

## Business Update and Financial Results for First Half of 2008

Leuven (BELGIUM) – August 28, 2008 – TiGenix (NYSE Euronext: TIG) gives an update of the business activities and announces the financial results for the half year ending June 30, 2008.

### Business Highlights

- ChondroCelect (TGX001) three-year clinical data confirm clinical benefit
- EMEA registration procedure ongoing, CHMP opinion anticipated by end of 4<sup>th</sup> quarter 2008
- Team strengthened in anticipation of the ChondroCelect launch
- Pipeline development progressing

### Financial Highlights

- Net loss of EUR 7.4 million
- Cash and cash equivalents of EUR 32.3 million

### Key Figures

<i>Thousands of Euro (€)</i>	<b>June 30</b>	<b>June 30</b>
<i>According to IFRS and based on limited review procedures by BDO</i>	<b>2008</b>	<b>2007</b>
<b>Revenues</b>	<b>129</b>	<b>78</b>
Research and development expenses	5,073	3,773
Selling, general and administrative expenses	2,986	2,321
Other operating income	0	0
Other operating expenses	0	0
<b>Operating Result (EBIT)</b>	<b>(7,930)</b>	<b>(6,016)</b>
Financial result	529	486
<b>Profit/(Loss) before taxes</b>	<b>(7,402)</b>	<b>(5,530)</b>
Income taxes	(1)	0
<b>Net Profit/(Loss)</b>	<b>(7,403)</b>	<b>(5,530)</b>
<b>Net Profit/(Loss) per share – basic</b>	<b>(0.30)</b>	<b>(0.23)</b>
Number of outstanding shares – basic	24,454,989	23,851,079
<b>Cash and cash equivalents</b>	<b>32,344</b>	<b>45,165</b>

## **BUSINESS UPDATE FIRST HALF 2008**

### **ChondroCelect (TGX001) three-year clinical data confirm clinical benefit**

A key event in the first half of this year was the announcement in April of the three-year follow-up data of the pivotal ChondroCelect (TGX001) trial at the annual meeting of the Arthroscopy Association of North America (AANA). The three-year follow-up data further strengthen the pivotal trial results and demonstrate significantly better structural regeneration and clinical outcome for the ChondroCelect treated patients as compared to the control group that received microfracture treatment. It was also demonstrated that the ChondroCelect group showed a lower failure rate than the microfracture group. Early treatment after onset of symptoms, as well as the quality of the cell product, measured by a ChondroCelect Score, are further important factors in supporting superior clinical outcome. These conclusions are corroborated by extensive statistical analysis of the clinical data and the MRI results that were presented at the annual conference of the European Society of Sports Traumatology, Knee Surgery and Arthroscopy (ESSKA) conference in May.

### **EMEA procedure ongoing, CHMP opinion anticipated by end of 4<sup>th</sup> quarter 2008**

The registration procedure for ChondroCelect (TGX001) at EMEA is on track and TiGenix expects the opinion of the Committee for Medicinal Products for Human Use (CHMP) by the end 4<sup>th</sup> quarter of this year. As ChondroCelect (TGX001) is the first cell therapy product that has been filed for central marketing authorisation in Europe, the review time has been used to the full extent in order to evaluate the product in all details adding ca 2 months to the anticipated timelines. Provided a positive CHMP opinion, TiGenix expects formal marketing approval in the 1<sup>st</sup> quarter of 2009, after which the product will be gradually rolled out in selected European countries.

The preparation of the Biologics License Application (BLA) to obtain product registration in the US is ongoing, including the manufacturing comparability testing between the European and US facilities. The company intends to apply for a pre-BLA meeting after the CHMP opinion and to file the BLA to the US Food and Drug Administration (FDA) in early 2009.

### **Team strengthened in anticipation of the ChondroCelect launch**

TiGenix has further strengthened its organisation. In order to accommodate the expansion, the company moved to a new office and R&D building in Leuven. The new facility has approximately 2,200m<sup>2</sup> of office and lab space. TiGenix has an option on an additional 700m<sup>2</sup> of space for the expansion of the production in Europe.

