

TIGENIX REGENERATING MOTION
At the Forefront of Regenerative Medicine

Business and Financial Update Full Year 2009

March 17, 2010

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Agenda

- **Introduction & Business update 2009** Gil Beyen, CEO
- **Financial update FY 2009** Frank Hazevoets, CFO
- **Feedback FDA and Outlook** Gil Beyen, CEO
- **Q&A**

Focus

Regenerative medicine - Innovative local treatments for damaged and osteoarthritic joints

Products

CHONDROCELECT  autologous cell-based product for cartilage repair. **First approved ATMP in Europe**
Chondromimetic™, resorbable implant for treatment of osteochondral defects. **Approved in Europe (CE)**

Pipeline

Complementary regenerative medicine products, integrating biomaterials and adult stem cells

Locations

HQ in Leuven (Belgium); Manufacturing in Leuven and Memphis (US); Cambridge (UK)

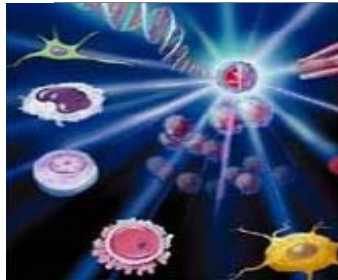
Finance

Listed on NYSE Euronext since March '07

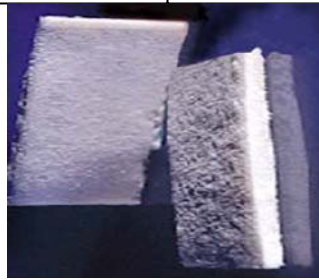
Regenerative Medicine

“Regenerative medicine replaces or regenerates human cells, tissue or organs, to restore or establish normal function”

Regenerative Medicine



Cells



Scaffolds



Signals

Cell Therapy

Tissue Engineering

Products to **regenerate** tissues and **cure** patients

An emerging industry, coming of age

- Ageing population and pressure on the healthcare budget create a strong demand for innovative cures
- Science develops at an accelerating rate & clinical evidence starts to demonstrate benefits
- First successes; first companies profitable
- Big pharma & device companies moving in
- Regulatory framework (finally) in place

“....Beyond the obvious health benefits of Regenerative Medicine, this technology is desperately needed to combat rising healthcare costs. ...”

