

TIGENIX

DEFINING THE CUTTING EDGE IN REGENERATIVE MEDICINE

Gewone Algemene Vergadering
Annual Shareholders' Meeting

Brussel, April 21, 2008



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Agenda

- **Business update 2007** Gil Beyen, CEO
- **Financial update 2007** Frank Hazevoets, CFO
- **Main Achievements & Outlook** Gil Beyen, CEO
- **Q&A**
- **Voting proposed resolutions (cf Agenda in invitation)**



Business update 2007

TiGenix

Focus

Regenerative medicine. OrthoBiologics
Innovative local treatments for damaged and
osteoarthritic joints.

Lead product

ChondroCelect[®], autologous cell-based medicinal
product for cartilage regeneration; Phase III trial
successfully completed; in registration phase in EU

Founded

2000, spin-off of the Universities of Leuven and Gent

Locations

Leuven (Belgium), New York & Memphis (US)

Finance

Listed on Euronext Brussels since March 22, 2007

TiGenix investment case

- TiGenix is a late-stage biomedical company focused on regenerative treatments for damaged and osteoarthritic joints
 - unique expertise in joint and cartilage biology
 - clear focus on a major unmet medical need
 - bridging the gap between symptom relief and joint replacement
- Product with successful Phase III data in cartilage repair
 - demonstration of clear structural superiority over standard of care
 - product set for registration in US and EU
 - targeting addressable market of more than 1 bn EUR
- Innovative treatments in pipeline
 - strategic collaboration with FAB for next generation 3D product
 - scope to broaden indications into osteoarthritic joints and meniscal repair
- Backed up by solid IP and experienced management team

Clear focus: joint function

Cartilage defects

- > 2 million articular cartilage defects diagnosed per year*
- Ca. 130.000 grade 3-4 full thickness defects*



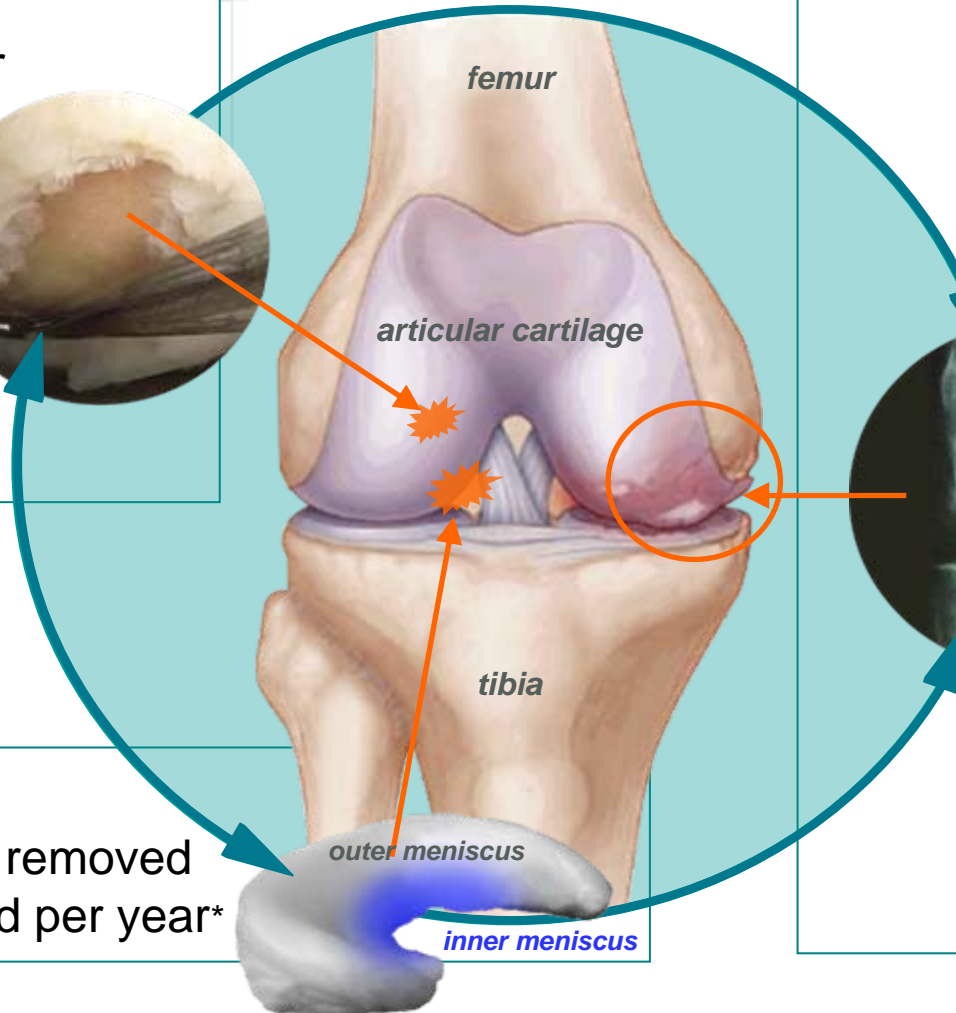
Osteoarthritis

- 2.5 to 5% of adult population in Western world has symptomatic knee osteoarthritis

