TiGenix

DEFINING THE CUTTING EDGE IN REGENERATIVE MEDICINE

**PRESS RELEASE**
**AUGUST 30, 2007**

# TiGenix - Business Update and Financial Results for First Half of 2007

**Leuven (BELGIUM) – August 30, 2007 – TiGenix (EURONEXT: TIG) gives an update of its business activities and announces its financial results for the half year ending June 30, 2007.**

## Business Highlights

- Successful completion of ChondroCelect pivotal phase III trial
- ChondroCelect enters registration phase
- Strategic alliance with Fidia Advanced Biopolymers
- Next generation ChondroCelect 3D (TGX002) development on track
- US manufacturing facility acquired and team in place
- Evolving regulatory environment confirms TiGenix development strategy

## Financial Highlights

- EUR 46 million raised in a successful Euronext IPO
- Results and net use of cash in line with expectations
- Cash and cash equivalents at EUR 45 million

"*The first half of 2007 has clearly been crucial for TiGenix. Not only did we achieve a number of critical business milestones, we also realized one of the most successful European biotech IPOs. By having delivered on the first IPO promises we have demonstrated that we have built a strong basis for our future growth.*" said Gil Beyen, CEO of TiGenix

TiGenix

DEFINING THE CUTTING EDGE IN REGENERATIVE MEDICINE

# BUSINESS UPDATE FIRST HALF 2007

## Successful completion of ChondroCelect pivotal phase III trial

In February, TiGenix announced positive Phase III results of a landmark trial comparing ChondroCelect to microfracture, which is a current standard of care for cartilage defects in the knee. This multi-centre prospective randomized controlled trial, in which a total of 118 patients have been treated, was designed to assess structural repair and improvement of clinical outcome. At 12 and 18 months, both structural and clinical primary endpoints were met, indicating that ChondroCelect has the potential to significantly increase the success rate of the cartilage regeneration process.

*Next milestones:*
- Publication of Phase III results in a peer reviewed orthopaedic journal
- Communication of long-term clinical data

## ChondroCelect enters registration phase

In June, TiGenix submitted the Marketing Authorization Application (MAA) for ChondroCelect to the European Medicines Agency (EMEA). TiGenix expects the first feedback from the European regulators in the 4$^{th}$ quarter of this year and that the full approval process may be completed in the second half of 2008.

Upon successful approval ChondroCelect will be the first cell therapy product for cartilage regeneration to receive central marketing authorization in all 27 EU member states as well as in Norway, Iceland and Lichtenstein.

In order to prepare the European commercial launch of ChondroCelect, the Company has been expanding its sales and marketing team as well as the key opinion leader network. TiGenix is also evaluating different options to increase the cell production capacity in Europe. A decision in this respect will be made before the end of the year.

TiGenix intends to file the Biologics License Application (BLA) to the US Food and Drug Administration (FDA) in 2008. Meanwhile, the required manufacturing comparability testing (between the European and US facilities) should have been performed and additional long-term (3 year) follow-up data should be available to support the clinical benefit of ChondroCelect.

*Next milestones:*
- Feedback from EMEA on MAA filing
- Decision on expansion of production capacity in Europe
- Filing of BLA for ChondroCelect
- Approval and launch of ChondroCelect in Europe

## Strategic alliance with Fidia Advanced Biopolymers

In January of this year, TiGenix entered into a strategic partnership with Fidia Advanced Biopolymers (FAB) for the development and commercialization of a new generation of cell based products for cartilage regeneration. The lead product in this partnership, ChondroCelect 3D (TGX002), combines ChondroCelect with FAB's Hyalograft C, a more easily handled scaffold (with adhesive properties) that can be applied through arthroscopic surgery, which would make the ChondroCelect implantation procedure more user friendly for the surgeon and less invasive for the patient.

**Next generation ChondroCelect 3D (TGX002) development on track**

In preparation of the clinical trials for this product in the US and in Europe, a dedicated team has been established, including a number of senior hires. Discussions on the development plan are currently ongoing with the regulatory authorities with the aim at commencing the clinical development in the first half of 2008. A pre-IND meeting with the US FDA is scheduled.

