



Kuros Biosciences

Establishing the new gold standard in bone regeneration

Targeting the US \$2billion spinal fusion market



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Executive summary

Experts in the science of bone regeneration (orthobiologics)

- 1 Biotech with MedTech risk profile & focus on bone healing / spinal fusion
- 2 **Large, growing market:** from USD 2.2bn in 2016 to USD 3.4bn¹ expected by 2030
- 3 Growth factor-based Fibrin-PTH: **Phase 2 Spine TLIF study** – enrollment initiated & **first patient treated**
- 4 De-risked Fibrin-PTH: **Two successful Phase 2 trials in trauma**²
- 5 MagnetOs: momentum of commercialisation is accelerating

1: Company estimates based on MedTech 360 reports on US and EU titled 'Orthopedic Biomaterials Market Analysis 2017'
2: Tibial Plateau Fractures (TPF), Tibial Shaft Fractures (TSF)

Company overview

- Founded in 2000 as a spinoff of Swiss Federal Institute of Technology in Zurich
- Acquired Xpand Biotechnology in 2017 to strengthen the orthobiologics platform
- Listed on the SIX Swiss Exchange (Ticker: KURN)



1: As of June-30-2020

2: As of June-30, 2020, cash and cash equivalents, trade receivables and other receivables

3: Based on the latest SIX stock exchange filings (June-30-2020)

Executive management team



Joost de Bruijn, PhD
Chief Executive Officer

- Founder & CEO of Xpand Biotechnology, Scinus Cell Expansion, RevisiOs and Progentix Orthobiology
- Head of Bone Tissue Engineering at IsoTis Orthobiologics
- Professor at Queen Mary University of London, UK
- 28+ years of experience in the field of orthobiologics research, product development and commercialisation



Executive management

>80 years pharma, MedTech and Biotech experience



Pascal Longlade, MD
Chief Medical Officer



Alistair Irvine, PhD
Chief Business Officer



Philippe Saudan, PhD
Chief Development Officer



Frank-Jan van der Velden, MBA
Head of Business Affairs



Michael Grau, MBA
Chief Financial Officer

- Senior financial executive in life sciences, including positions at Morphosys and EndoSense
- Ex-CFO of Correvio LLC, a hospital specialty pharma company with commercial operations globally



Commercial management

≈40 years global spine industry experience



John Griffin, MBA
Head of Commercial Operations



Charlie Campion, PhD
Head of Global Marketing

Product pipeline

 = **Priority asset**

MedTech

Product	Therapeutic Areas	Preclinical	Regulatory Submission	Market Clearance
MagnetOs Granules (EU) and MagnetOs Putty (EU)	Orthopedics, Spine, Dental			
MagnetOs Granules (US) and MagnetOs Putty (US)	Granules: Spinal fusion (posterolateral) Putty: Spinal fusion, Orthopedics			

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Product	Therapeutic Area	Non-clinical	Pilot	Pivotal	Registration
KUR-023/Neuroseal (EU and US ¹)	Dural sealant				

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Biotech

Product	Therapeutic Area	Preclinical	Phase 1	Phase 2	Phase 3
Fibrin-PTH KUR-113 (EU & US)	Spinal Interbody Fusion ²				
KUR-111 (EU & US)	Tibial Plateau Fractures				
KUR-113 (EU & US)	Tibial Shaft Fractures				
CMP-001 (US) (out-licensed)	Melanoma				

 Kuros Biosciences

 Kuros Biosciences

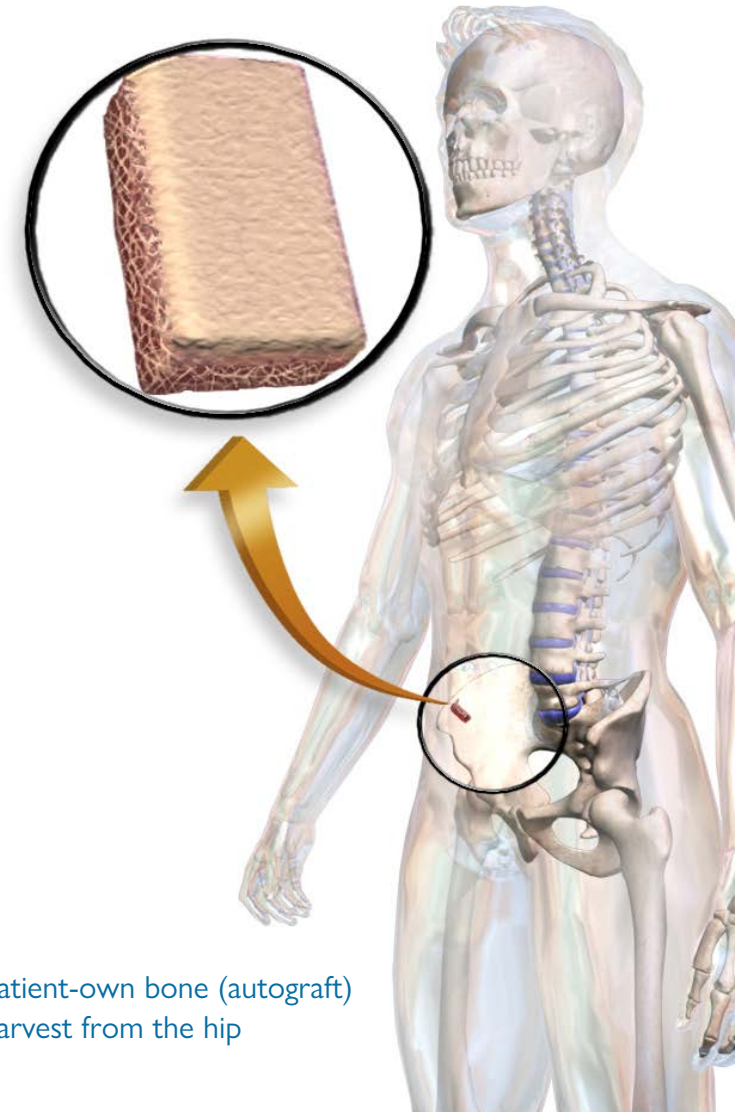
 **CHECKMATE**
PHARMACEUTICALS

Kuros to receive up to \$56m in pre-commercial milestones and high single-digit to low-teens royalties for CMP-001 from Checkmate Pharmaceuticals

1. In the US, Neuroseal has undergone non-clinical trials and a pilot study only
2. Anticipated phase 2 & 3 clinical study utilizing safety data from KUR-113 tibial shaft fracture trial

Why target bone grafting indications?