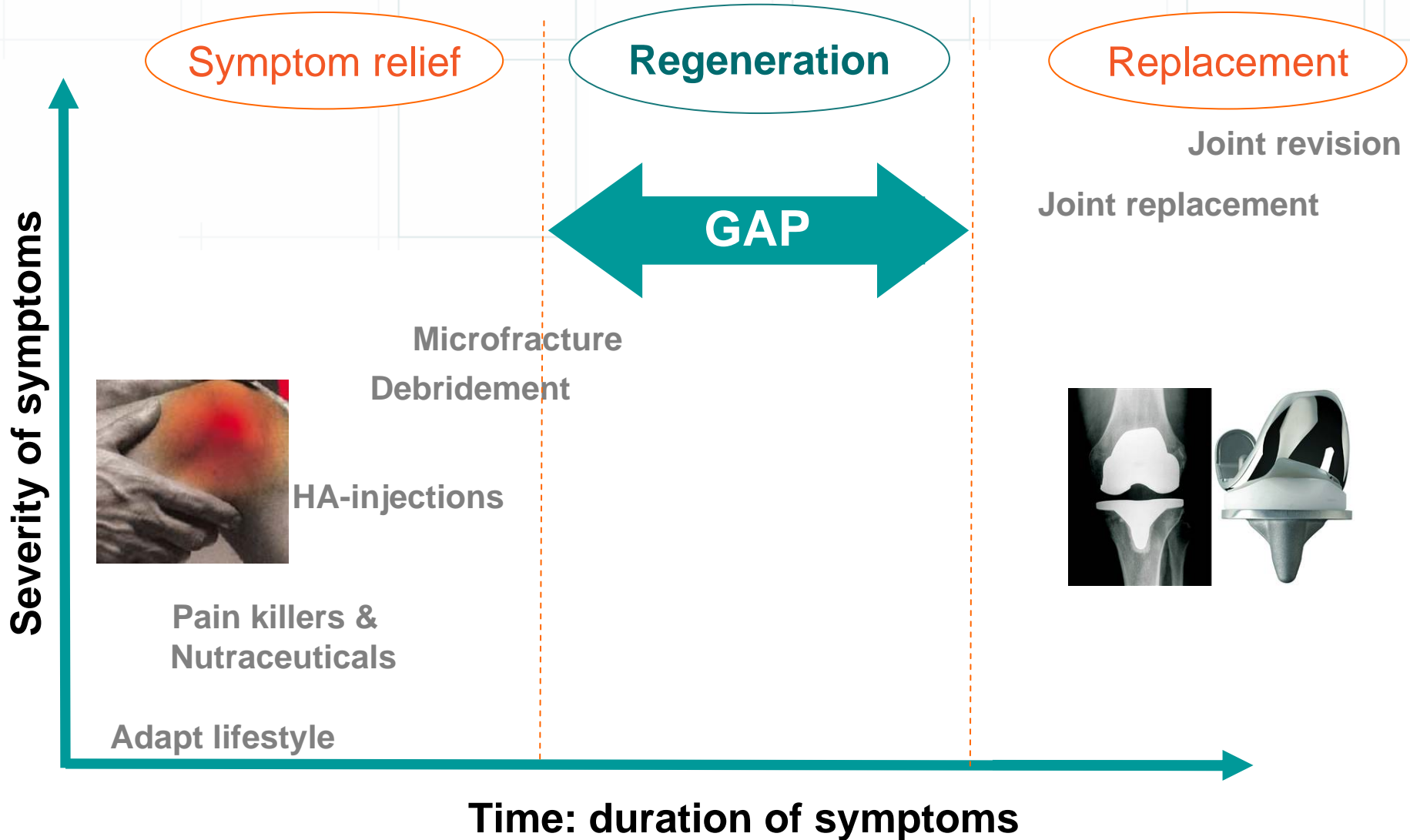


Meniscus trauma

- 2.2 million menisci removed or partially removed per year*

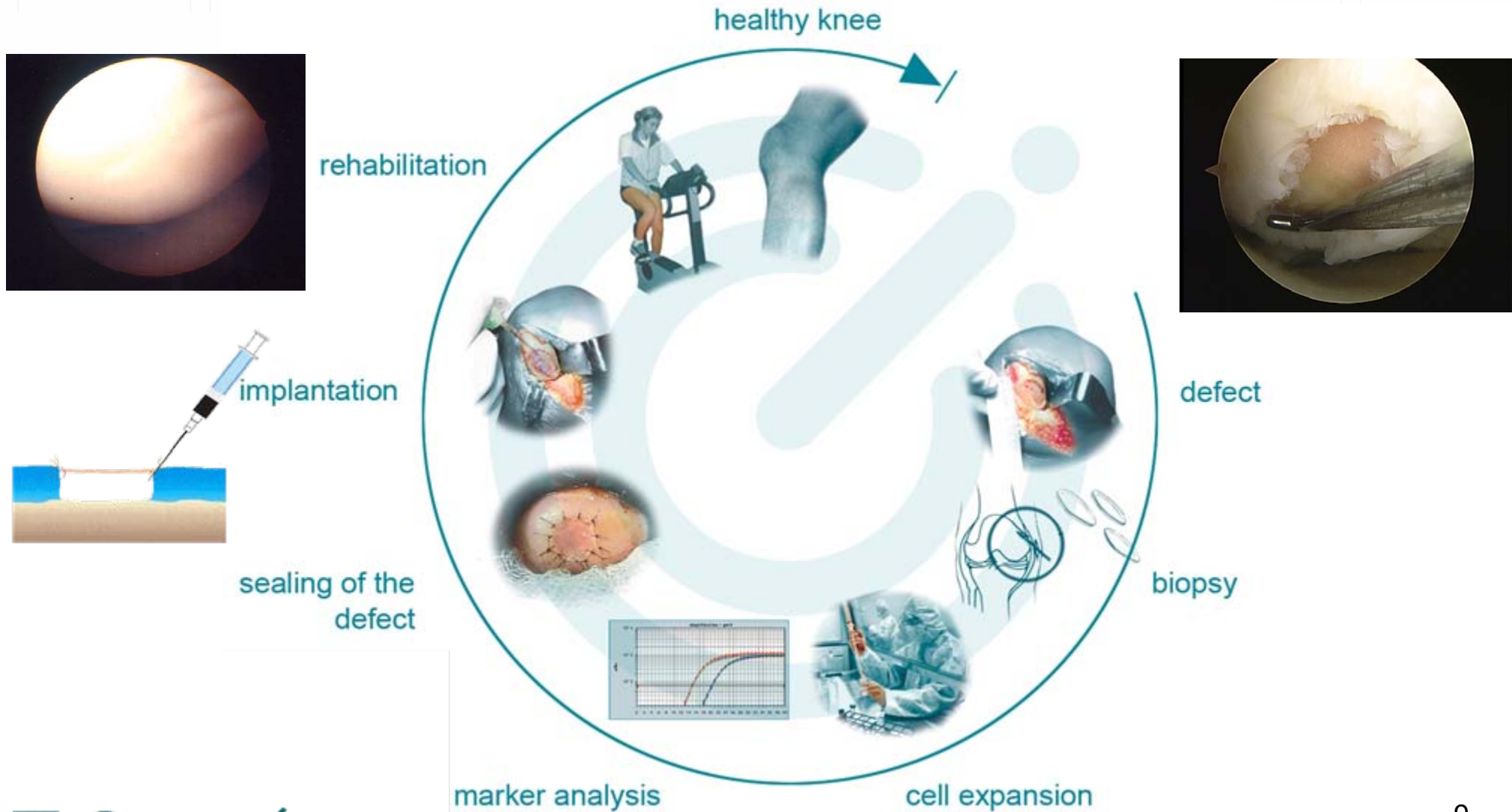


Regenerative solutions to bridge the gap



Durable regeneration with ChondroCelect[®]

Characterised Chondrocyte Implantation (CCI)