*Next milestones::*
- Finalize clinical development plan
- Submit Investigational New Drug (IND) application for a clinical trial in the US

**US manufacturing plant acquired and team in place**

In anticipation of the BLA filing for ChondroCelect and in view of manufacturing ChondroCelect-3D for use in the US clinical trial, TiGenix acquired a cell expansion facility and installed a US-based manufacturing team. The facility is located in Memphis, Tennessee and has approximately 1,500 m² fully equipped and ready-to-use GMP space for cell culture and an additional 2,000 m² of expansion space. For the management of the facilities, TiGenix has set-up a US joint venture with Cognate Bioservices. Both companies will use parts of the facility for their respective cell production activities.

A manufacturing team, consisting of a Head of Manufacturing and 5 manufacturing and QA/QC associates was recruited and has started to prepare the plant for the upcoming manufacturing operations.

*Next milestones:*
- Complete manufacturing comparability testing for ChondroCelect

**Evolving regulatory environment confirms TiGenix development strategy**

Recently, the European Council adopted the new EU Regulation on Advanced Therapies. This Regulation means that all advanced therapies, including cell therapies, will fall under the scope of the European pharmaceutical legislation for medicinal products and will benefit from a single EU Marketing Authorisation. Controlled pivotal clinical trials will be the basis for approval and will follow a scientific and clinical evaluation by a new Committee of Advanced Therapy Experts at the EMEA.

The new Regulation on Advanced Therapies will bring the European situation more in line with the existing regulatory environment for cell-based products in the United States, where cell therapies are regulated as biologicals by the FDA. Recently new US guidelines were issued for the regulation of products for cartilage repair (“Draft guidance: Preparation of IDEs and INDs for Products Intended to Repair or Replace Knee Cartilage”).

Both documents confirm that TiGenix has well anticipated the evolving regulatory environment in defining the development strategy for its products. This will ultimately lead to a competitive edge for the Company over its competitors.

TiGenix

DEFINING THE CUTTING EDGE IN REGENERATIVE MEDICINE

# FINANCIAL UPDATE FIRST HALF 2007

## EUR 46 million raised in successful Euronext IPO

In March, TiGenix raised EUR 46 million in an Initial Public Offering (IPO) on the Eurolist by Euronext Brussels. The IPO was priced at EUR 5.0 per share and was subscribed by a solid mix of high quality institutional investors and retail investors. The IPO was 4.5 times oversubscribed.

## Results and net use of cash in line with expectations

The net loss for the first six months of 2007 amounted to EUR 5.5 million. This represents an increase of 42% compared to the same period last year. This increase reflects the planned increased activity level and is in line with the projections made by the analysts who cover TiGenix stock.

Total research and development expenses for the first half of 2007 were EUR 3.8 million compared with EUR 2.7 million for the first half of 2006. This increase of 41% is mainly attributable to a milestone payment to FAB for the license on their Hyalograft biomaterial, and the increased regulatory costs related to the filing of the MAA for ChondroCelect.

Selling, general and administrative expenses also increased by 41% to EUR 2.3 million, mainly due to the costs incurred to prepare the pricing and reimbursement in Europe, the increase of the staff costs to accommodate the growth of the company and the listing on the Eurolist by Euronext Brussels.

The net use of cash in operating and investing activities for the first six months of 2007 was EUR 5.7 million, also in line with expectations.

## Cash and cash equivalents at EUR 45 million

The financing activities, mainly the net proceeds out of the IPO of EUR 42.7 million, resulted in a net increase of the cash position by EUR 43.1 million. Taking into account the net cash used, a net increase of EUR 37.4 million in cash and cash equivalents was recorded during the first half of 2007.

As a result, TiGenix had a strong balance sheet with cash and cash equivalents of EUR 45.2 million at end June 2007 compared to 7.7 million on December 31, 2006.

