Algemene vergadering

20 april, 2009

TiGENIX REGENERATING MOTION

Agenda

Opening van de vergadering	Willy Duron, Voorzitter
Formaliteiten	Willy Duron, Voorzitter
Goedkeuring besluiten	Willy Duron, Voorzitter
Business update	Gil Beyen, CEO
Financiële update	Frank Hazevoets, CFO
Outlook	Gil Beyen, CEO
Q&A	

Goedkeuring van de besluiten

TiGenix

1. Kennisname en bespreking van het jaarverslag

- Naast de structurele superioriteit, toont verdere analyse van de data ook een klinische superioriteit op 36 maanden van ChondroCelect in vergelijking met microfractuur;
- De Europese registratieprocedure voor ChondroCelect vordert goed. Midden 2009 wordt de CHMP opinie verwacht;
- De voorbereiding van de Biologics License Application (BLA) om een marktvergunning te verkrijgen in de VS voor ChondroCelect loopt;
- De bestaande Europese faciliteit voor celexpansie bekomt GMP-status;
- Het team werd verder versterkt en het bedrijf verhuisde tevens naar een nieuw kantoor- en R&D gebouw;
- Er werden reeds meer dan 500 patienten behandeld met ChondroCelect;
- TiGenix' basisoctrooi is toegekend in de VS;
- De verdere inspanningen voor de ontwikkeling van de pijplijn, hebben geleid tot het bekomen van locale en Europese subsidies voor het onderzoek naar meniscusherstel en osteoartrose.

2. Goedkeuring van de jaarrekening

Voorstel tot besluit :

De algemene vergadering keurt de jaarrekening over het boekjaar afgesloten op 31 december 2008 goed.

3. Bestemming van het resultaat

Voorstel tot besluit :

De algemene vergadering keurt de door de raad van bestuur voorgestelde bestemming van het resultaat over het boekjaar afgesloten op 31 december 2008 goed.

4. Kennisname en bespreking van het jaarverslag

- Sterke balansstructuur : het eigen vermogen van de groep bedraagt 86% van de totale activa;
- Netto kasmiddelen aangewend in 2008 bedroeg 13,8 miljoen EURO;
- Inkomsten beperkt, in afwachting van de goedkeuring van ChondroCelect;
- Kasmiddelen van meer dan 25 miljoen EURO einde 2008.

5. Goedkeuring van de geconsolideerde jaarrekening

Voorstel tot besluit :

De algemene vergadering keurt de geconsolideerde jaarrekening over het boekjaar afgesloten op 31 december 2008 goed.

6. Benoeming van Galenos SPRL als bestuurder

Voorstel tot besluit :

De algemene vergadering neemt akte van het ontslag van de heer Sven Andréasson als onafhankelijke bestuurder, vanaf vandaag en benoemt Galenos SPRL, met maatschappelijke zetel te Jean Baptiste Meunierstraat 25, 1050 Elsene (ondernemingsnummer 0807.691.185, RPR Brussel), tot onafhankelijke bestuurder. Het mandaat van Galenos SPRL eindigt onmiddellijk na de gewone algemene vergadering die zich dient uit te spreken over de goedkeuring van de jaarrekening van het boekjaar afgesloten op 31 december 2010 Galenos SPRL wordt voor de uitoefening van dit mandaat vast vertegenwoordigd door de heer Sven Andréasson. De algemene vergadering beslist dat Galenos SPRL, overeenkomstig het Corporate Governance Charter van de vennootschap, als onafhankelijke bestuurder een vaste jaarlijkse bezoldiging van EUR 15.000 zal ontvangen, gebaseerd op zes vergaderingen van de raad van bestuur en twee vergaderingen van comités per jaar, aangevuld met een bedrag van EUR 1.500 voor elke bijkomende vergadering waaraan Galenos SPRL deelneemt.