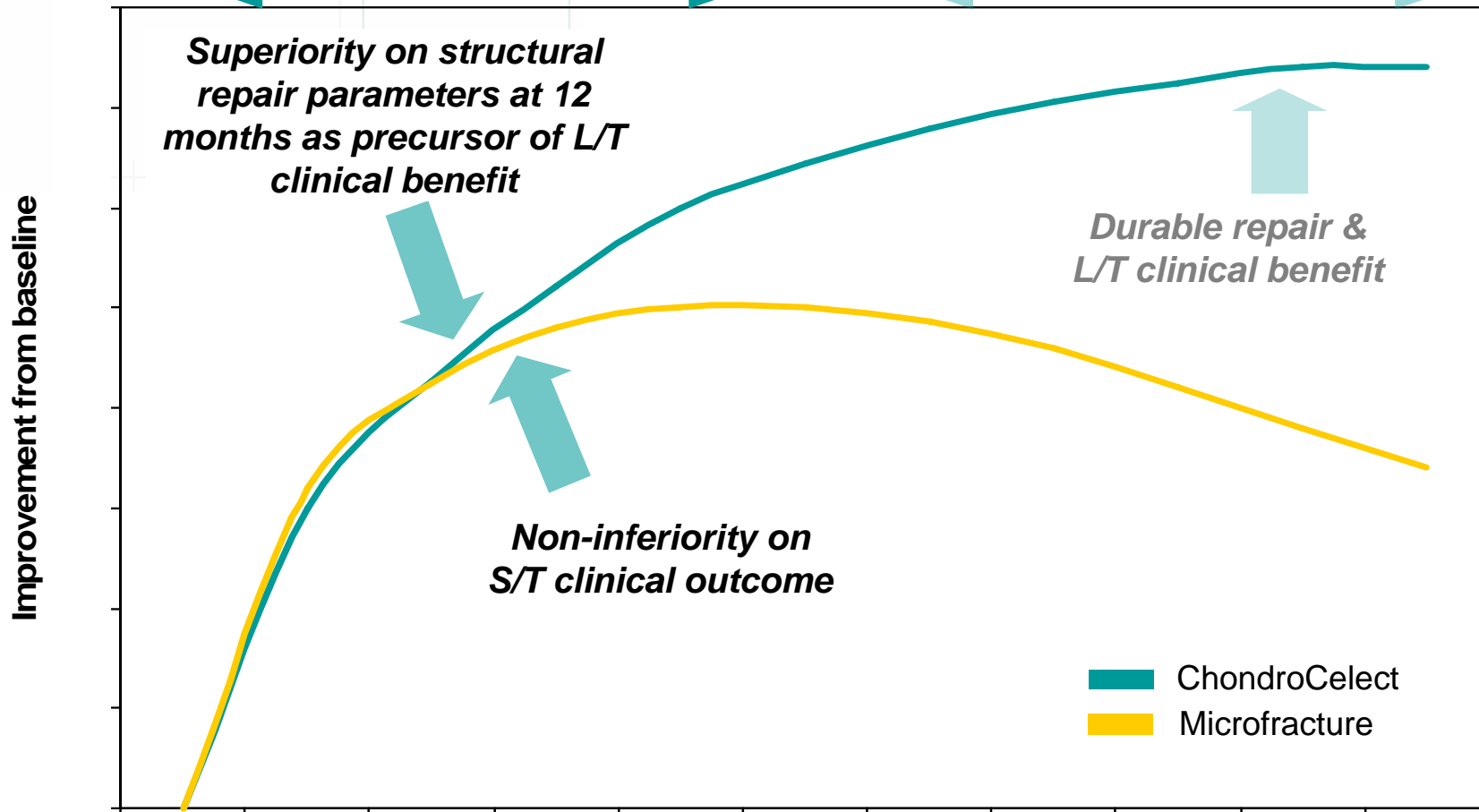


Successful completion of phase III trial

Prospective Randomized Controlled Trial of ChondroCelect versus Microfracture in the Repair of Symptomatic Cartilage Defects of the Knee

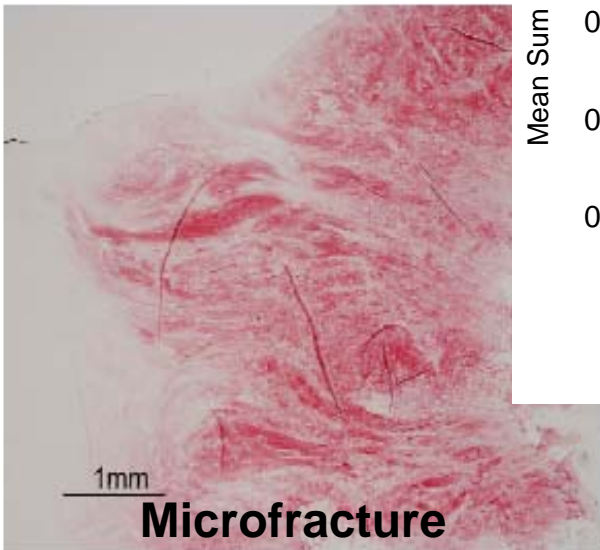
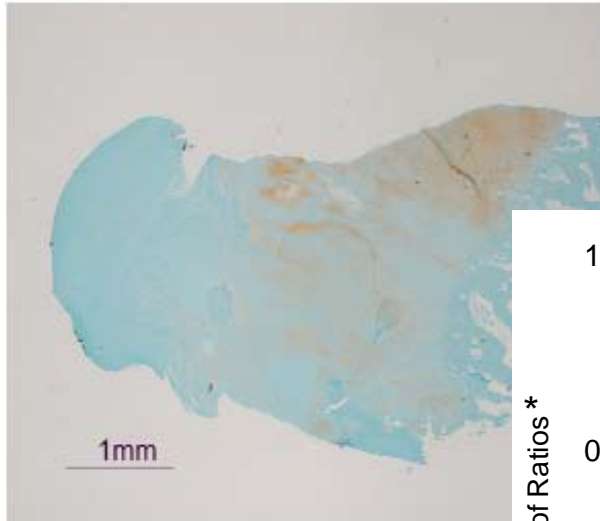
- **Primary endpoint:** superiority on structural repair at 12 months vs. microfracture AND clinical non-inferiority at 12 and 18 months
- 118 patients treated in nine Belgian and three international centres
- 107 end-point biopsies at 12 months
- 5 year patient follow-up to confirm long term clinical benefit
- State-of-the-art trial management and monitoring
- Central approval track at EMEA and FDA

Study hypothesis

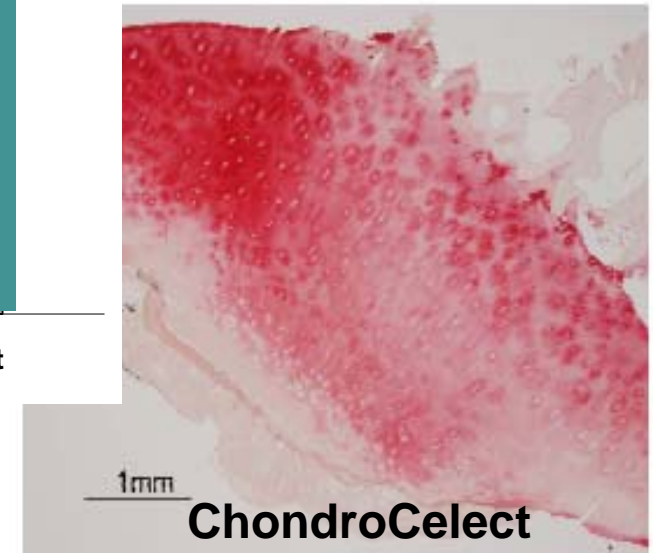
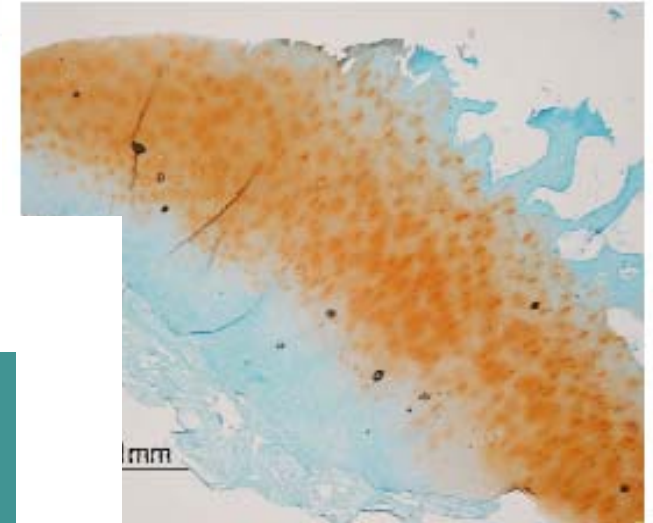
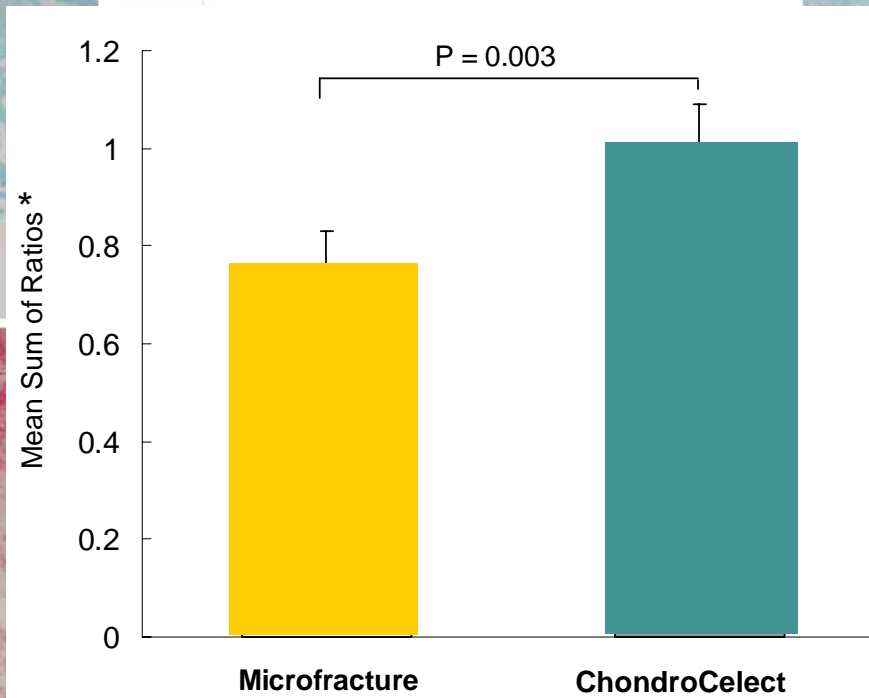