TiGenix

DEFINING THE CUTTING EDGE IN REGENERATIVE MEDICINE

## CONSOLIDATED INCOME STATEMENT
## FOR SIX MONTHS ENDED JUNE 30 2007 AND 2006

| *Thousands of Euro (€)* | **June 30** | **June 30** |
|---|---|---|
| *According to IFRS and based on limited review procedures by BDO* | **2007** | **2006** |
| Sales | 0 | 0 |
| Other revenues | 78 | 264 |
| **Revenues** | **78** | **264** |
| Research and development expenses | 3,773 | 2,667 |
| Selling, general and administrative expenses | 2,321 | 1,644 |
| Other operating income | 0 | 0 |
| Other operating expenses | 0 | 0 |
| **Total operating charges** | **6,094** | **4,311** |
| **Operating Result (EBIT)** | **(6,016)** | **(4,047)** |
| Financial result | 486 | 163 |
| **Profit/(Loss) before taxes** | **(5,530)** | **(3,884)** |
| Income taxes | 0 | 0 |
| **Net Profit/(Loss)** | **(5,530)** | **(3,884)** |

| | | |
|---|---|---|
| **Net Profit/(Loss) per share – basic** | **(0.23)** | **(0.28)** |
| Number of outstanding shares – basic | 23,851,079 | 13,782,014 |

TiGenix

DEFINING THE CUTTING EDGE IN REGENERATIVE MEDICINE

# CONSOLIDATED BALANCE SHEET
# AT JUNE 30 2007 COMPARED TO DECEMBER 31 2006

| **ASSETS** | | |
|---|---|---|
| *Thousands of Euro (€)* | **June 30** | **December 31** |
| *According to IFRS and based on limited review procedures by BDO* | **2007** | **2006** |
| Intangible assets | 393 | 311 |
| Tangible assets | 1,226 | 437 |
| Other non current assets | 37 | 32 |
| **Non-current assets** | **1,656** | **780** |
| Stock | 75 | 0 |
| Receivables | 517 | 444 |
| Cash and cash equivalents | 45,165 | 7,738 |
| Deferred charges & Accrued income | 477 | 117 |
| **Current assets** | **46,234** | **8,299** |
| **TOTAL ASSETS** | **47,890** | **9,079** |

| **EQUITY AND LIABILITIES** | | |
|---|---|---|
| *Thousands of Euro (€)* | **June 30** | **December 31** |
| *According to IFRS and based on limited review procedures by BDO* | **2007** | **2006** |
| Share capital | 18,878 | 13,044 |
| Share premium | 52,223 | 15,335 |
| Accumulated profit/(loss) | (21,911) | (13,665) |
| Result of the year | (5,530) | (8,246) |
| Share-based compensation | 912 | 693 |
| Translation Reserves | (15) | (3) |
| **Equity attributable to equity holders** | **44,557** | **7,158** |
| **Total equity** | **44,557** | **7,158** |
| Subordinated loan | 391 | 391 |
| Financial loan | 380 | 0 |
| Finance lease obligations | 8 | 8 |
| **Non-current liabilities** | **779** | **399** |
| Current portion of lease debt | 0 | 5 |
| Current portion of financial loan | 20 | 0 |
| Trade payables | 2,022 | 749 |
| Other current liabilities | 512 | 768 |
| **Current liabilities** | **2,554** | **1,522** |
| **TOTAL EQUITY AND LIABILITIES** | **47,890** | **9,079** |