7. Kwijting aan de bestuurders en de commissaris

Voorstel tot besluit :

De algemene vergadering verleent kwijting aan elk van de bestuurders en aan de commissaris van de vennootschap voor de uitoefening van hun mandaat gedurende het boekjaar afgesloten op 31 december 2008. Er wordt bovendien verduidelijkt dat deze kwijting eveneens aan Capricorn Venture Partners NV (ontslagnemende bestuurder per 15 februari 2008) evenals haar vaste vertegenwoordiger, en mevrouw Marie-Hélène Plais (ontslagnemend per 31 december 2008) betreft.

Business update

Notice

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Business Highlights 2008

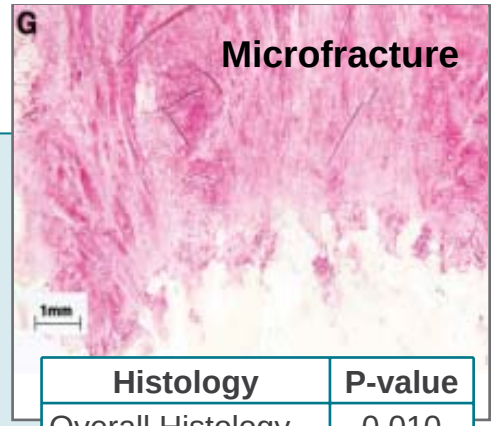
- Preparing for European launch of ChondroCelect
  - ChondroCelect three-year clinical data analysis confirms clinical superiority
  - EMEA registration procedure progressing; CHMP opinion anticipated by end H1 2009
  - More than 500 patients treated with ChondroCelect to-date
- Organization strengthened
  - Commercial team almost complete for EU launch ChondroCelect
  - Move to new facilities
  - Cell expansion facility obtained GMP status
- Progress in pipeline development
  - EUR 3 million in grants awarded to support meniscus repair, stem cells and osteoarthritis programs
  - Core patents granted in the US

Feb ’08: superior structural repair at 12 months

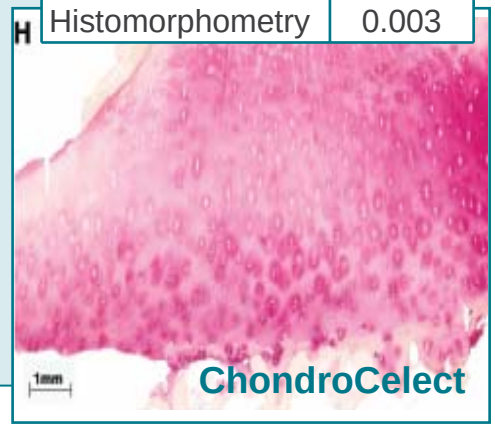
Characterized Chondrocyte Implantation Results in Better Structural Repair When Treating Symptomatic Cartilage Defects of the Knee in a Randomized Controlled Trial Versus Microfracture

Daniel B. F. Saris,*[a] MD, PhD, Johan Vanlauwe,[b] MD, Jan Victor,[c] MD, Miroslav Haspl,[d] MD, PhD, Michael Bohnsack,[e] MD, Yves Fortems,[f] MD, Bruno Vandekerckhove,[g] MD, K. Frederik Almqvist,[h] MD, PhD, Toon Claes,[i] MD, Frank Handelberg,[j] MD, Koen Lagae,[k] MD, Jan van der Bauwhede,[l] MD, Hilde Vandenneucker,[b] MD, K. Gie Auw Yang,[a] MD, PhD, Mislav Jelic,[d] MD, PhD, Rene Verdonk,[h] MD, PhD, Nancy Veulemans,[m] Ir, Johan Bellemans,[b] MD, PhD, and Frank P. Luyten,[n] MD, PhD

Conclusion: One year after treatment, characterized chondrocyte implantation was associated with a tissue regenerate that was superior to that after microfracture. Short-term clinical outcome was similar for both treatments. The superior structural outcome may result in improved long-term clinical benefit with characterized chondrocyte implantation. Long-term follow-up is needed to confirm these findings.