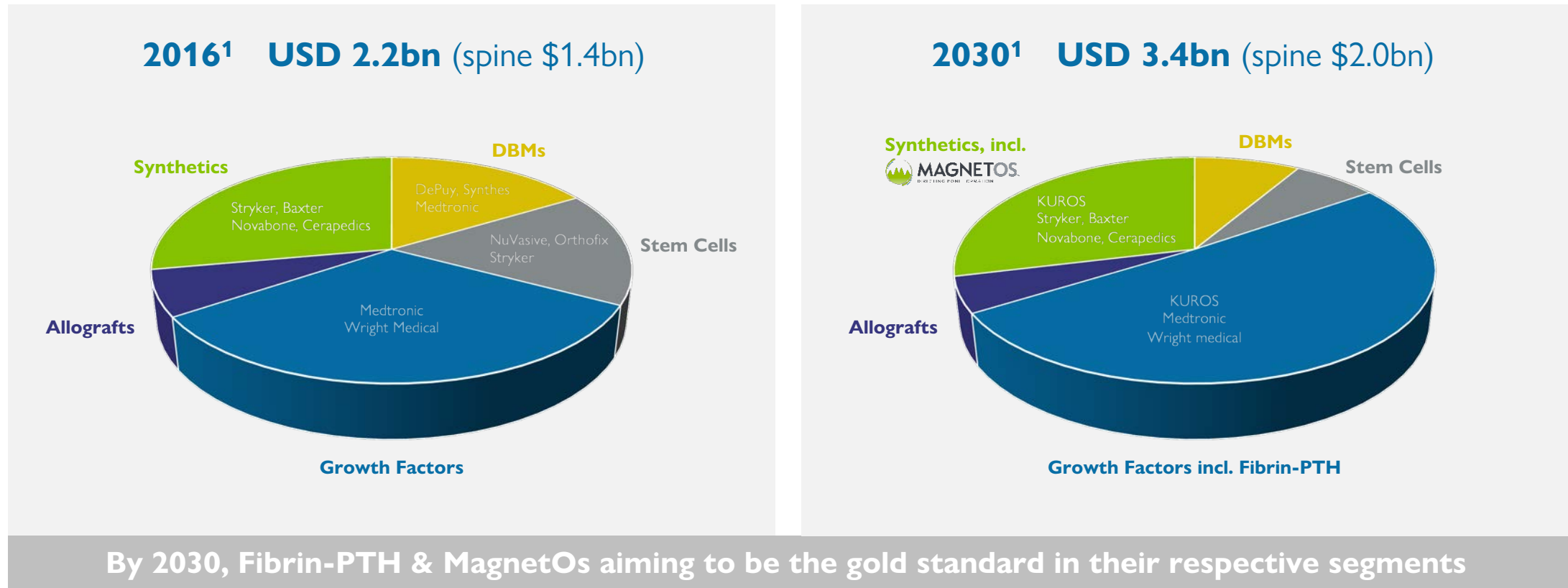
- Bone grafting is often used to augment the body's own ability to heal bone following trauma or surgery. This ability may be compromised due to numerous patient-related factors.
- The “gold-standard” bone grafting technique (autografting), where bone is harvested directly from the patient, can lead to post-operative complications. Non-fusion rates are also problematic, potentially resulting in additional procedures and increased treatment costs.
- The Company believes that there is a significant opportunity to improve clinical outcomes and gain market share with advanced orthobiologic technologies.



Patient-own bone (autograft)
harvest from the hip

A large, growing orthobiologics market

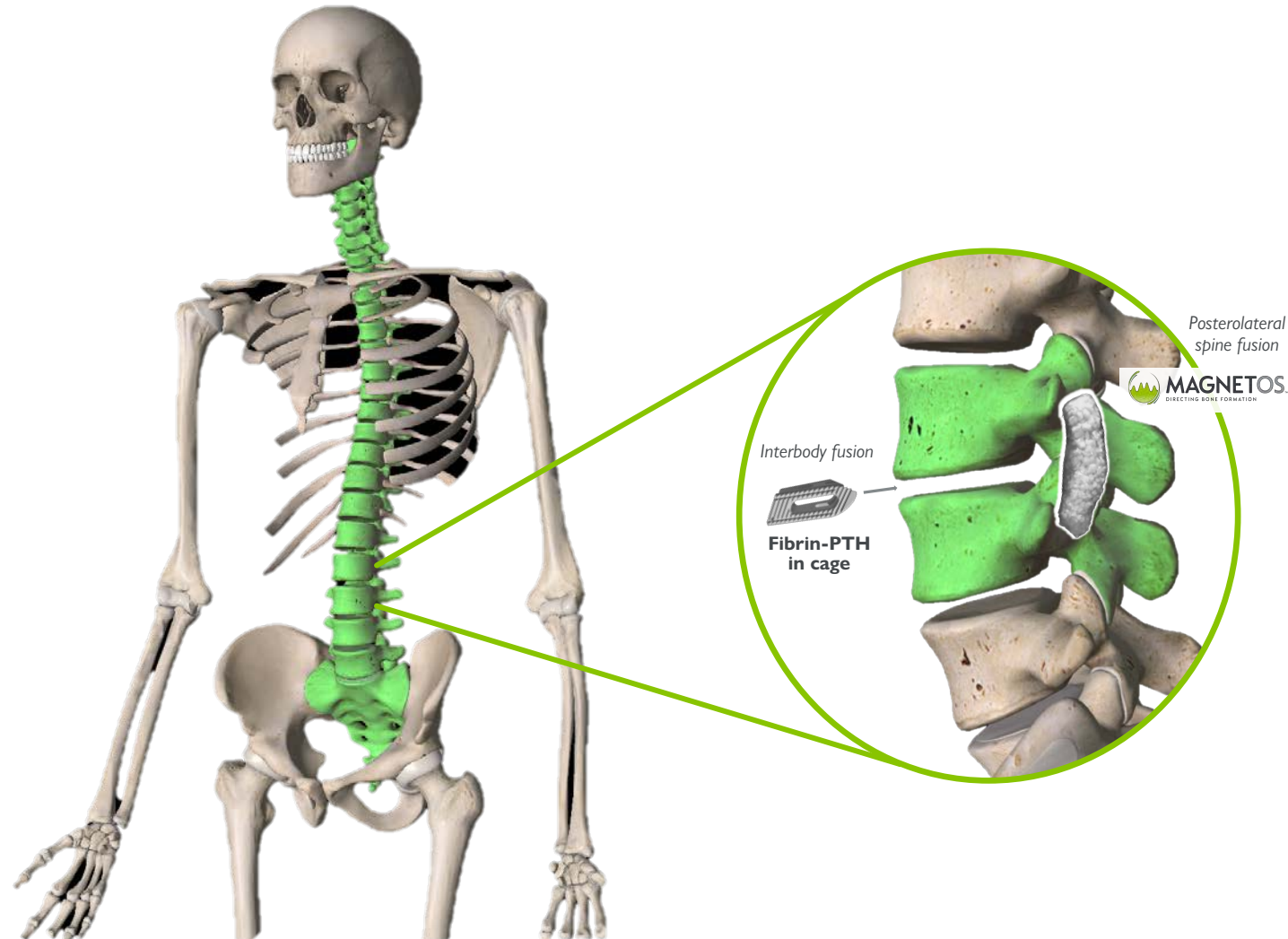
Ageing population and increased treatment rate are expected to drive market growth
 Focusing on the spinal segment