US Department of Health and Human Services

materials 25

cell therapy
in vivo engineering
new era

Regenerative Medicine

The Industry Comes of Age

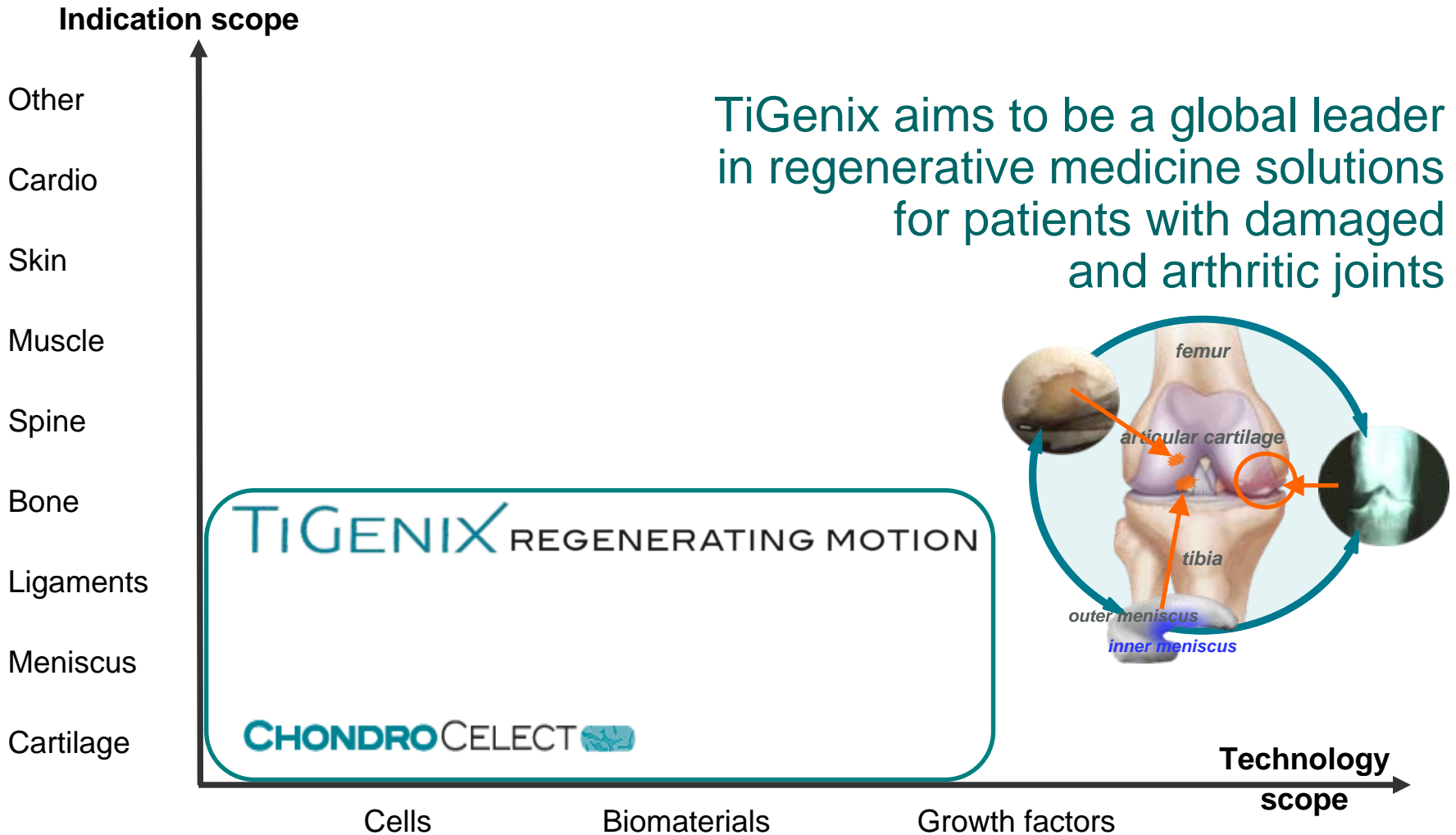
C. Mason
Regenerative Medicine Bioprocessing Unit, Advanced Centre for Biochemical Engineering, University College London, UK.

The regenerative medicine industry has moved into a new era in which commercialisation and not research is the number one priority. To achieve its new goal, much has had to change, including the introduction of expert business management, simpler but superior products and scalability of manufacture. Mass public and political support is supplying both long-term resources and the market demand to finally create a sustainable new health-care sector.

Image: iStockphoto

TiGenix, targeting focused leadership

TiGenix aims to be a global leader in regenerative medicine solutions for patients with damaged and arthritic joints



Business highlights 2009

- ChondroCelect[®] approved and launch started
 - ChondroCelect[®] approved in EU as the first ATMP
 - Sales started. First pre-reimbursement patients treated
 - Pricing and reimbursement applications filed in key target markets
 - *Post-approval commitments agreed with EMA*
- Regulatory path in the US clarified
- Organization and infrastructure strengthened
 - New EU manufacturing facility secured, construction started
 - UK biomaterials company Orthomimetics acquired
 - Team further strengthened
- Pipeline and technology development progressing
 - Second approved product added to product portfolio
 - Proprietary biomaterials platform acquired
 - Quality and ease of use of ChondroCelect further increased

First approved ATMP



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 5.10.2009
C(2009)7726

COMMISSION DECISION

of 5.10.2009

granting marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for "ChondroCelect - Characterised viable autologous cartilage cells expanded ex vivo expressing specific marker proteins", a medicinal product for human use



European Medicines Agency
Press office

London, 26 June 2009
Doc. Ref. EMEA/CHMP/394741/2009

PRESS RELEASE

European Medicines Agency recommends first marketing authorisation for an advanced therapy medicinal product

The European Medicines Agency has recommended the first marketing authorisation for an advanced therapy medicinal product, following a positive opinion from the Agency's Committee for Advanced Therapies (CAT) and the Committee for Medicinal Products for Human Use (CHMP).