Histology	P-value
Overall Histology	0.010
Histomorphometry	0.003



The American Journal of Sports Medicine, Vol. 36, No. 2

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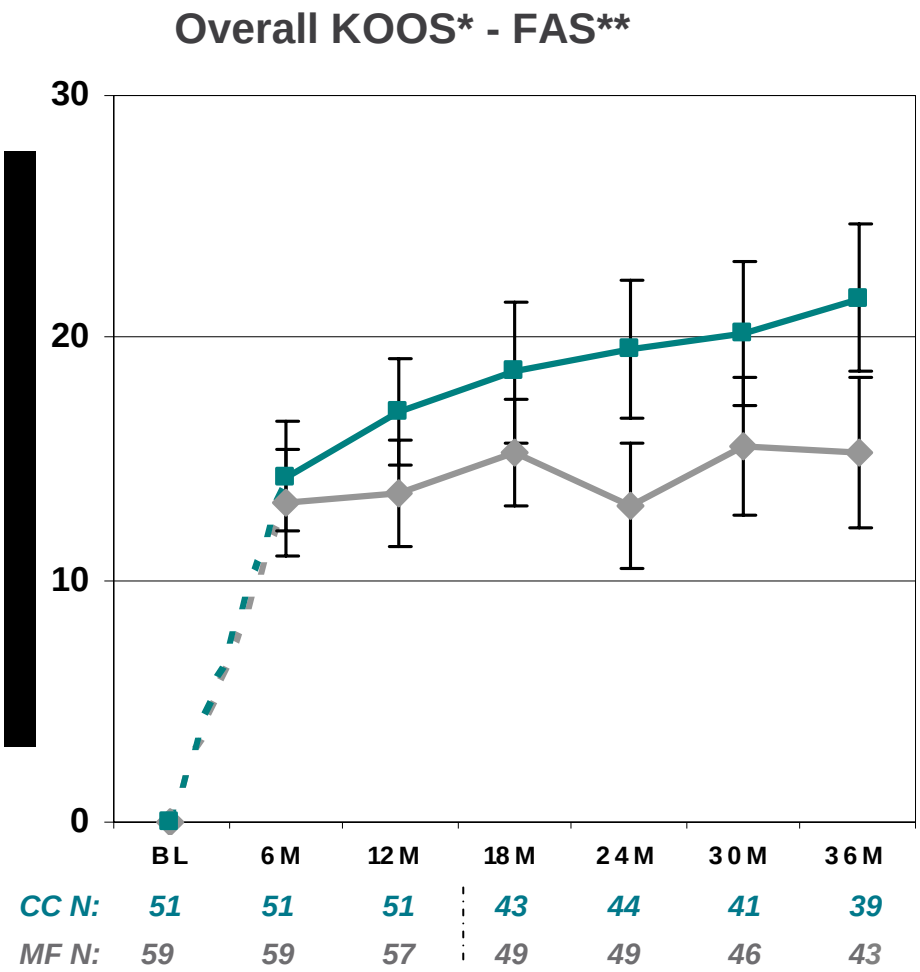
Oct ’08: superior clinical outcome at 36m



Longitudinal analysis:
treatment effect at 36m
(Mixed Linear Model)

KOOS	P-value
Overall*	0.018
Pain	0.028
ADL	0.035

Treatment failures
(reinterventions)
CC: 2 MF: 7

* Average of all KOOS domains, except Sports
** FAS without imputation for missing data or failures

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EMEA registration process progressing

- Mid 2007: first cell-based product to go for central approval at EMEA (as somatic cell therapy medicinal product)
- Oct 2008: most of the outstanding questions resolved; remaing questions on product and process validation
- Jan 2009: Advanced Therapy Medicinal Product regulation implemented
- Q1 2009: answers to remaining questions being compiled for submission;
- Q2 2009: CHMP opinion expected

Commercial Launch Strategy

- Goal: Establish ChondroCelect as First-in-Class treatment of symptomatic cartilage defects of the knee