¹: Company estimates based on Medtech 360 reports on US and EU titled "Orthopedic Biomaterials Market Analysis 2017"

Spinal fusion

- A combination of Kuros products



What is spinal fusion?

- Surgical procedure where two or more vertebrae are fused together to eliminate painful motion

What symptoms does it cure?

- Lower back pain and/or leg pain as result of e.g. degenerative disk disease, spondylolisthesis, recurrent disc herniations, etc.

Number of treatments

- By 2022, estimated annual fusions will be 876k in the USA and 470k across major EU countries¹

Techniques

- Posterolateral fusion (PLF) uses rods and screws with bone graft on either side of the vertebrae to create a solid fusion mass - **MagnetOs application**
- Transforaminal lumbar interbody fusion (TLIF) uses a cage filled with bone graft placed between the vertebrae to promote fusion - **Fibrin-PTH application**

On a mission to eliminate non-unions

A unique business model - combination of MedTech & Biotech opportunities

MedTech



Description

Bone graft substitute (BGS) with *advanced submicron surface topography* that directs the body to form bone

Value

Equivalence to autograft and superiority to other BGS¹, avoiding negative side-effects of harvesting autograft

Status – commercially available

Commercial sales since H2 2018, initial focus on the US market and UK through a network of key opinion leader surgeons, distributors and agents (hybrid model)

Biotech

Fibrin-parathyroid Hormone (PTH)

Description

Drug-biologic combination aimed to deliver targeted and controlled bone formation

Value

Proven safety and efficacy in two orthopedic Phase 2 trials (~400 patients) and preclinical studies and superior handling vs competing products²





Status – clinical development

Phase 2 clinical study - enrolment initiated, first patient treated (FPI) & several active sites

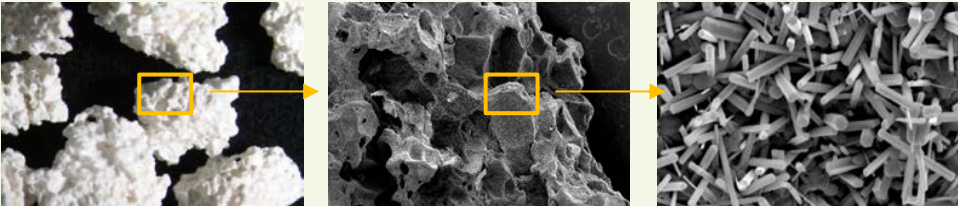
1: Shown in clinically-relevant preclinical studies
2: Based on results of a ten-month model in sheep, US (vs. Autograft and rhBMP2)

What is MagnetOs?

Revolutionary bone graft with superior surface topography

			
<p>Properties/mechanism of action</p> <ul style="list-style-type: none"> ✓ Surface topography directs bone formation ✓ Equivalent to autograft & superior to other synthetics 	<p>Indications & regulatory status (Granules & Putty)</p> <ul style="list-style-type: none"> ✓ US: FDA 510k for posterolateral spine fusion, pelvis & extremities ✓ EU: CE-mark with broad indications & inductive claim 	<p>Benefits & positioning</p> <ul style="list-style-type: none"> ✓ Key differentiator: surface topography ✓ Case studies & randomized controlled trial / clinical data generation 	<p>Commercial rollout</p> <ul style="list-style-type: none"> ✓ Commercial in US & EU since H2 2018 ✓ Direct sales targeting KOLs, to hybrid model & agents distributor network