ChondroCelect[®], cell-based medicinal product aimed at durable regeneration of knee cartilage

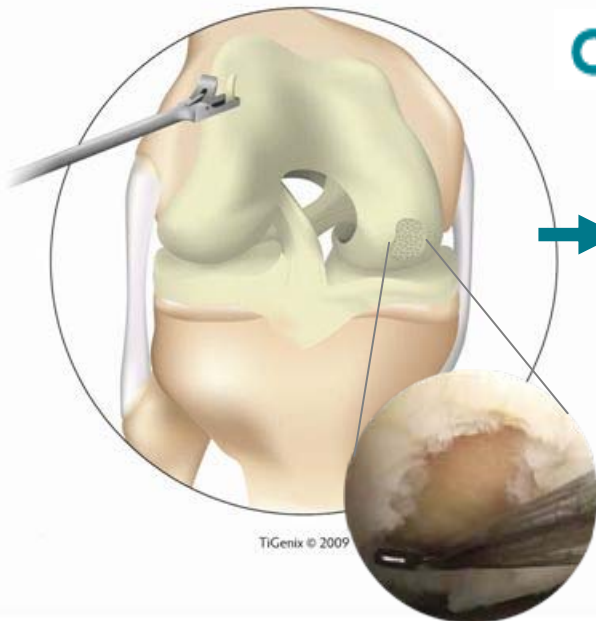
Active substance

Characterised autologous cartilage cells expanded *ex vivo* expressing specific marker proteins

Indication

Repair of single symptomatic cartilage defects of the femoral condyle of the knee (ICRS grade III or IV) in adults.

Biopsy

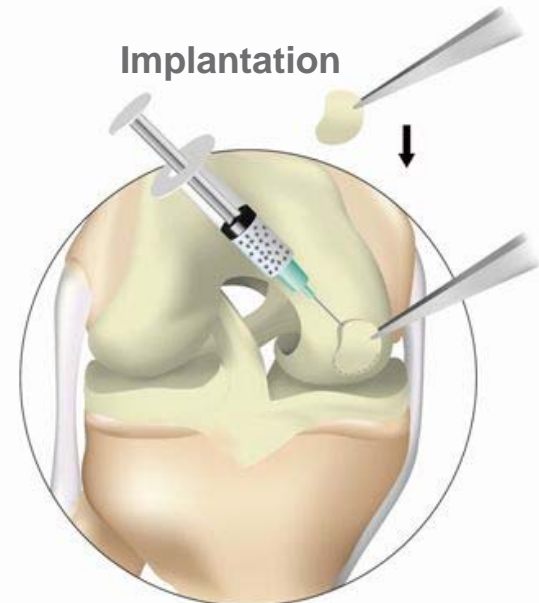


CHONDROCELECT 



Controlled manufacturing process & quality control

Implantation



EU market launch

- ✓ First pre-reimbursement sales
 - Germany
 - Belgium
 - UK
 - Netherlands
- ✓ Reimbursement progressing
 - NUB Status 1
 - Reimbursement applications in target markets
- ✓ Reinforcing commercial core team



**INTRODUCING CARTILAGE REGENERATION
BASED ON CLINICAL EVIDENCE**

In a level 1, randomized, controlled clinical trial, ChondroSelect is the only medicinal product for use in autologous chondrocyte implantation (ACI) procedures which has demonstrated clinical superiority* in addition to superior structural repair as compared to microfracture.

Over the years TiGenix has perfected its quality-controlled manufacturing process to produce phenotypically stable cells. In vivo, these characterized chondrocytes have been shown to form more stable cartilage as compared to dedifferentiated cells. With ChondroSelect your patients will experience better clinical outcomes with less need for re-intervention than microfracture.