- Approach:
  - Reference centers
    - Target 2009: 50 centers
    - 30 centers already trained
    - 15 centers have treated patients
  - Direct high-level core team
    - 11 people; 14 by end 2009
  - Focus on pricing & reimbursement
    - Head Market Access appointed
    - Core Value Dossier ready

More than 500 patients treated to-date

- Pivotal study: 51 ChondroCelect® treated (of 118 patients)
- Military Hospital study: 20 patients
- Expanded Access Program: 22 patients
- Compassionate Use/Named Patient Programs: >420 patients

Move to new office and R&D facilities

TiGenix NV
Researchpark Haasrode
Romeinse straat 12 bus 2
3001 Leuven
Belgium

TiGenix

EU manufacturing facility GMP approved

- Belgium based cell expansion facility approved for commercial production
- EU capacity secured for product launch
- Evaluation of expansion options ongoing

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Pipeline development progressing

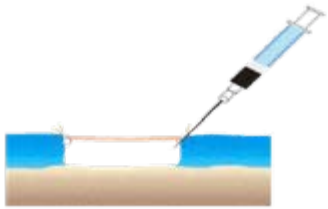
Broaden indication

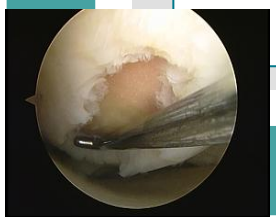
Stem cell therapies

MeniscoCelect
Allogeneic cell therapy

ChondroCelect-3D®
in combination with 3D scaffold

ChondroCelect®
Characterized Chondrocytes





Increase ease of use and patient friendliness

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EUR 3 million in grants awarded

TiGenix

REGULATED INFORMATION
DECEMBER 12, 2008

TiGenix receives a EUR 1.8 million grant for its meniscus repair program over the next two years

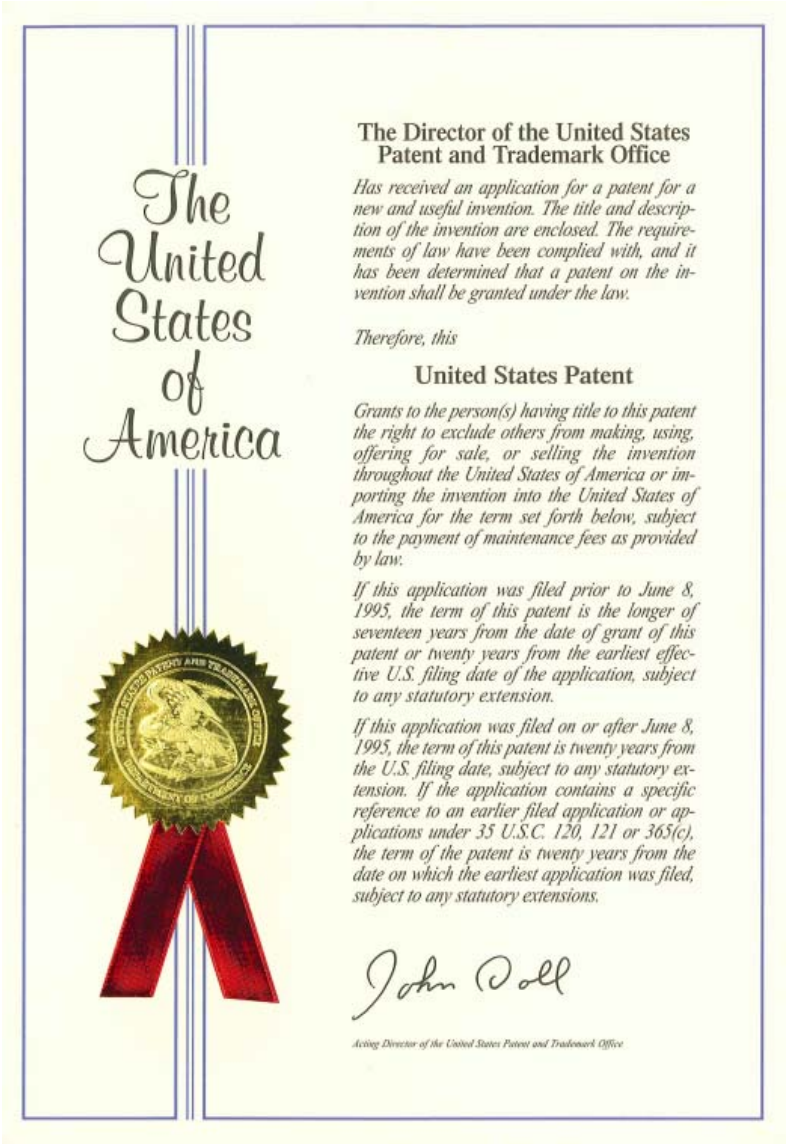
Leuven (BELGIUM) – December 12, 2008 – TiGenix (NYSE EURONEXT: TIG) announces that it has been awarded a EUR 1.81 million grant from the Flemish government to support its research and development efforts in the field of meniscus repair.