Advance submicron surface topography



Market opportunity est. USD 2bn by 2030¹

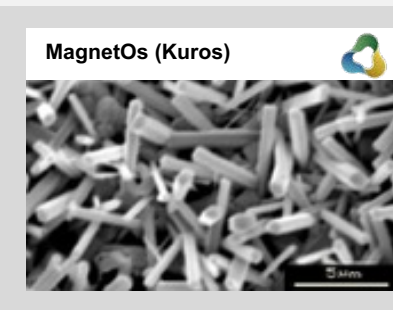
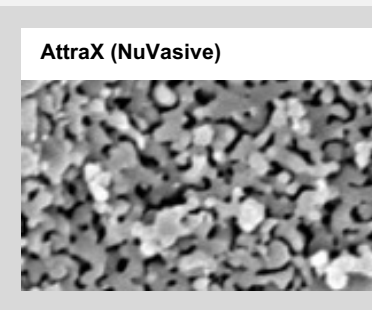
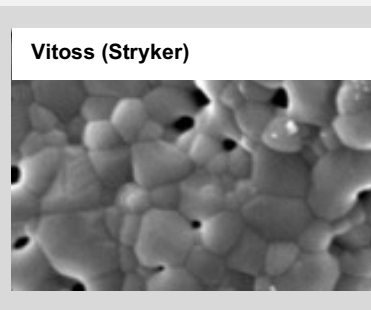
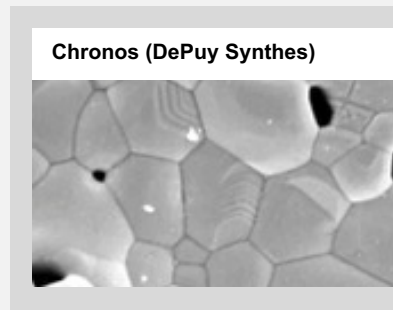
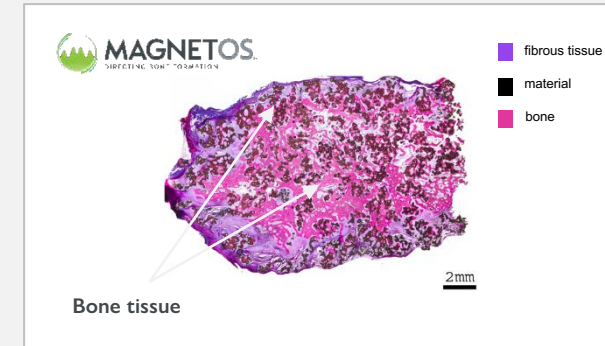
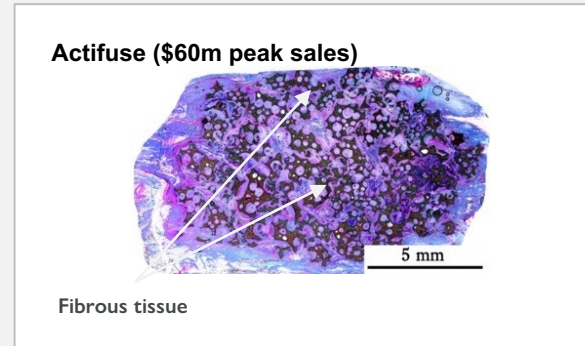
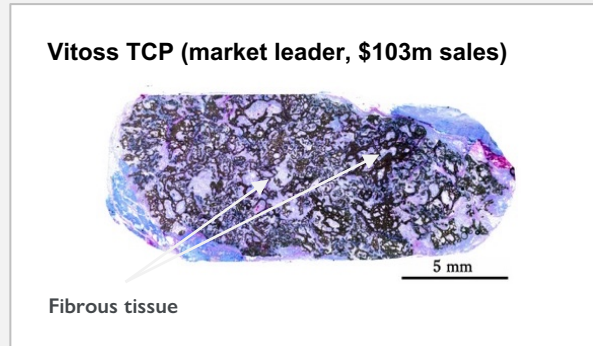
Indication	2016 - Market Size US + EU	2030 - Market Size US + EU
Spinal Fusion (Focus area)	USD 1,402m	USD 1,979m
Synthetics (in spinal fusion)	USD 350m	USD 600m
Total Bone Graft Mkt Size	USD 2,191m	USD 3,381m

3D Animation: <http://kurosbio.com/resources/magnetos-3d-animation-the-science-behind-the-surface/>

1: Company estimates based on MedTech 360 reports (US/EU) "Orthopedic Biomaterials Market Analysis 2017"

MagnetOs' key differentiator

Superior surface structure promotes bone in soft tissues without added cells or growth factors^{1,*} †



ADVANCING TECHNOLOGY

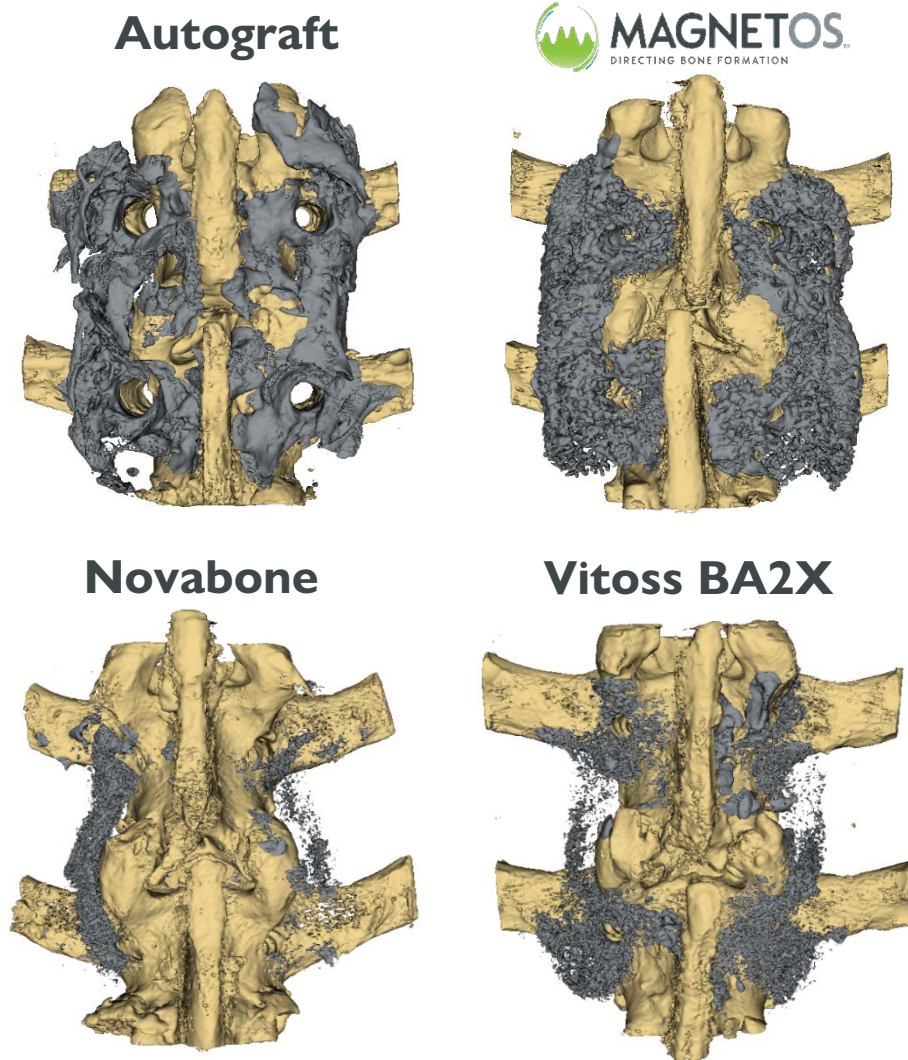
MagnetOs preferentially directs early wound healing towards the bone-forming pathway