Follow up: **Baseline** **Short-term** **Long-term**

Superior structural repair

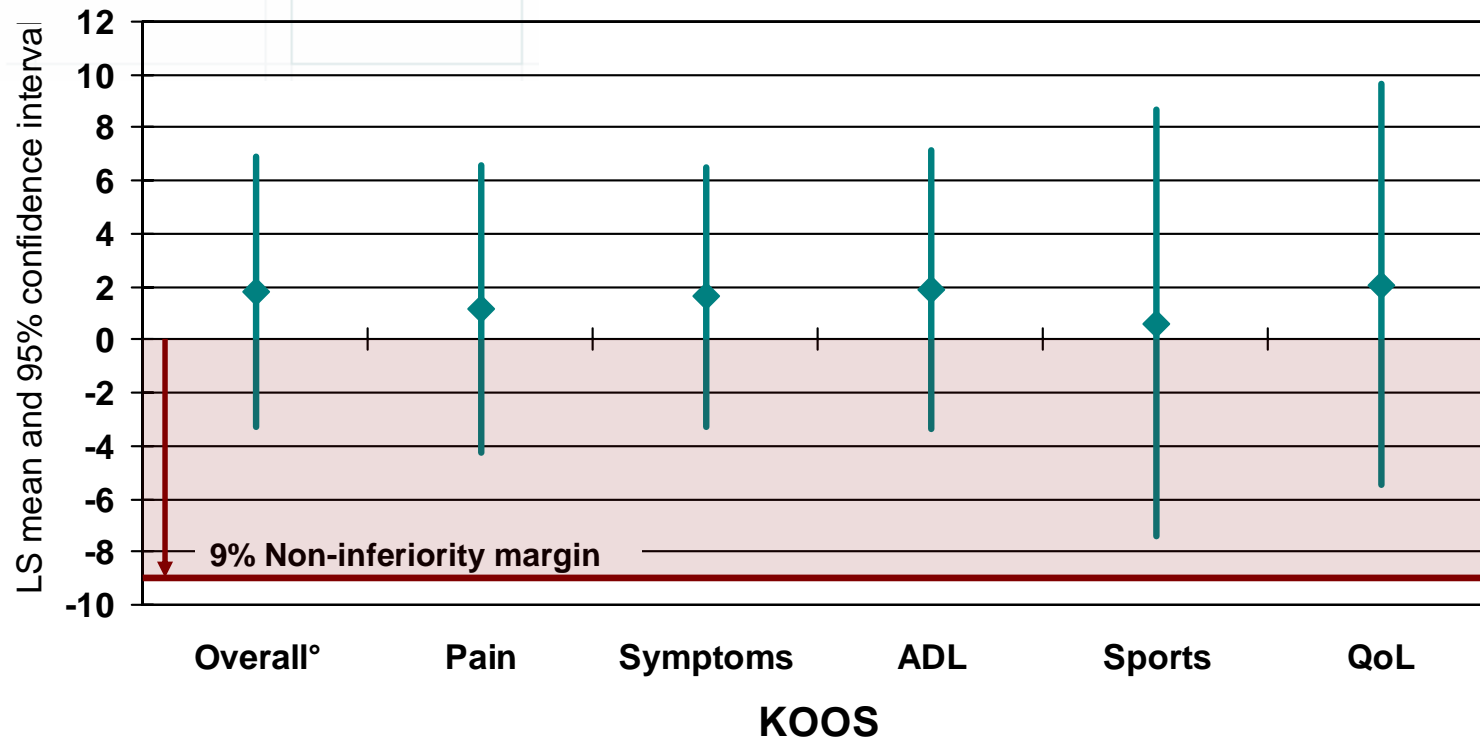


Histomorphometry



Similar clinical outcome (in the short term)

Difference between CC and MF in change from baseline at average of 12 & 18 months

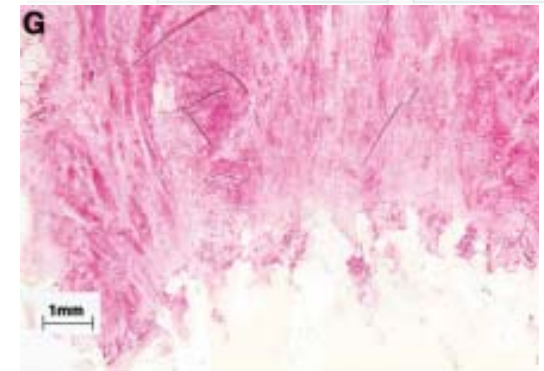


° Average of all KOOS domains , except Sports

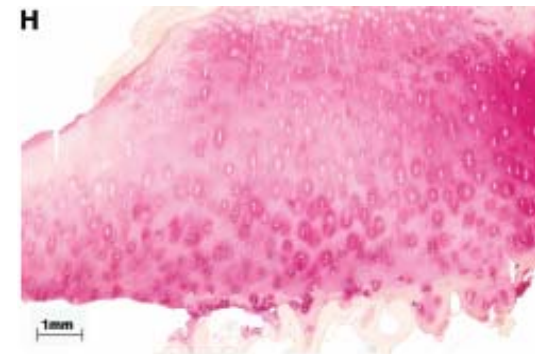
Trial conclusions

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



Microfracture

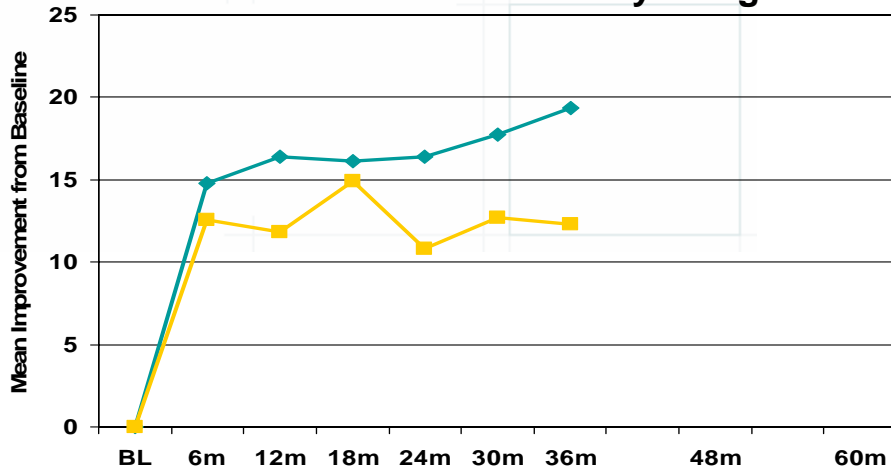


CCI

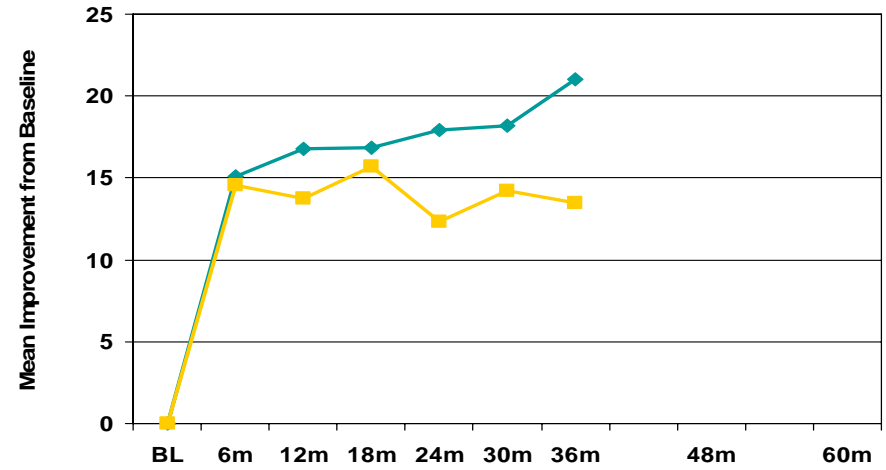
Conclusion: One year after treatment, characterized chondrocyte implantation was associated with a tissue regenerate that was superior to that after microfracture. Short-term clinical outcome was similar for both treatments. The superior structural outcome may result in improved long-term clinical benefit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