PRESS RELEASE
JUNE 10, 2008

TiGenix awarded European Union grant

Leuven (BELGIUM) – June 10, 2008 – TiGenix (EURONEXT: TIG) announced today that it has been awarded a EUR 1.2 million grant from the European Union for its participation in TREAT-OA, a research consortium focused on the development of novel diagnostics and treatments for osteoarthritis.

Core patents granted in the US



The United States of America

The Director of the United States Patent and Trademark Office

Has received an application for a patent for a new and useful invention. The title and description of the invention are enclosed. The requirements of law have been complied with, and it has been determined that a patent on the invention shall be granted under the law.

Therefore, this

United States Patent

Grants to the person(s) having title to this patent the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States of America or importing the invention into the United States of America for the term set forth below, subject to the payment of maintenance fees as provided by law.

If this application was filed prior to June 8, 1995, the term of this patent is the longer of seventeen years from the date of grant of this patent or twenty years from the earliest effective U.S. filing date of the application, subject to any statutory extension.

If this application was filed on or after June 8, 1995, the term of this patent is twenty years from the U.S. filing date, subject to any statutory extension. If the application contains a specific reference to an earlier filed application or applications under 35 U.S.C. 120, 121 or 365(c), the term of the patent is twenty years from the date on which the earliest application was filed, subject to any statutory extensions.

John Doll

Acting Director of the United States Patent and Trademark Office

(12) **United States Patent**
Luyten et al.

(10) **Patent No.: US 7,485,310 B2**
(45) **Date of Patent: Feb. 3, 2009**

(54) **USE OF CXCL6 CHEMOKINE IN THE PREVENTION OR REPAIR OF CARTILAGE DEFECTS**

(75) Inventors: **Frank Luyten**, Kraainem (BE); **Cosimo De Bari**, Aberdeen (GB); **Francesco Dell'Accio**, Bromley (GB)

(73) Assignee: **Tigenix N.V.**, Leuven (BE)

2005/0019865 A1* 1/2005 Kihm et al. 435/69.1
2006/0153817 A1* 7/2006 Kihm et al. 424/93.7
2006/0154366 A1* 7/2006 Brown et al. 435/366
2006/0154367 A1* 7/2006 Kihm et al. 435/366

FOREIGN PATENT DOCUMENTS

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OTHER PUBLICATIONS

Haringman et al. Chemokines in joint disease: the key to inflamma-

(12) **United States Patent**
Luyten et al.