¹: Duan et al., European Cells Mater 37:60-73 (2019)

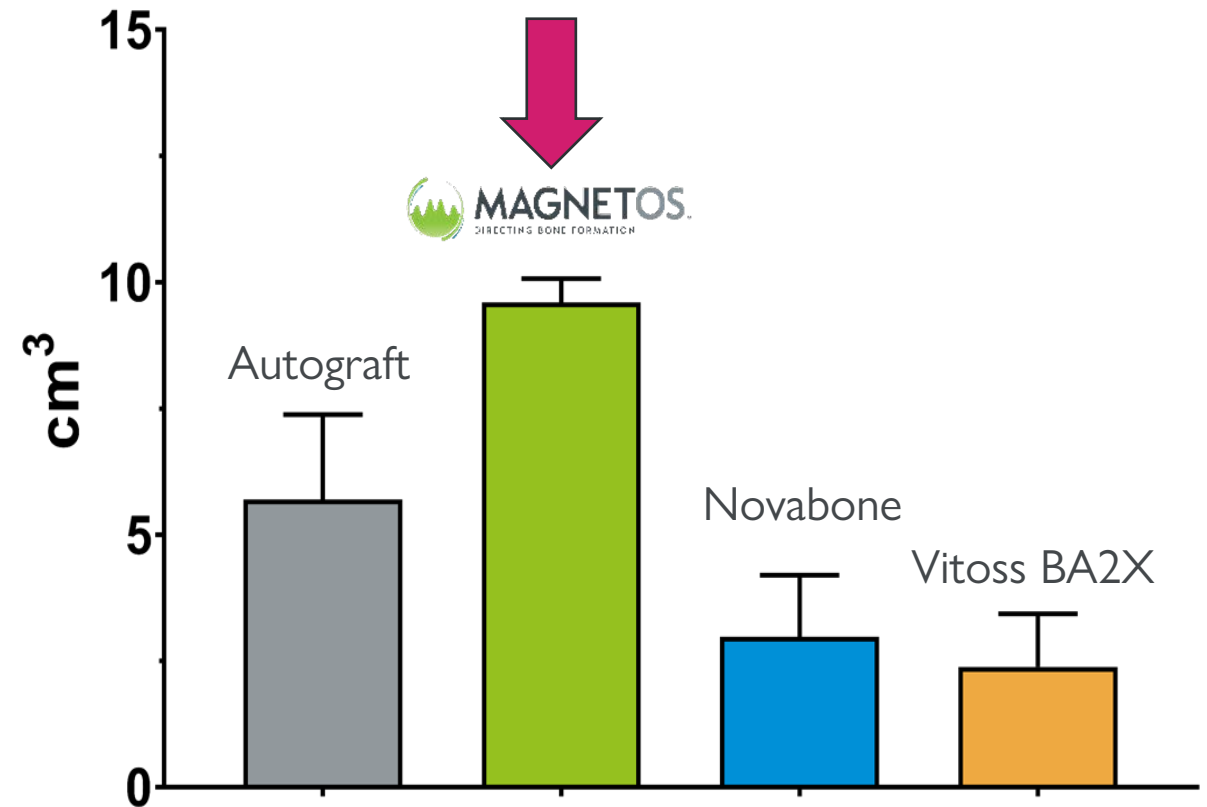
* Results from in vitro or in vivo laboratory testing may not be predictive of clinical experience in humans

† Osteoinductive claim in EU; MagnetOs is not cleared by FDA as an osteoinductive graft

MagnetOs shows no reduction in fusion mass



- MagnetOs shows no reduction in fusion mass compared to autograft and market-leading products^{1, *}



1: Clin Spine Surg. 2020 Jul;33(6):E276-E287

* Results from in vitro or in vivo laboratory testing may not be predictive of clinical experience in humans.

Retrospective clinical study shows excellent results



**Dr. Kornelis
Poelstra,
MD, PhD**

The Robotic Spine Institute of
Silicon Valley, USA

“Our center conducted an investigator-led retrospective chart review of 25 cervical and 52 lumbar reconstruction patients, who underwent circumferential- or anterior column only interbody reconstruction surgery with MagnetOs to achieve solid spinal arthrodesis. Lumbar fusion rates were 94/97 levels (96.9%) while cervical fusion was confirmed in 75/80 (93.8%) levels. Modified Prolo scores showed Meaningful Clinically Important Differences (MCID) in 74/77 patients.

