165)
Currency translation differences	107	(124)
<b>Other comprehensive income/(loss)</b>	<b>107</b>	<b>(124)</b>
<b>Total comprehensive income/(loss)</b>	<b>(13,991)</b>	<b>(15,289)</b>
Attributable to:		
• <i>Equity holders of TiGenix NV</i>	(13,991)	(15,289)

\* EBIT: Earnings before interest and taxes

**CONSOLIDATED STATEMENT OF FINANCIAL POSITION**  
**AT DECEMBER 31, 2009 COMPARED TO DECEMBER 31, 2008**

	Years ended December 31	
	Thousands of Euro (€)	
	2009	2008
<b>ASSETS</b>		
Intangible assets	20,562	441
Tangible assets	2,856	2,484
Other non current assets	130	34
<b>Non-current assets</b>	<b>23,548</b>	<b>2,959</b>
Inventories	156	158
Receivables	1,315	792
Cash and cash equivalents	24,745	25,162
Deferred charges & Accrued income	282	335
<b>Current assets</b>	<b>26,497</b>	<b>26,447</b>
<b>TOTAL ASSETS</b>	<b>50,045</b>	<b>29,406</b>

	Years ended December 31	
	Thousands of Euro (€)	
	2009	2008
<b>EQUITY AND LIABILITIES</b>		
Share capital	24,956	19,484
Share premium	72,480	52,633
Shares to be issued	3,377	0
Accumulated profit/(loss)	(49,045)	(33,881)
Result of the year	(14,098)	(15,165)
Share-based compensation	3,509	2,369
Translation reserves	21	(86)
<b>Equity attributable to equity holders</b>	<b>41,199</b>	<b>25,355</b>
<b>Total equity</b>	<b>41,199</b>	<b>25,355</b>
Subordinated loan	260	391
Financial loan	520	600
Finance lease obligations	12	40
Deferred tax liability	3,886	0
<b>Non-current liabilities</b>	<b>4,679</b>	<b>1,031</b>
Current portion of subordinated loan	130	0
Current portion of financial loan	80	80
Current portion of finance lease obligation	28	28
Trade payables	2,045	1,498
Other current liabilities	1,884	1,414
<b>Current liabilities</b>	<b>4,167</b>	<b>3,020</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>50,045</b>	<b>29,406</b>

**CONSOLIDATED STATEMENT OF CASH FLOWS**  
**FOR 12 MONTHS ENDED DECEMBER 31, 2009 AND 2008**

Thousands of Euro (€)	Years ended December 31	
	2009	2008
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
<b>Operating Result</b>	<b>(14,398)</b>	<b>(16,505)</b>
Depreciation, amortisation and impairment results	909	697
Capitalized development costs	(781)	0
Share-based compensation	1,140	931
Other financial result	(170)	102
Interest paid	(20)	(47)
Income taxes	0	0
Increase/(decrease) in Trade payables	65	151
Increase/(decrease) in Other current liabilities	(61)	507
(Increase)/decrease in Inventories	2	(76)
(Increase)/decrease in Receivables	139	(300)
(Increase)/decrease in Deferred charges & Accrued income	(76)	(61)
<b>Total Adjustments</b>	<b>1,146</b>	<b>1,904</b>
<b>Net cash provided by/(used in) operating activities</b>	<b>(13,252)</b>	<b>(14,601)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Interest received	656	1,490
Purchase of tangible assets	(428)	(1,446)
Purchase of intangible assets	(19)	(247)
Acquisition of subsidiaries, net of cash acquired	(12,595)	0
<b>Net cash provided by/(used in) investing activities</b>	<b>(12,387)</b>	<b>(203)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Payments cash deposits	(96)	11
Payments on financial loan	(80)	(80)
Payments on leases	(28)	(24)
Proceeds of subordinated loan	0	0
Proceeds of financial loan	0	0
Proceeds from long-term leases	0	82
Proceeds from issuance of shares (net of issue costs)	25,318	999
<b>Net cash provided by/(used in) financing activities</b>	<b>25,114</b>	<b>989</b>
<b>Net increase/(decrease) in cash and cash equivalents</b>	<b>(524)</b>	<b>(13,815)</b>
Cash and cash equivalents at beginning of year	25,162	39,101
Effect on exchange rate changes	107	(124)
<b>Cash and cash equivalents at end of period</b>	<b>24,745</b>	<b>25,162</b>

**CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS' EQUITY**  
**DURING THE 12 MONTHS ENDED DECEMBER 31, 2009 AND 2008**

Thousands of Euro (€)	Attributable to equity holders of the Company								
	Numbers of shares	Issued capital	Issuance Cost	Share premium	Shares to be issued	Retained loss	Share-based compensation	Translation reserves	Total Equity
Balance at Dec. 31, 2007	23,851,079	23,288	(4,410)	52,240		(33,881)	1,438	38	38,714
Issuance of shares	713,410	713	(108)	393					999
Share-based compensation							931		931
Total comprehensive income						(15,165)		(124)	(15,289)
Balance at Dec. 31, 2008	24,564,489	24,002	(4,518)	52,633	0	(49,045)	2,369	(86)	25,355
Issuance of shares	6,301,679	6,176	(704)	19,847					25,318
Shares to be issued*					3,377				3,377
Share-based compensation							1,140		1,140
Total comprehensive income						(14,098)		107	(13,991)
Balance at Dec. 31, 2009	30,866,168	30,178	(5,222)	72,480	3,377	(63,144)	3,509	21	41,199

\* as part of the consideration in business combinations

## **Conference call webcast**

On March 17, at 11:30 Central European Time (CET), the management of TiGenix will conduct a conference call webcast.

To participate in the conference call, please dial-in at:

**+32 2 401 53 09 (Belgium)**  
**+44 20 30432 462 (UK)**

The online live webcast can be followed via the link:

[http://pulse.companywebcast.nl/Playerv1\\_0/default.aspx?id=3694](http://pulse.companywebcast.nl/Playerv1_0/default.aspx?id=3694)

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, please contact**

Gil Beyen  
Chief Executive Officer  
+32 16 39 60 60

Kris Motmans  
Corporate Communications  
investor@tigenix.com

## **About TiGenix**

*Based in Leuven, Belgium, TiGenix NV (NYSE Euronext Brussels: TIG) is a biomedical company that focuses on 'Regenerating Motion'. The company is exploiting the power of Regenerative Medicine to develop durable treatments, validated through controlled clinical trials, for damaged and osteoarthritic joints.*

*TiGenix is developing a portfolio of products that address specific musculoskeletal problems. The lead indication among these is cartilage damage, which is a debilitating affliction affecting the mobility and functioning of patients. Western societies are characterised by ageing populations that place an increasing emphasis on high quality of life and life-long mobility, and, as such, cartilage problems represent a large and growing unmet medical need. Current therapies do not provide satisfying, long-term durable repair and TiGenix therefore believes there is a need for more effective treatments for cartilage damage.*

## **About ChondroCelect®**

*ChondroCelect®, the company's lead product for cartilage regeneration in the knee, is the first cell-based product that successfully completed the entire development track from research, over clinical development to central European registration as a medicinal product. ChondroCelect® consists of characterised cultured chondrocytes derived from the patient's own cartilage and is used for autologous chondrocyte implantation (ACI), a surgical procedure to treat cartilage defects. Cartilage defects of the knee are very common, and the spontaneous healing capacity of cartilage is limited. On October 5, 2009 ChondroCelect® received European marketing authorisation as the first Advanced Therapy Medicinal Product, indicated for repair of single symptomatic cartilage defects of the femoral condyle of the knee (International Cartilage Repair Society [ICRS] grade III or IV) in adults.*

## **Forward-looking information**

*This document contains 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 recognized 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.*