(10) **Patent No.: US 7,479,367 B1**
(45) **Date of Patent: Jan. 20, 2009**

(54) **IN VIVO ASSAY AND MOLECULAR MARKERS FOR TESTING THE PHENOTYPIC STABILITY OF CELL POPULATIONS AND SELECTED CELL POPULATIONS FOR AUTOLOGOUS TRANSPLANTATION**

(75) Inventors: **Frank Luyten**, Kraainem (BE); **Cosimo De Bari**, Leuven (BE); **Francesco Dell'Accio**, Heverlee (BE)

(73) Assignee: **Tigenex N.V.**, Leuven (BE)

Hamada et al, "Immunohistochemical localization of fibroblast growth factor receptors in the rat mandibular condylar cartilage and tibial cartilage," (Journal of Bone and Mineral Metabolism), 1999, vol. 17, pp. 274-282.*
Binette et al, "Expression of a Stable Articular Cartilage Phenotype without Evidence of Hypertrophy by Adult Articular Chondrocytes In Vitro," (Journal of Orthopaedic Research), vol. 16, pp. 207-216.*
Erlacher, "Cartilage-Derived Morphogenetic Proteins and Osteogenic Protein-I Defferentially Regulate Osteogenesis", Journal of Bone and Mineral Research, vol. 13, No. 3, 1998, pp. 383-392.
Bradham, "In Vivo Cartilage Formation From Growth Factor Modulated Articular Chondrocytes", Clinical Orthopaedics and Related Research, No. 352, 1998, pp. 239-249

(12) **United States Patent**
Luyten et al.

(10) **Patent No.: US 7,482,114 B2**
(45) **Date of Patent: *Jan. 27, 2009**

(54) **IN VIVO ASSAY AND MOLECULAR MARKERS FOR TESTING THE PHENOTYPIC STABILITY OF CELL POPULATIONS, AND SELECTED CELL POPULATIONS FOR AUTOLOGOUS TRANSPLANTATION**

(75) Inventors: **Frank Luyten**, Kraainem (BE); **Cosimo De Bari**, Leuven (BE); **Francesco Dell'Accio**, Heverlee (BE)

(73) Assignee: **Tigenix N.V.**, Leuven (BE)

Kolettas et al, "Expression of cartilage-specific molecules is retained on long-term culture of human articular chondrocytes," (Journal of Cell Science), 1995, vol. 108, pp. 1991-1999.*
Si et al, "Eexpression of BMP-2 and TGF-beta 1 mRNA during healing of the rabbit mandible," (Eur. J. of Oral Science), Aug. 1997, vol. 105, No. 4, Abstract only.*
Hamada et al, "Immunohistochemical localization of fibroblast growth factor receptors in the rat mandibular condylar cartilage and tibial cartilage," (J. of Bone and Mineral Metab.), 1999, vol. 17, pp. 274-282.*
Meyer et al, "Mapping the Type I Collagen-binding Site on Pigment Epithelium-derived Factor," (The J. of Biol. Chem.), Nov. 2002, vol. 277, No. 47, pp. 45400-45407.*
Quan et al, "Localization of Pigment Epiothelium-Derived Factor in

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Financiële update

TiGenix

Financial highlights 2008

- Net cash used of EUR 13.8 million in 2008
- Cash and cash equivalents of EUR 25.2 million at year end

Financial Results for FY 2008

Net loss of EUR 15.2 mio.

Thousands of Euro	**31/12/08**	**31/12/07**
Sales	0	0
Other revenues	321	227
Revenues	**321**	**227**
Research and development expenses	9,975	8,139
Selling, general and admin. expenses	6,851	5,232
Total operating charges	**16,825**	**13,371**
Operating Result (EBIT)	**(16,505)**	**(13,144)**
Financial result	1,340	1,175
Profit/(Loss) before taxes	**(15,165)**	**(11,969)**
Income taxes	0	0
Net Profit/(Loss)	**(15,165)**	**(11,969)**

Table is drawn up in accordance with IFRS and based on full review procedures by the auditor

Financial Results for FY 2008

Cash and cash equivalents of EUR 25.2 mio.