Increasing clinical benefit

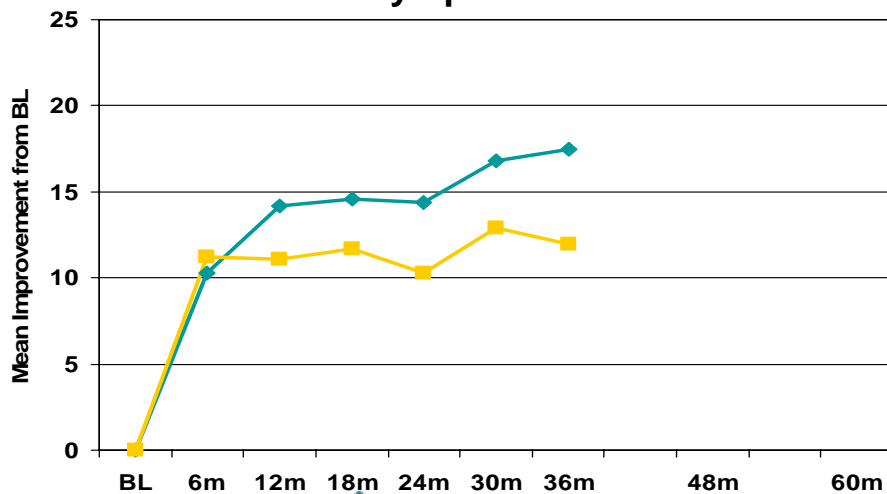
KOOS Activities of daily living



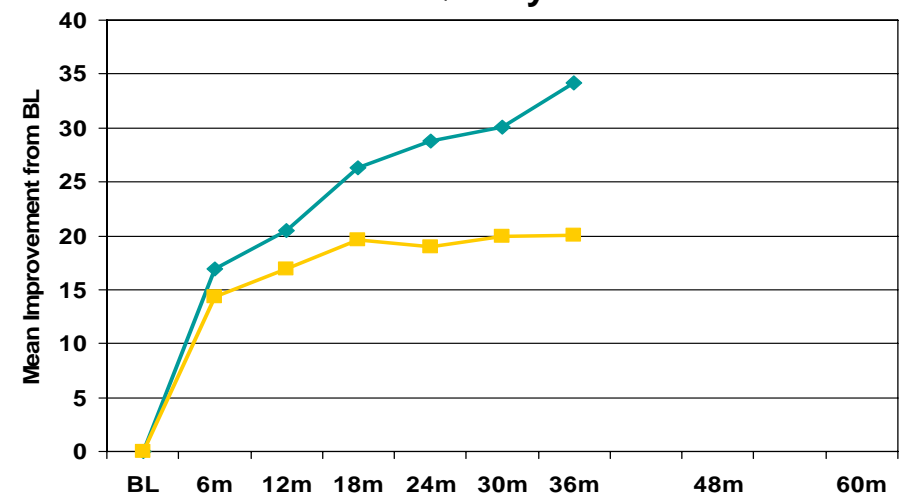
KOOS Pain



KOOS Symptoms/Stifness

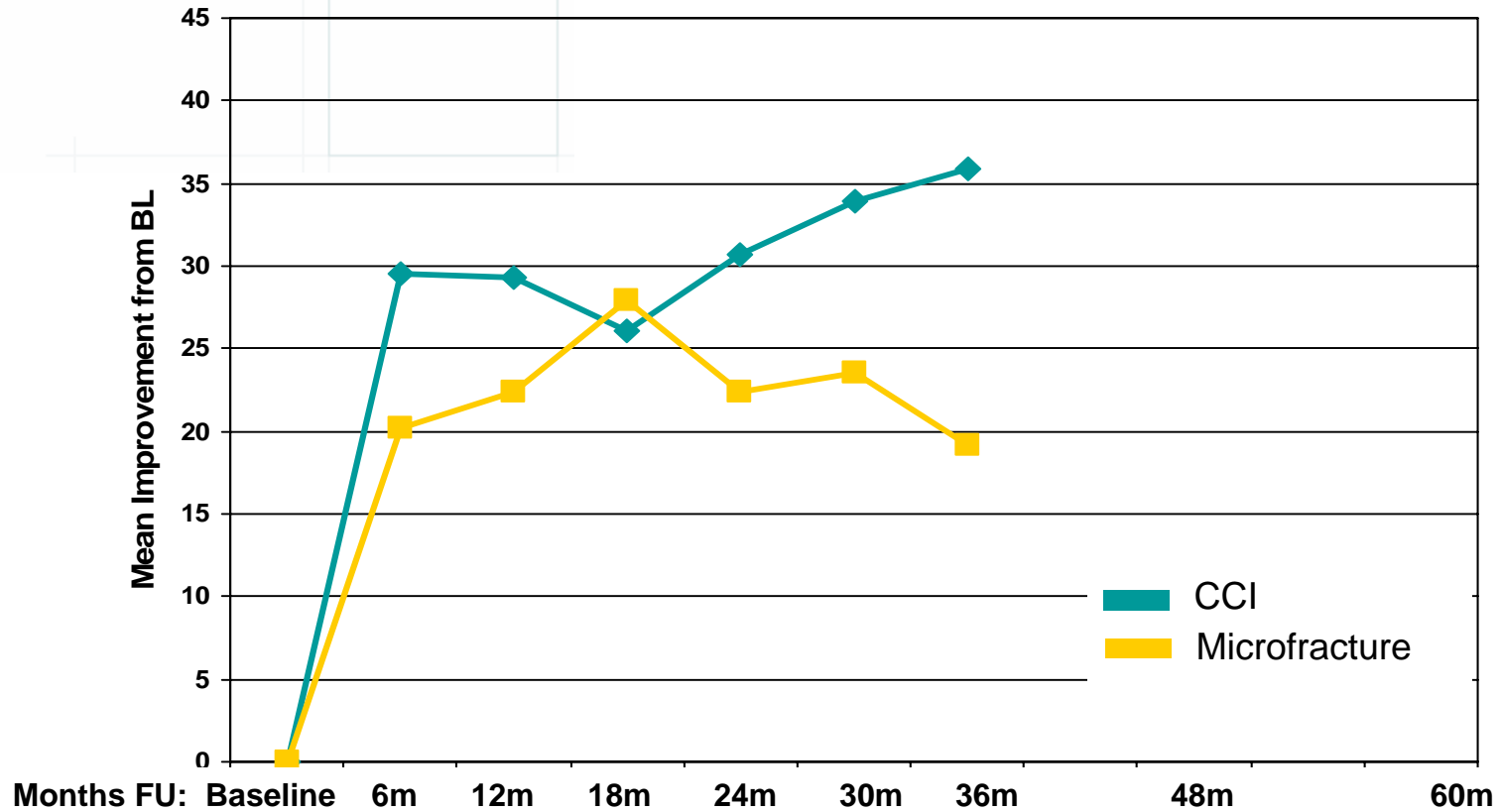


KOOS Quality of Life



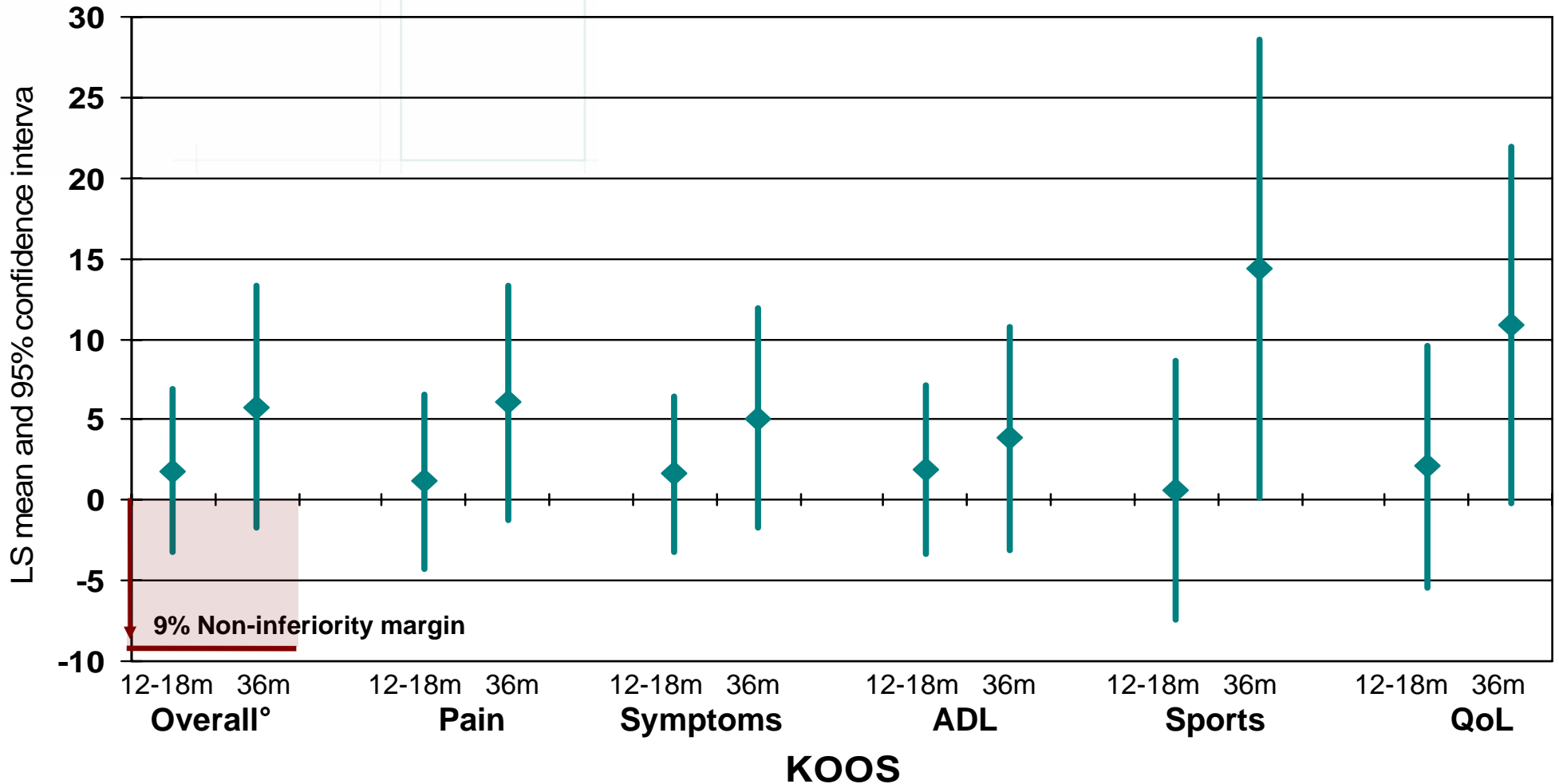