Our work clearly demonstrates that for patients in need of complex cervical or lumbar reconstruction surgery, MagnetOs is a viable substitute to autograft for reliable augmentation of interbody arthrodesis formation with excellent clinical outcomes.” #

#Poelstra, K. Retrospective Evaluation of Spinal Fusion Using a Biphasic Calcium Phosphate Bone Graft with a Novel Submicron Surface Topography; Submitted in July 2020 to Clinical Spine Surgery

Momentum of MagnetOs commercialisation is accelerating

Since start of commercialisation (June 2018) to date ~\$3.9m sales
(Sales growth of 81% in H2 19 vs. H1 19 and 42% in H1 20 vs. H1 19)

Growth of direct sales force

Successful, rapid commercialisation of MagnetOs achieved with 6 sales reps

Increased number of agents

Enhanced number of surgeon users
Take-up of repeat sales

OEM agreement signed



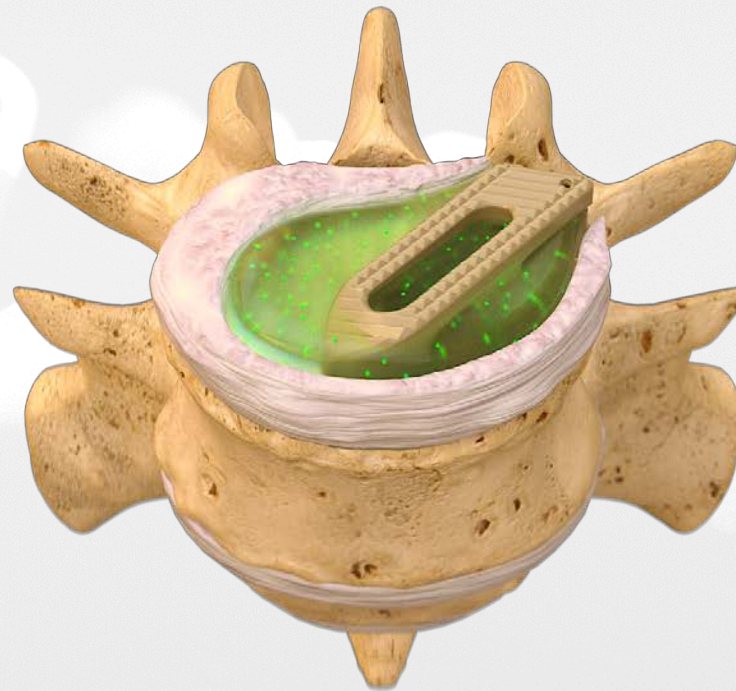
What is Fibrin-PTH?

Our latest product candidate, Fibrin-PTH (KUR-113), aims to deliver targeted and controlled bone formation

This product candidate functions via the **well-established mechanism of action** of parathyroid hormone – or PTH – and the natural healing matrix fibrin

Proven safety profile of PTH (Lilly's blockbuster drug Forteo®)

Unlike rhBMP-2 (peak sales c.\$1bn)¹, Fibrin-PTH only **affects cells already committed to form bone**



Fibrin-PTH has been implanted in trials with **~400 patients**, reaching its primary endpoint in two human studies for bone healing

Fibrin-PTH[#] was demonstrated in animal studies of spinal fusion to have **comparable efficacy as rhBMP-2**

Its **excellent flowability and setting** properties make it ideal for open or minimally invasive surgical techniques

Enrolment Phase 2 spinal fusion trial initiated²

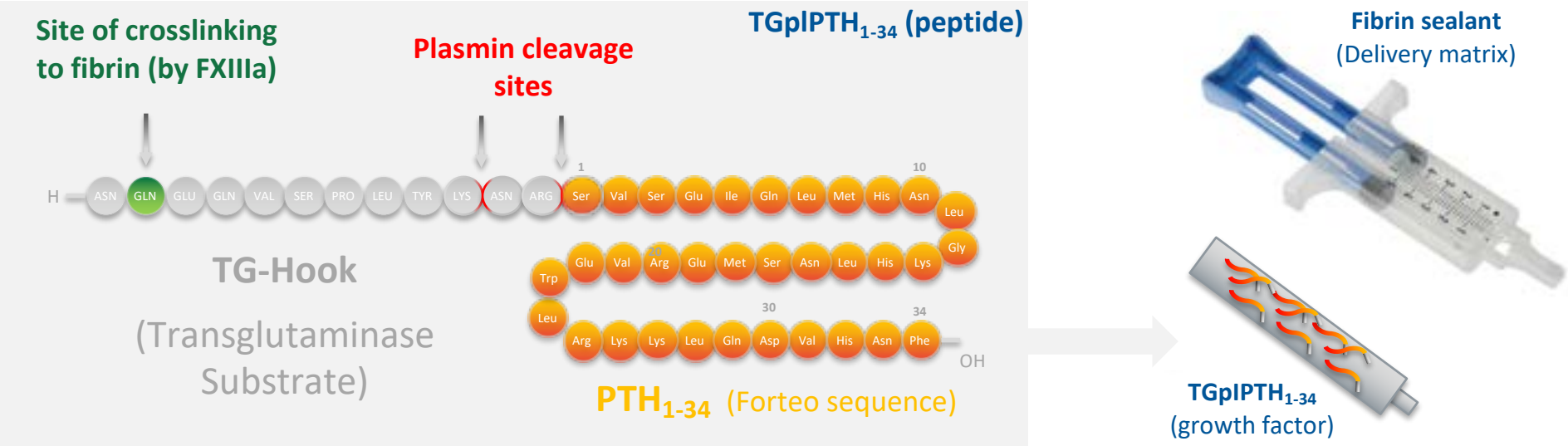
3D Animation: <http://kurosbio.com/resources/fibrin-ptk-kur-113-3d-animation/>

¹: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5310069/#CR37>

²: <https://clinicaltrials.gov/ct2/results/cond=&term=NCT04294004&cntry=&state=&city=&dist=>

[#] Fibrin-PTH (KUR-113) is an investigational drug/biologic combination product candidate. Fibrin-PTH (KUR-113) has been evaluated in animals for use in lumbar interbody fusion. The safety & efficacy of Fibrin-PTH (KUR-113) has not yet been evaluated for spinal fusion in humans

Fibrin-PTH is novel & suited to the growing field of Minimally Invasive Surgery (MIS)




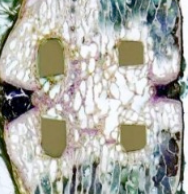

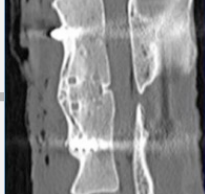
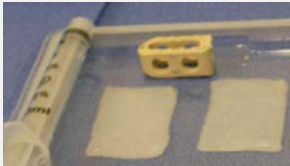