In anticipation of the ChondroCelect launch, the commercial team has been expanded with regional business heads for Germany and the United Kingdom. Patrick Haelterman has been hired as the new VP Marketing and Sales Europe. Patrick has close to 20 years experience in the medical device industry and held several senior commercial and management positions at Lilly, Guidant and Abbott. As Area Manager Nordics, Central and Eastern Europe at Abbott Vascular International he had P&L responsibility for 23 countries and was responsible for setting up operations in Russia and Hungary. François Meurgey,



who was ad interim in charge of Marketing and Sales, will continue to provide support in the commercial development, mainly in the US.

### **Pipeline development progressing**

TGX/FAB002 is a 3D combination product combining ChondroCelect (TGX001) with Hyalograft C, a biocompatible and biodegradable three-dimensional matrix, developed by Fidia Advanced Biopolymers (FAB). In September of last year a Pre-IND meeting was held with the FDA to discuss the development plan for the combination product. Based on the input received, the company has initiated a number of formulation studies. The outcome of these studies will form the basis of the IND (Investigational New Drug) application for a phase II study in the US. TiGenix intends to file the IND application in the 1<sup>st</sup> quarter of 2009.

In the meantime, TiGenix is pursuing the development work on its meniscus repair and adult stem cell programs according to plan.

## **FINANCIAL UPDATE FIRST HALF 2008**

### **Net loss of EUR 7.4 million**

The net loss for the first six months of 2008 amounted to EUR 7.4 million compared to EUR 5.5 million in the same period of 2007. This 34% increase primarily reflects the costs related to the strengthening of the team at all levels, the operational expansion in the manufacturing, the preclinical efforts for TGX002 and to the continuous efforts with respect to the MAA filing in Europe.

Total research and development expenses for the first half of 2008 were EUR 5.1 million compared with EUR 3.8 million for the first half of 2007. This increase of 34% is mainly attributable to activities associated with the comparability testing in manufacturing and the regulatory filing of the MAA at EMEA for ChondroCelect and with the preclinical development of TGX002 and TGX003.

Total selling, general and administrative expenses for the first half of 2008 were EUR 3.0 million compared with EUR 2.3 million for the first half of 2007. This increase of 29% is mainly due to the costs related to the preparation of the ChondroCelect launch in Europe, the pricing and reimbursement file for ChondroCelect, together with an increase in personnel costs in marketing and sales and various administrative functions.

### **Cash and cash equivalents of EUR 32.3 million**

The net decrease in cash and cash equivalents for the first half of 2008 was EUR 6.9 million.

The net cash used in operating activities of EUR 7.1 million consists of the operating result of EUR (7.9) million and total adjustments of EUR 0.8 million. The total adjustments are non-cash items of EUR 0.8 million, other financial result of EUR (0.2) million and changes in working capital of EUR 0.2 million.

The net cash used in investing activities was EUR 0.4 million. The cash used for investments in tangible and intangible assets of EUR 1.1 million, mainly the new R&D labs and office, was partially compensated by the interests received on the cash and cash equivalents.

The net cash provided by financing activities of EUR 0.7 million mainly consists of the net proceeds from the exercise of warrants.

The cash burn over the next 6 to 12 months is expected to increase as a function of the launch activities for the lead product ChondroCelect and the preparation of the BLA filing in the US. A possible decision on an investment in a European cell production facility is under review.

On June 30 2008, TiGenix had a strong balance sheet with cash and cash equivalents of EUR 32.3 million.

## OUTLOOK

- CHMP opinion for ChondroCelect
- Pre-BLA meeting and filing of BLA for ChondroCelect in the US
- Approval and launch of ChondroCelect in selected European countries
- IND application for TGXFAB-002 phase II trial in the US
- Expansion of the cell manufacturing capacity in Europe

## CONFERENCE CALL

Today, August 28 at 11:30 Central European Time (10:30 GMT), the management of TiGenix will host a public conference call and web presentation.