Increasing clinical benefit

KOOS Sports & recreational activities



Increasing clinical benefit

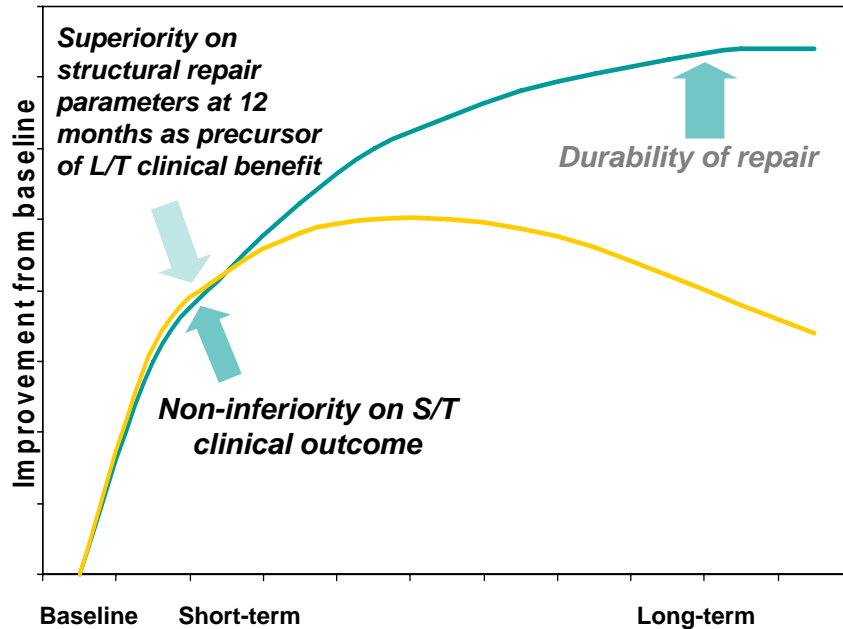
Difference in clinical improvement between CCI and MF at 12-18 and 36months



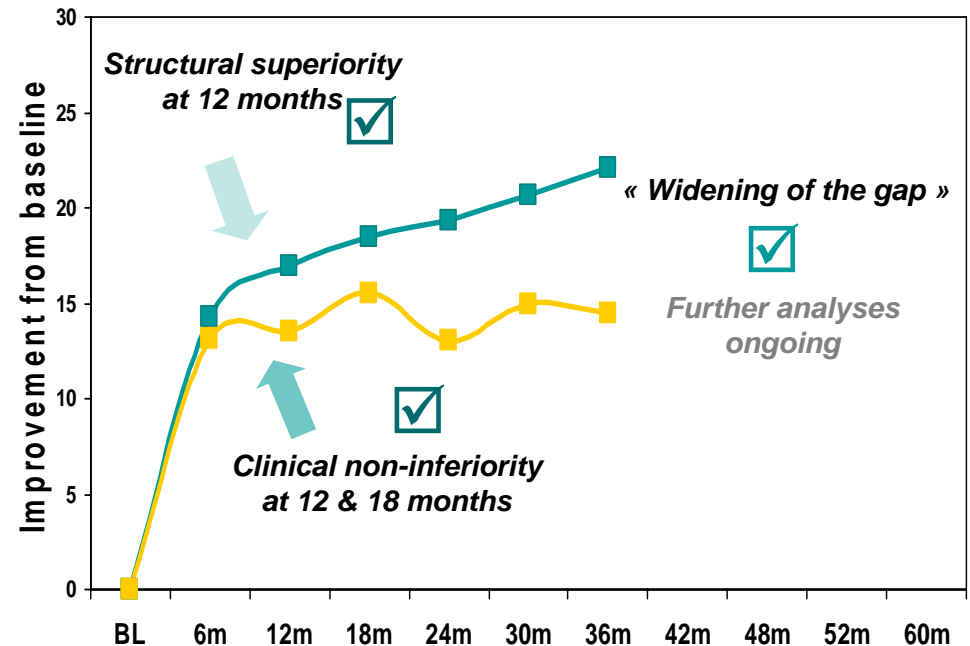
[°] Average of all KOOS domains , except Sports