Thousands of Euro	31/12/08	31/12/07
Cash at beginning of the year	**39,101**	**7,738**
EBIT	(16,505)	(13,144)
Total adjustments	1,951	1,094
Net cash used in operating activities	**(14,554)**	**(12,050)**
Net cash used in investing activities	**(250)**	**(109)**
Net cash provided by financing activities	**989**	**43,482**
Net increase/(decrease) in cash	**(13,815)**	**31,323**
Effect on exchange rate changes	**(124)**	**40**
Cash at end of the year	**25,162**	**39,101**

Table is drawn up in accordance with IFRS and based on full review procedures by the auditor

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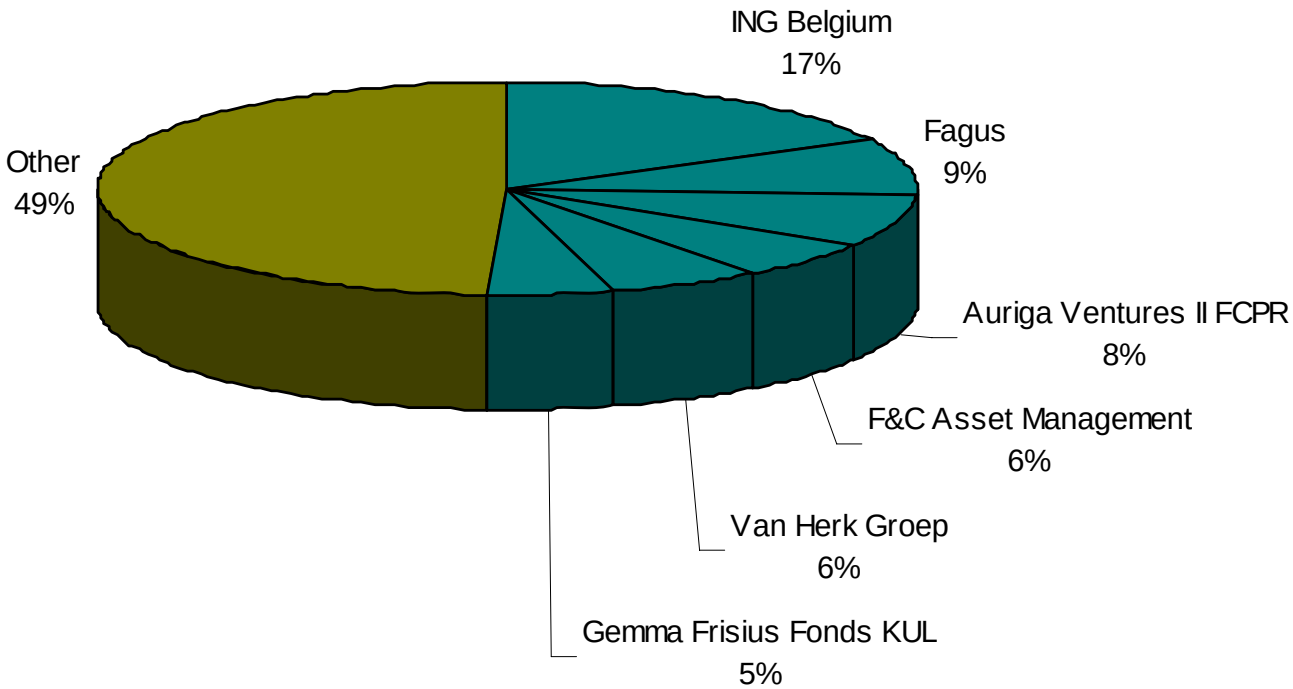
Outstanding financial instruments

Outstanding shares : **24,564,489**

Outstanding warrants : **1,335,736**



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Outlook

Outlook

- CHMP Opinion for ChondroCelect
- Approval and launch of ChondroCelect in selected European countries
- Expansion of cell manufacturing capacity in Europe
- Filing of the BLA for ChondroCelect in the US
- Start of clinical development of the 3D product

Q&A

TiGenix

Thank you for your attention

TiGenix NV
Romeinse straat 12 bus 2
3001 Leuven, Belgium
T: +32 (0)16 39 60 60