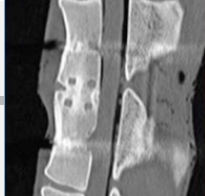



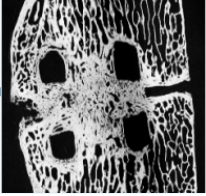
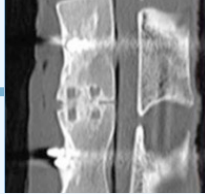
1 PREPARATION
 TGpPTH₁₋₃₄ is directionally conjugated to the fibrin matrix upon polymerization

2 APPLICATION
 Fibrin/TGpPTH₁₋₃₄ can easily be applied as a gel that solidifies in situ

3 ACTIVATION
 Biologically active PTH is gradually released by enzymatic (plasmin) cleavage at the site of implantation

Fibrin-PTH has comparable high fusion rates to InFuse and Autograft in sheep

Current Alternatives

		Histology	Micro-radiographs	CT Images		% Fusion (μCT)	% Fusion (Histology)	Bone Area in Cage (net tissue %)
Current Alternatives	Autograft (Gold standard) 				Intervertebral disc space	100%	100%	48% ± 8%
	InFuse (rhBMP2) 				Intervertebral disc space	100%	100%	43% ± 7%
	 Fibrin/PTH 				Intervertebral disc space	100%	100%	54% ± 7%

Financial highlights for the first six months 2020 (1)

Condensed Consolidated Income Statement	June 30 2020	June 30 2019
<i>IFRS in TCHF</i>		
Product sales	1,295	910
Total Revenue	1,295	910
Cost of goods sold	(152)	(138)
Research & Development costs	(3,128)	(3,423)
General and administrative costs	(2,438)	(2,007)
Sales & Marketing costs	(2,069)	(882)
Other income	120	182
Operating loss	(6,372)	(5,358)
Net financial result	(130)	(243)
Loss before tax	(6,502)	(5,601)
Income taxes	662	374
Net loss	(5,840)	(5,227)

- Revenues have increased by 42% compared to H1 2019
- Growth in sales and marketing costs reflects ramp up commercialization of MagnetOs

Financial highlights for the first six months 2020 (2)

Consolidated balance sheet	June 30 2020	December 31 2019
<i>IFRS in TCHF</i>		
Total non-current assets	63,078	64,562
Current Assets		
Inventories	1,230	954
Prepayments and other assets	474	459
Trade receivables	522	759
Other receivables	309	316
Cash & cash equivalents	15,212	20,802
Total Current assets	17,747	23,290
Total assets	80,825	87,852
Total shareholders equity	72,100	77,855
Non current liabilities		
Pension liabilities	714	727
Deferred tax liabilities	2,743	3,488
Non-current lease liabilities	2,173	2,142
Total non-current liabilities	5,630	6,357
Current liabilities		
Trade and other payables	490	1,059
Accrued expenses	2,229	2,335
Short term borrowing	104	-
Current lease liabilities	272	246
Total current liabilities	3,095	3,640
Toal shareholders` equity and liabilities	80,825	87,852

- Cash and cash equivalents trade and other receivables amount to TCHF 16,043

Reasons to invest in Kuros

Credibility

Unparalleled depth & breadth of experience in the orthobiologics sector



- >80 years MedTech, Biotech, Pharma amongst senior management
- ~150 years collective orthobiologics research
- Several start-up successes delivered in this sector by the members of the Kuros team

Data

Our products work by truly unique mechanisms that are expected to be backed by a high level of clinical evidence



- MagnetOs is the subject of 4 peer-reviewed research publications
- Unlike most other synthetic bone grafts, MagnetOs is expected to be supported by 10 post-market clinical studies
- Fibrin-PTH has been de-risked by two successful PhII orthopedic clinical trials

Strategy

Our go-to-market strategy is based on extensive experience in the spine industry



- Targeting based on proprietary market research
- Low risk approach to commercialization using blended sales channel and competitive pricing
- Validated by strategic partnerships with specialist spine distributors

Advocacy

Kuros has already secured the support of leading names in this therapy area









- 5 of the leading names in US spinal surgery have put their backing behind Kuros
- Endorsed by pre-eminent professor of orthopedic research
- Long history of use by some of the leading names in spine surgery in EU

Backup



Current treatments either lack efficacy or ease of use

	Treatment method	Avoids tissue harvesting	Targeted bone regeneration	Clinical proof focused	Low procedure complexity	Safety/patient recovery time	Properties
GOLD STANDARD	 AUTOGRAFT Create a defect to fill another	x	✓	✓	x	x/✓	+ Complete histocompatibility - Second surgery often required - Donor site pain and morbidity - Limited availability
GROWING ALTERNATIVES	 INFUSE rhBMP2	✓	x	✓	x/✓	x/✓	+ Induces rapid bone formation - Uncontrolled burst release - Swelling & inflammation (off-label use) - Not target-specific (uncontrolled growth)
	 OTHER SUBSTITUTES Synthetics, DBM, stem cells, allograft	✓	x/✓	x	x/✓	✓	+ Supports bone growth - Mainly passive bone formation - Story-based, limited clinical proof - Inferior alternative to autograft
	 FIBRIN-PTH (KUR-113)	✓	✓	✓ ¹	✓	✓	+ Stimulates rapid bone formation + Targeted to (pre)osteoblasts + Controlled release + Robust safety/efficacy profile ¹
	 MAGNETOS DIRECTING BONE FORMATION	✓	✓	✓	✓	✓	+ Advanced submicron surface topography directs bone formation + Novel mechanism of action based on early wound healing + Osteoinductive (EU claim) + Ambition to strengthen clinical proof

¹: Based on two successful phase 2 studies incl. ~400 patients, and proven safety of Forteo (Lilly's PTH blockbuster drug)