Summary: three year data strengthen pivotal phase III results at 12 & 18 months

Study Hypothesis



Study results (up to 36 months)

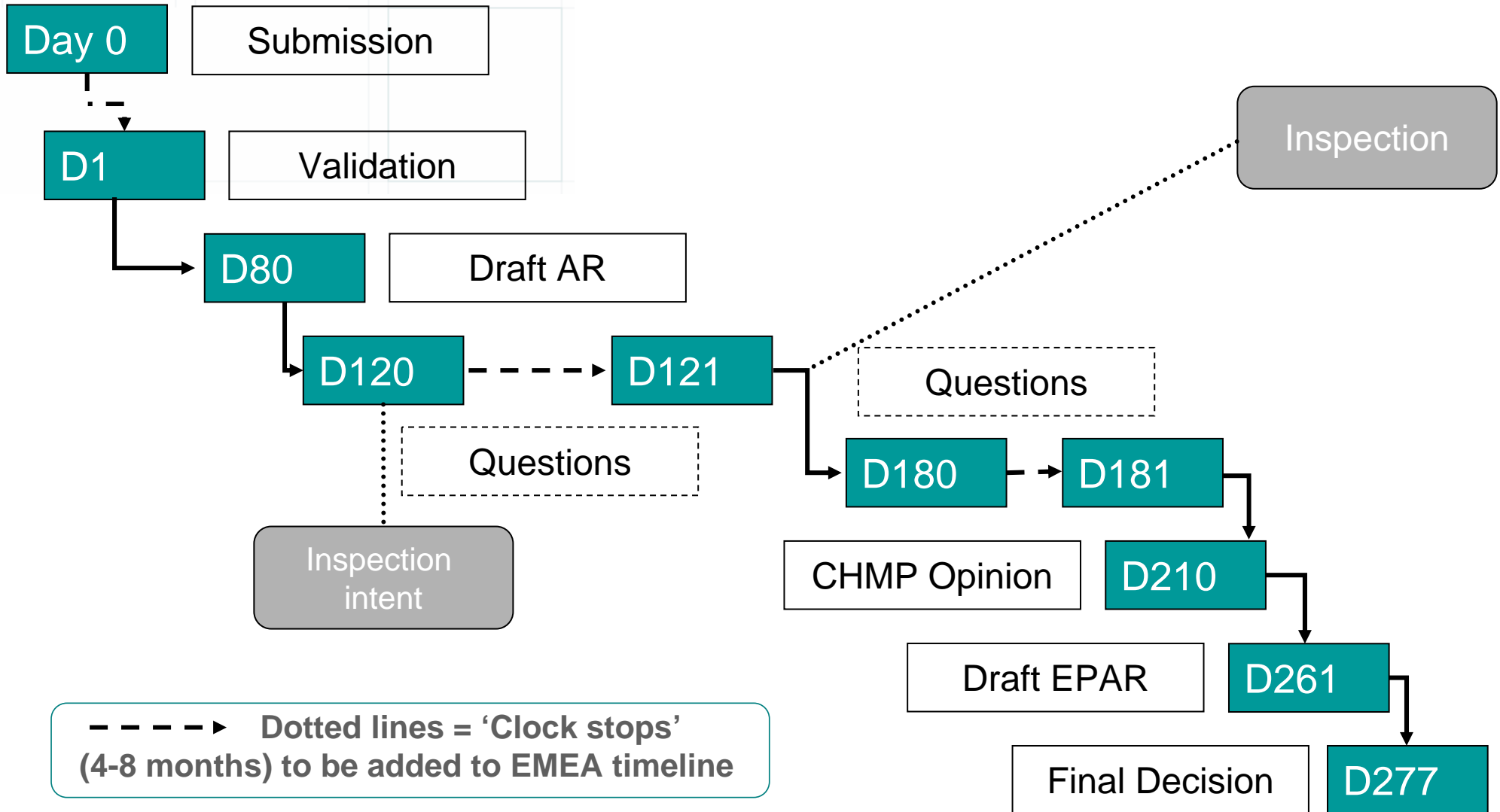


ChondroCelect® in registration phase

- Well-positioned for regulatory approvals
 - First cell-based product for cartilage repair to go for central approval at EMEA
 - Study designed according to FDA guidelines for autologous cell products intended for structural repair
- Process for regulatory approvals has been initiated
 - EU : MAA filed with EMEA →
 - US: BLA filing with FDA targeted in 2008



EMEA timeline



Commercialisation strategy

EU

- Own GMP cell manufacturing facility in Leuven
- Compassionate use at selected reference centres prior to launch (2008)
- Launch: reference centre approach; gradual roll-out
- Direct sales team, complemented by local partners

US

- Own GMP cell manufacturing facility in Memphis (TN)
- Launch: reference centre approach
- Direct sales team, complemented by local partners
- A strategic alliance with a specialised orthobiologics player will be considered for the launch of the next generation product

Development strategy



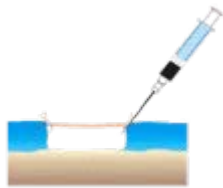
Broaden indication

Stem cell
therapies

Meniscus repair
(TGX003)

Next Generation-3D
(TGX002-FAB002)
Combination product (TIG-FAB)

ChondroCelect (TGX001)



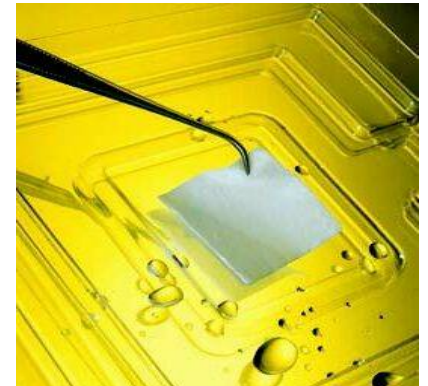
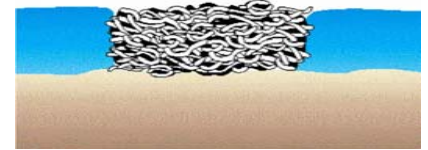
Increase ease of use and patient friendliness



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TGX002 trial in preparation

- Partnership with Fidia Advanced Biopolymers
 - Combination of 'best cells and best scaffold' for implantable 3D construct
 - Hyaff scaffold used in over 4000 patients
 - Proven surgical handling - arthroscopic implantation
 - No stitch approach opens perspective to treat focal defects in OA
- TGX002 trial in preparation
 - Dedicated development team in place
 - Pre-IND meeting with US FDA
 - Preclinical work ongoing
 - IND for Phase II trial end 2008



Organization strengthened

- Grown from 44 to 65 people in 2007
- VP Regulatory & Corporate Quality
- Commercial team EU
- Clinical development US
- Complete manufacturing team in US



Financial update 2007

Net loss of EUR 12 mio reflects the planned increased activity level

<i>Thousands of Euro</i>	<u>31/12/07</u>	<u>31/12/06</u>
Sales	0	0
Other revenues	227	416
Revenues	227	416
Research and development expenses	8,139	5,765
Selling, general and admin. expenses	5,232	3,201
Total operating charges	13,371	8,966
Operating Result (EBIT)	(13,144)	(8,550)
Financial result	1,175	304
Profit/(Loss) before taxes	(11,969)	(8,246)
Income taxes	0	0
Net Profit/(Loss)	(11,969)	(8,246)