To participate in the conference call, please register at:

**+32 2 404 03 34**

The web presentation can be followed at:

**<https://www.anywhereconference.com>**

**Web login: 105241151**

**PIN Code: 47958560**

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

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

The conference call will be recorded. A replay will be available a couple of hours after the call and is accessible at:

**Access Number: +32 2 401 89 89**

**Conference Reference: 241151#**

### **For more information, please contact**

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**CONSOLIDATED INCOME STATEMENT**  
**FOR SIX MONTHS ENDED JUNE 30 2008 AND 2007**

<i>Thousands of Euro (€)</i>	<b>June 30</b>	<b>June 30</b>
<i>According to IFRS and based on limited review procedures by BDO</i>	<b>2008</b>	<b>2007</b>
Sales	0	0
Other revenues	129	78
<b>Revenues</b>	<b>129</b>	<b>78</b>
Research and development expenses	5,073	3,773
Selling, general and administrative expenses	2,986	2,321
Other operating income	0	0
Other operating expenses	0	0
<b>Total operating charges</b>	<b>8,060</b>	<b>6,094</b>
<b>Operating Result (EBIT)</b>	<b>(7,930)</b>	<b>(6,016)</b>
Financial result	529	486
<b>Profit/(Loss) before taxes</b>	<b>(7,402)</b>	<b>(5,530)</b>
Income taxes	(1)	0
<b>Net Profit/(Loss)</b>	<b>(7,403)</b>	<b>(5,530)</b>
<b>Net Profit/(Loss) per share – basic</b>	<b>(0.30)</b>	<b>(0.23)</b>
Number of outstanding shares – basic	24,454,989	23,851,079

**CONSOLIDATED BALANCE SHEET**  
**AT JUNE 30 2008 COMPARED TO DECEMBER 31 2007**

<b>ASSETS</b>	<i>Thousands of Euro (€)</i>	<b>June 30</b>	<b>December 31</b>
<i>According to IFRS and based on limited review procedures by BDO</i>		<b>2008</b>	<b>2007</b>
Intangible assets		513	474
Tangible assets		2,269	1,374
Other non current assets		46	46
<b>Non-current assets</b>		<b>2,828</b>	<b>1,894</b>
Stock		60	81
Receivables		996	523
Cash and cash equivalents		32,344	39,101
Deferred charges & Accrued income		369	448
<b>Current assets</b>		<b>33,769</b>	<b>40,153</b>
<b>TOTAL ASSETS</b>		<b>36,598</b>	<b>42,047</b>

<b>EQUITY AND LIABILITIES</b>	<i>Thousands of Euro (€)</i>	<b>June 30</b>	<b>December 31</b>
<i>According to IFRS and based on limited review procedures by BDO</i>		<b>2008</b>	<b>2007</b>
Share capital		19,417	18,879
Share premium		52,409	52,240
Accumulated profit/(loss)		(33,881)	(21,912)
Result of the year		(7,403)	(11,969)
Share-based compensation		1,902	1,438
Translation Reserves		133	38
<b>Equity attributable to equity holders</b>		<b>32,578</b>	<b>38,714</b>
<b>Total equity</b>		<b>32,578</b>	<b>38,714</b>
Subordinated loan		391	391
Financial loan		640	680
Finance lease obligations		4	4
<b>Non-current liabilities</b>		<b>1,035</b>	<b>1,075</b>
Current portion of lease debt		0	4
Current portion of financial loan		80	80
Trade payables		1,280	1,267
Other current liabilities		1,625	907
<b>Current liabilities</b>		<b>2,984</b>	<b>2,258</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>36,598</b>	<b>42,047</b>