All of this makes ChondroSelect the first evidence-based product for autologous chondrocyte implantation use!†

CHONDROSELECT

WWW.TIGENIX.COM

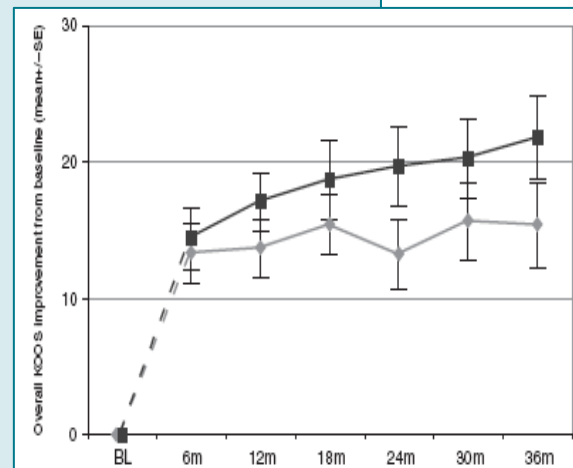
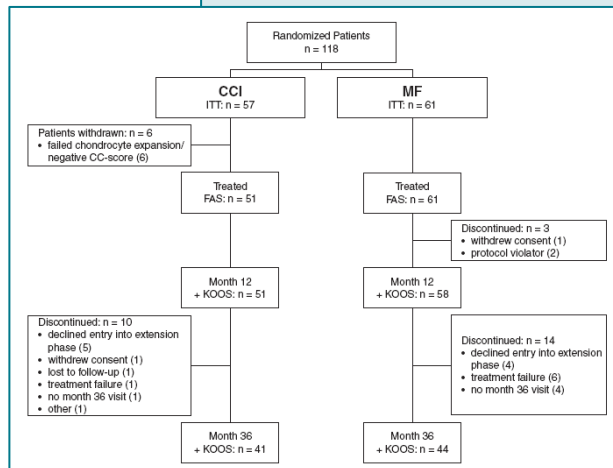
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* Using ICDI measurements (pHDI), except for the sports subdomain. Longitudinal analysis. Treatment effect at 36m. Mixed linear model (two-way interaction: treatment x time as categorical variable). Statistical significance could not be demonstrated when using the structural variance-covariance model.
† ChondroSelect has received Marketing Authorization from the European Commission. The product is currently not approved in the US.

Three year data published

Characterized Chondrocyte Implantation Results in Better Clinical Outcome at 36 Months in a Randomized Trial Compared to Microfracture

Daniel B. F. Saris,^{*†} MD, PhD, Johan Vanlauwe,[‡] MD, Jan Victor,[§] MD, PhD, Karl Fredrik Almqvist,^{||} MD, PhD, Rene Verdonk,^{||} MD, PhD, Johan Bellemans,[‡] MD, PhD, and Frank P. Luyten,[¶] MD, PhD, for the TIG/ACT/01/2000&EXT Study Group



Conclusion: Characterized chondrocyte implantation for the treatment of articular cartilage defects of the femoral condyles of the knee results in significantly better clinical outcome at 36 months in a randomized trial compared with MF. Time to treatment and chondrocyte quality were shown to affect outcome.

Patient follow-up continuing

- Five year data expected in May/June
 - Excellent retention
- Post-approval commitment agreed with EMA
 - Confirmatory study
 - Stratification for lesion size