TiGenix

DEFINING THE CUTTING EDGE IN REGENERATIVE MEDICINE

## CONSOLIDATED STATEMENT OF CASH FLOWS FOR SIX MONTHS ENDED JUNE 30 2007 AND 2006

| *Thousands of Euro (€)* | **June 30** | **June 30** |
|---|---|---|
| *According to IFRS and based on limited review procedures by BDO* | **2007** | **2006** |
| | | |
| **CASH FLOWS FROM OPERATING ACTIVITIES** | | |
| Operating Result | (6,016) | (4,047) |
| Depreciation, amortization and impairment results | 163 | 81 |
| Share-based compensation | 219 | 120 |
| Other financial result | (18) | (2) |
| Income taxes | 0 | 0 |
| Increase/(decrease) in Trade payables | 1,209 | (20) |
| Increase/(decrease) in Other current liabilities | (256) | 70 |
| (Increase)/ decrease in Stock | (75) | |
| (Increase)/ decrease in Receivables | (73) | (50) |
| (Increase)/ decrease in deferred charges &accrued income | (360) | 52 |
| Total Adjustments | 809 | 251 |
| **Net cash provided by/(used in) operating activities** | **(5,207)** | **(3,796)** |
| | | |
| **CASH FLOWS FROM INVESTING ACTIVITIES** | | |
| Interest received | 505 | 166 |
| Interest paid | (1) | (1) |
| | | |
| Purchase of tangible assets | (859) | (134) |
| Purchase of intangible assets | (112) | (6) |
| **Net cash provided by/(used in) investing activities** | **(467)** | **25** |
| | | |
| **CASH FLOWS FROM FINANCING ACTIVITIES** | | |
| Payments cash deposits | (5) | 0 |
| Payments on long-term leases | 0 | (5) |
| Payments on short-term leases | (4) | 0 |
| Proceeds of subordinated loan | 0 | 0 |
| Proceeds of financial loan | 400 | 0 |
| Proceeds from long-term leases | 0 | 0 |
| Proceeds from issuance of shares (net of issuance cost) | 42,722 | 47 |
| **Net cash provided by/(used in) financing activities** | **43,113** | **42** |
| | | |
| **Net increase/(decrease) in cash and cash equivalents** | **37,439** | **(3,729)** |
| | | |
| Cash and cash equivalents at beginning of year | 7,738 | 14,899 |
| Effect on exchange rate changes | (12) | () |
| **Cash and cash equivalents at end of period** | **45,165** | **11,170** |

TiGenix

DEFINING THE CUTTING EDGE IN REGENERATIVE MEDICINE

## CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS' EQUITY CHANGES DURING THE SIX MONTHS ENDED JUNE 30 2007

| *Thousands of Euro (€)* | Attributable to equity holders of the Company | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **Number of shares** | **Issued capital** | **Issuance cost** | **Share premium** | **Retained loss** | **Share-based compen-sation** | **Trans-lation reserves** | **Total Equity** |
| **Balance at 31/12, 2006** | **14,157,014** | **14,115** | **(1,071)** | **15,335** | **(21,911)** | **693** | **(3)** | **7,158** |
| Issuance of shares | 9,694,065 | 9,173 | (3,339) | 36,888 | | | | 42,722 |
| Net Profit/(Loss) | | | | | (5,530) | | | (5,530) |
| Share-based compensation | | | | | | 219 | | 219 |
| Translation reserves | | | | | | | (12) | (12) |
| **Balance at 30/06, 2007** | **23,851,079** | **23,288** | **(4,410)** | **52,223** | **(27,441)** | **912** | **(15)** | **44,557** |

### Conference call

Today, August 30, at 15:00 Central European Time (14:00 GMT), the management of TiGenix will conduct a conference call.

To participate in the conference call, please register at:

https://eventreg1.conferencing.com/webportal3/reg.html?Acc=811441&Conf=148898

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.

### For more information, please contact


Gil Beyen
Chief Executive Officer
+32 16 39 60 60
gil.beyen@tigenix.com

Kris Motmans
representative of MC-Services Group
Corporate Communications
+32 16 39 60 63
+32 473 74 20 57
kris.motmans@tigenix.com

***About TiGenix***

*TiGenix NV (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 Universities of Leuven and 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 characterized 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 is TiGenix' lead product for cartilage repair, an innovative cell-based medicinal product focusing on durable repair of cartilage defects of the knee. The product is used in combination with autologous chondrocyte implantation (ACI), a surgical procedure to treat cartilage defects by using patient's own cells. Cartilage defects of the knee are very common and the spontaneous healing capacity of cartilage is limited. Patients having had a traumatic cartilage injury at a younger age are at risk of developing osteoarthritis (OA) later in life. By focusing on the regeneration of stable hyaline-like cartilage, ChondroCelect aims at realizing durable repair of cartilage defects and postponing the progression towards OA. ChondroCelect has successfully completed a randomized Phase III clinical trial and will be launched in Europe and/or in the United States, pending necessary regulatory approvals.*

***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.*