**CONSOLIDATED STATEMENT OF CASH FLOWS**  
**FOR SIX MONTHS ENDED JUNE 30 2008 AND 2007**

<i>Thousands of Euro (€)</i>	<b>June 30</b>	<b>June 30</b>
<i>According to IFRS and based on limited review procedures by BDO</i>	<b>2008</b>	<b>2007</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Operating Result	(7,930)	(6,016)
Depreciation, amortization and impairment results	294	163
Share-based compensation	464	219
Other financial result	(181)	(18)
Income taxes	(1)	0
Increase/(decrease) in Trade payables	(110)	1,209
Increase/(decrease) in Other current liabilities	717	(256)
(Increase)/ decrease in Stock	21	(75)
(Increase)/ decrease in Receivables	(472)	(73)
(Increase)/ decrease in deferred charges & accrued income	78	(360)
Total Adjustments	810	809
<b>Net cash provided by/(used in) operating activities</b>	<b>(7,120)</b>	<b>(5,207)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Interest received	733	505
Interest paid	(23)	(1)
Purchase/sale of tangible assets	(999)	(859)
Purchase of intangible assets	(105)	(112)
<b>Net cash provided by/(used in) investing activities</b>	<b>(395)</b>	<b>(467)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Payments cash deposits	(1)	(5)
Payments of financial loan	(40)	0
Payments on long-term leases	0	0
Payments on short-term leases	(4)	(4)
Proceeds of subordinated loan	0	0
Proceeds of financial loan	0	400
Proceeds from long-term leases	0	0
Proceeds from issuance of shares (net of issuance cost)	707	42,722
<b>Net cash provided by/(used in) financing activities</b>	<b>662</b>	<b>43,113</b>
<b>Net increase/(decrease) in cash and cash equivalents</b>	<b>(6,853)</b>	<b>37,439</b>
Cash and cash equivalents at beginning of year	39,101	7,738
Effect on exchange rate changes	96	(12)
<b>Cash and cash equivalents at end of period</b>	<b>32,344</b>	<b>45,165</b>

## CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS' EQUITY CHANGES DURING THE SIX MONTHS ENDED JUNE 30 2008

<i>Thousands of Euro (€)</i>	Attributable to equity holders of the Company							Total Equity
	Number of shares	Issued capital	Issuance cost	Share premium	Retained loss	Share- based compen- sation	Trans- lation reserves	
<b>Balance at 31/12, 2007</b>	<b>23,851,079</b>	<b>23,288</b>	<b>(4,410)</b>	<b>52,240</b>	<b>(33,881)</b>	<b>1,438</b>	<b>38</b>	<b>38,714</b>
Issuance of shares	603,910	604	(66)	169				707
Net Profit/(Loss)					(7,403)			(7,403)
Share-based compensation						464		464
Translation reserves							96	96
<b>Balance at 30/06, 2008</b>	<b>24,454,989</b>	<b>23,892</b>	<b>(4,475)</b>	<b>52,409</b>	<b>(41,283)</b>	<b>1,902</b>	<b>133</b>	<b>32,578</b>

### STATUTORY AUDITOR'S LIMITED REVIEW REPORT

We have performed a limited review of the consolidated balance sheet as of June 30, 2008, the consolidated income statement and the cash flow statement (jointly the "interim financial information") of TiGenix NV for the six month period ended June 30, 2008. This interim financial information has been prepared under the responsibility of the Board of Directors.

Our examination has been conducted in accordance with the recommendation of the Institute of Company Auditors (Instituut der Bedrijfsrevisoren/Institut des Réviseurs d'Entreprises) with regard to limited review procedures. Therefore, our review consisted mainly of the examination, comparison and discussion of the financial information. As a consequence, our review is substantially less in scope than an audit conducted in accordance with generally accepted auditing standards.

Based on our limited review, no elements or facts have come to our attention that cause us to believe that the interim financial information for the six month period ended June 30, 2008 is not prepared in accordance with legal and regulatory requirements and the recognition and measurement criteria of IFRS as adopted by the European Union."

Zaventem, August 25, 2008

BDO Atrio Réviseurs d'Entreprises Soc. Civ. SCRL  
Statutory Auditor  
Represented by Luc Annick

## **About TiGenix**

*TiGenix NV (NYSE Euronext: TIG) is a late-stage biomedical company that focuses on innovative local treatments for damaged and osteoarthritic joints. The Company is exploiting the power of regenerative medicine to develop durable treatments, validated through controlled clinical trials, for these indications. Based in Leuven, Belgium, TiGenix was founded as a spin-off from the Katholieke Universiteit Leuven and the Universiteit Gent.*

*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.*

## **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 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.*