Regulatory path in the US clarified

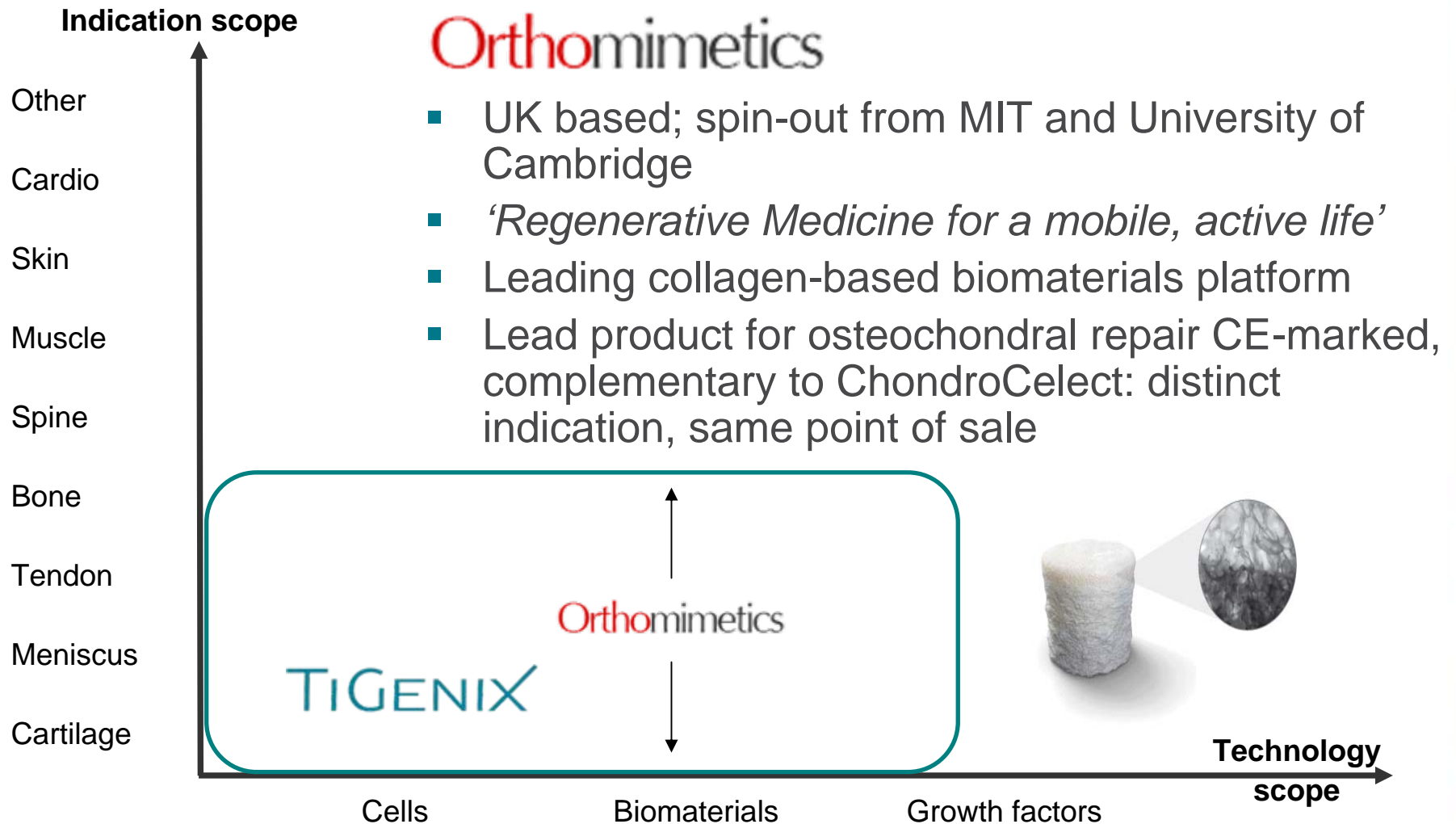
- Clinical data package submitted to the US FDA
- FDA advised TiGenix to seek Special Protocol Assessment
- Additional study will be required prior to BLA filing
- Positive feedback on protocol design of European confirmatory study
- Next steps:
 - Seek advice from FDA and EMA on possible alignment of the two studies
 - Define US strategy for ChondroCelect based on outcome

Location and financing for new European cell expansion facility secured

- New EU manufacturing facility: Sittard-Geleen – NL
 - Site selected: logistical, technical and financial criteria
 - Lease agreement signed
 - Financing secured
 - Construction on track



Acquisition of Orthomimetics (Dec 2009)



Complementary market-ready product portfolio

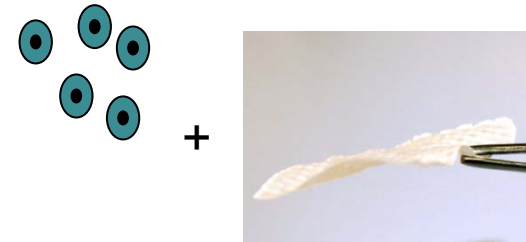
Small lesions

Large Lesions

Cartilage
Damage
Only

TIGENIX

CHONDROCELECT 



Orthomimetics

Cartilage and
Subchondral
Bone Damage

Chondromimetic
Osteochondral Plug



Team strengthened

- Executive Management completed
 - Koenraad Blot, Chief Medical Officer
 - Andrew Lynn, Chief Business Officer
 - Patrick Haelterman, Vice President, Sales and Marketing EU
 - Wilfried Dalemans, Chief Technical Officer
 - Frank Hazevoets, Chief Financial Officer
- Key positions filled
 - Philippe Van Wilder, Director Market Access, Pricing & Reimbursement