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

Cash and cash equivalents of EUR 39 mio at year end

Thousands of Euro

31/12/07

31/12/06

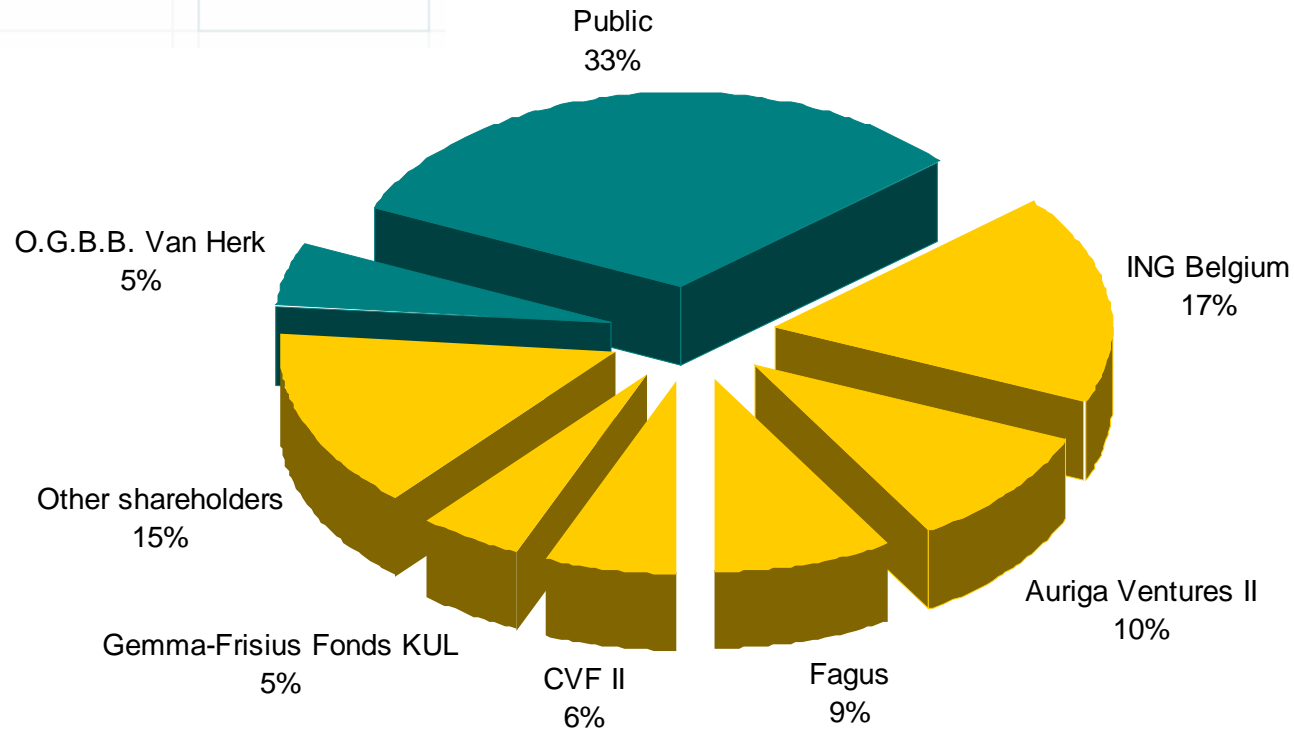
Cash at beginning of the year	7,738	14,899
EBIT	(13,144)	(8,550)
Total adjustments	1,094	807
Net cash used in operating activities	(12,050)	(7,743)
Net cash used in investing activities	(109)	(225)
Net cash provided by financing activities	43,482	810
Net increase/(decrease) in cash	31,323	(7,158)
Effect on exchange rate changes	40	(3)
Cash at end of the period	39,101	7,738

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

Outstanding financial instruments

Outstanding shares : 24,454,989

Outstanding warrants : 1,189,581





Main achievements & Outlook

Main achievements 2007

- Strategic partnership with Fidia Advanced Biopolymers
- Successful completion of pivotal phase III trial (ChondroCelect®)
- Successful IPO on Euronext
- US manufacturing facility acquired and team in place
- ChondroCelect entered registration phase (MAA submitted)
- ChondroCelect clinical trial results published in AJSM
- ChondroCelect three year clinical data strengthen phase III results
- TGX002 clinical trial in preparation
- Organisation strengthened in anticipation of the ChondroCelect launch

Outlook - 2008

- Presentation of the full three-year follow-up data at AANA on April 24
- Finalisation of manufacturing comparability testing of US production facility
- Filing of the BLA for ChondroCelect[®] in the US
- Preparation of core value dossier for pricing & reimbursement discussions in EU and US
- Expansion of cell manufacturing capacity in Europe
- Approval and launch of ChondroCelect[®] in selected European countries
- IND application for TGX002 phase II trial in the US

Q & A



Voting on proposed resolutions

Voorstellen tot besluit - *Proposed resolutions*

1. Kennisname en bespreking van het jaarverslag van de raad van bestuur en het verslag van de commissaris over de jaarrekening over het boekjaar afgesloten op 31 december 2007.
 - *Acknowledgment and discussion of the annual report of the board of directors and the report of the auditor on the annual accounts for the financial year ending 31 December 2007.*
2. Kennisname en goedkeuring van de jaarrekening over het boekjaar afgesloten op 31 december 2007.

Voorstel van besluit: De algemene vergadering keurt de jaarrekening over het boekjaar afgesloten op 31 december 2007 goed.

- *Acknowledgment and approval of the annual accounts for the financial year ending 31 December 2007.*

Proposed resolution: *The shareholders' meeting approves the annual accounts for the financial year ending 31 December 2007.*

Voorstellen tot besluit - *Proposed resolutions*

3. Bestemming van het resultaat van het boekjaar afgesloten op 31 december 2007.

Voorstel van besluit: De algemene vergadering keurt de door de raad van bestuur voorgestelde bestemming van het resultaat over het boekjaar afgesloten op 31 december 2007 goed.

- *Allocation of results for the financial year ending 31 December 2007.*

Proposed resolution: *The shareholders' meeting approves the allocation of results for the financial year ending 31 December 2007 as proposed by the board of directors.*

4. Kennisname en bespreking van het jaarverslag van de raad van bestuur en het verslag van de commissaris over de geconsolideerde jaarrekening over het boekjaar afgesloten op 31 december 2007.

- *Acknowledgment and discussion of the annual report of the board of directors and the report of the auditor on the consolidated annual accounts for the financial year ending 31 December 2007.*

Voorstellen tot besluit - *Proposed resolutions*

5. Kennisname en goedkeuring van de geconsolideerde jaarrekening over het boekjaar afgesloten op 31 december 2007.

Voorstel van besluit: De algemene vergadering keurt de geconsolideerde jaarrekening over het boekjaar afgesloten op 31 december 2007 goed.

- *Acknowledgment and approval of the consolidated annual accounts for the financial year ending 31 December 2007.*

Proposed resolution: *The shareholders' meeting approves the consolidated annual accounts for the financial year ending 31 December 2007.*

Voorstellen tot besluit - *Proposed resolutions*

6. Kwijting aan de bestuurders en aan de commissaris voor de uitoefening van hun mandaat tijdens het boekjaar afgesloten op 31 december 2007.

Voorstel van 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 2007. Er wordt bovendien verduidelijkt dat deze kwijting eveneens Auriga Partners S.A., Sogam NV (beiden ontslagnemende bestuurders per 27 februari 2007) en Capricorn Venture Partners NV (ontslagnemende bestuurder per 15 februari 2008), evenals hun respectievelijke vaste vertegenwoordigers, betreft.

- *Release from liability to be granted to the directors and the auditor for the performance of their duties in the course of the financial year ending 31 December 2007.*

Proposed resolution: The shareholders' meeting releases the directors and the auditor of the company from any liability arising from the performance of their duties during the financial year ending 31 December 2007. Furthermore, it is clarified that this release from liability also applies to Auriga Partners S.A., Sogam NV (both resigned as director as from 27 February 2007) and Capricorn Venture Partners NV (resigned as director as from 15 February 2008), as well as to their respective permanent representatives.

TIGENIX

GIVE YOUR DREAMS **WINGS**



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