Pipeline and technology development

- Further improvements to ChondroCelect
 - Biopsy tool: ChondroCelect Harvester™ (CE marked)
 - Cryopreservation
 - Development of enhanced delivery systems
- Development of an adult stem cell platform
 - In view of allogeneic treatments
 - For treatment of other tissues
- Development of products for meniscus repair
 - Cell based product for repair of mensical tears
 - Cell free scaffold for repair after partial meniscectomy
 - Combination product
- Leveraging Orthomimetics' biomaterials platform

Financial highlights

- Operating loss (EBIT) of EUR 14.4 million, 13% lower compared to 2008
- Cash and cash equivalents of EUR 24.7 million at year end
- Net proceeds from issuance of shares of EUR 25.3 million in 2009

EBIT decreased with 13% compared to 2008

Consolidated income statement*

<i>Thousands of Euro</i>	31/12/09	31/12/08
Sales	46	0
Other revenues	986	321
Revenues	1,032	321
Research and development expenses	8,114	9,975
Selling, general and administrative expenses	7,316	6,851
Total operating charges	15,430	16,825
Operating Result (EBIT)	(14,398)	(16,505)
Financial result	300	1,340
Profit/(Loss) before taxes	(14,098)	(15,165)
Income taxes	0	0
Net Profit/(Loss)	(14,098)	(15,165)

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

Cash & cash equivalents of EUR 24.7 million

Consolidated cash flow statement*

Thousands of Euro

	<u>31/12/09</u>	<u>31/12/08</u>
Cash at beginning of the period	25,162	39,101
EBIT	(14,398)	(16,505)
Total adjustments	<u>1,146</u>	<u>1,904</u>
Net cash used in operating activities	(13,252)	(14,601)
Net cash used in investing activities	(12,387)	(203)
Net cash provided by financing activities	25,114	989
Net increase/(decrease) in cash	(524)	(13,815)
Effect on exchange rate changes	107	(124)
Cash at end of the period	24,745	25,162

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

Proceeds from issuance of shares of EUR 25.3 M

- 2 financing rounds, raising a total of EUR 13.1 million :
 - Private placement in June '09 raising EUR 5.4 million
 - ABB in December '09 raising EUR 7.7 million
- Acquisition of Orthomimetics Ltd. :
 - Share deal
 - Initial consideration of EUR 12.9 million
- Issue costs of EUR 0.7 million to be deducted

- Shares and warrants at year end :
 - 30.87 million of shares outstanding
 - 1.49 million of warrants outstanding
 - 0.79 million of shares to be issued

Outlook for 2009 was

- CHMP Opinion for ChondroCelect
- Approval and launch of ChondroCelect in selected European countries
- Expansion of cell manufacturing capacity in Europe
- Publication of 3-year data of ChondroCelect trial
- Filing of the BLA for ChondroCelect in the US
- Start of clinical development of the 3D product
- Active partnering (building leadership in regenerative medicine)

Summary and Outlook

2009 has been a transformational year

- ✓ ChondroCelect approved in EU by EMEA as first ATMP
- ✓ New EU manufacturing site acquired and financed
- ✓ Acquisition of Orthomimetics
- ✓ Cash use financed through private placements

2010 will (again) be a banner year

- Launch and reimbursement of ChondroCelect in Europe
- Launch and reimbursement of Chondromimetic in Europe
- Start confirmatory trial for EU and US
- Bring meniscus product in exploratory clinical trial
- Progress biomaterials and stem cells pipeline

Concluding (2)

TiGenix, a frontrunner in the emerging field of “Regenerative Medicine”

- First approved advanced therapy in Europe
- Launching two approved products in Europe
- Pipeline of innovative cell-based products
- Strong biomaterials platform
- Leading manufacturing capability

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Thank you for your attention



GIVE YOUR MOVES WINGS

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