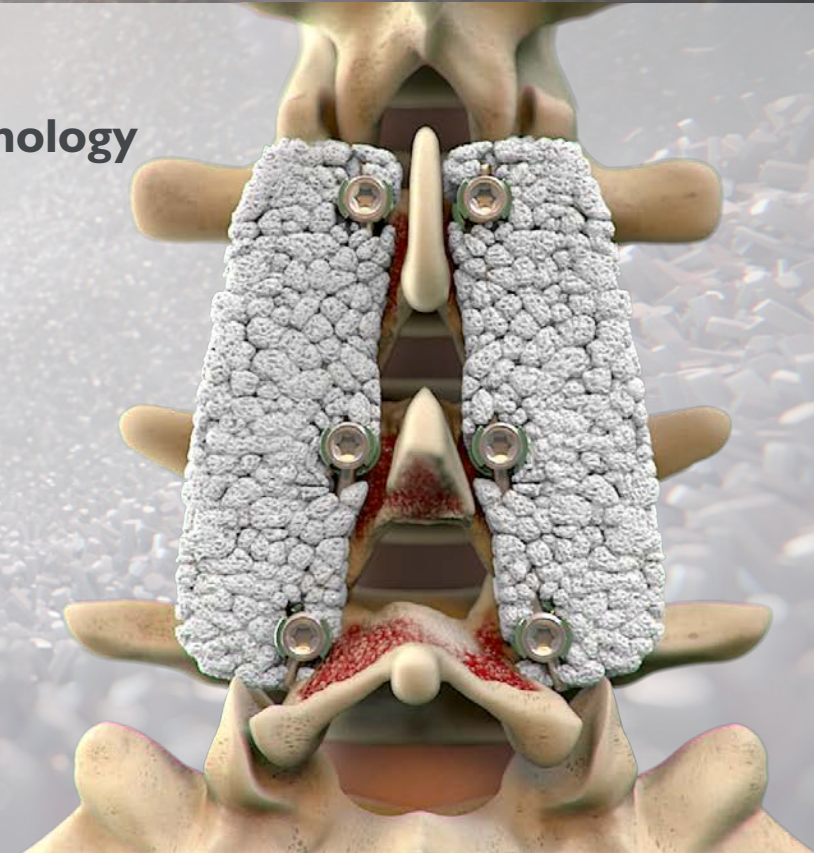
MagnetOs

MagnetOs, our flagship product, is a revolutionary bone graft with success in the surface.

Harnessing the power of macrophage polarization and osteoimmunology

Made of biphasic calcium phosphate (BCP), MagnetOs mimics the porous, trabecular structure of cancellous bone¹. It has a unique submicron surface topography that harnesses the power of macrophage polarization² and osteoimmunology, to deliver uniform, stable and reliable fusions.^{3*}

Head-head preclinical studies against autograft and leading competitors showed – using multiple fusion end-point analysis at the 12-week mark – MagnetOs' performance was equivalent to the 'gold standard' of autograft & superior to the current market-leading alternatives.^{4*}



1: MagnetOs Instructions for Use

2: Data on file, 2019

3: Van Dijk, LA, et al. J Biomed Mater Res B Part B 2019;99999B:1–11

4: Walsh et al., NASS 2019 annual meeting, oral presentation & Clin Spine Surg. 2020 Jul;33(6):E276-E287

* Results from in vitro or in vivo laboratory testing may not be predictive of clinical experience in humans

Strategic advisory board

Five opinion-leading US spine surgeons and a professor of orthopedic research who are considered experts within their field but with the focus, mentality and motivation to help shape the future of our organization.



Dr Patel, MD
Northwestern, Chicago



Dr Sandhu, MD
Georgetown, DC



Dr Allen, MD
UCSD, San Diego



Dr Sama, MD
HSS, New York



Dr Poelstra, MD
Ortho Northcal, CA



Prof Walsh, PhD
UNSW, Australia

Proven in real-world application – Lumbar spine



STUDY BACKGROUND

AIM

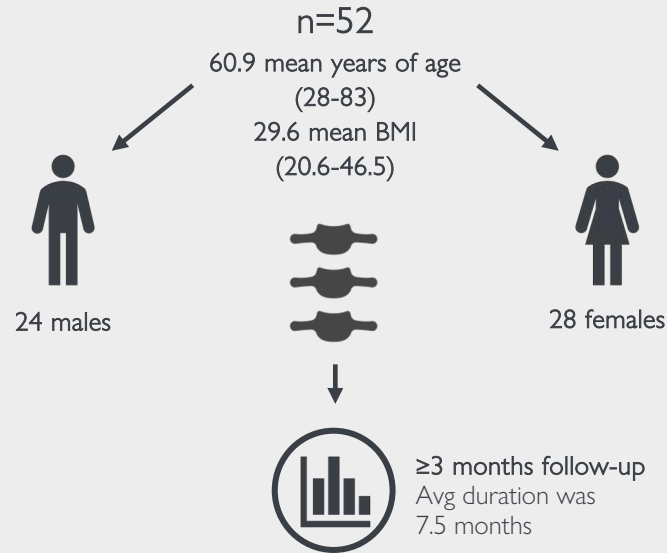
Evaluate the clinical and radiographic outcomes in patients treated over a 9-month period.

COHORT

Reconstructions with posterior, lateral, or anterior interbody fusions with or without posterior lumbar instrumented fusions, retrospective cohort study.

Clinical outcome was assessed using a modified Prolo scale and clinical evaluation at varied timepoints.

SINGLE / MULTILEVEL INTERBODY LUMBAR SPINE ARTHRODESIS



COMPILATION OF SUCCESSFUL FUSIONS BETWEEN 3-12 MONTHS POST-OPERATIVELY

	PATIENTS (n)	LEVELS (n)
Total	52	97
Fused	49	94
Non-Fused	3	3
Fusion %	94%	97%

Pseudoarthrosis was observed in 3 out of 97 levels (3.1%).

CLINICAL OUTCOME WAS ASSESSED USING A MODIFIED PROLO SCALE (0-20) AND CLINICAL EVALUATION



Patient reported outcomes showed a **substantial improvement** in pain and functional grade

Proven in real-world application – Cervical spine



STUDY BACKGROUND

AIM

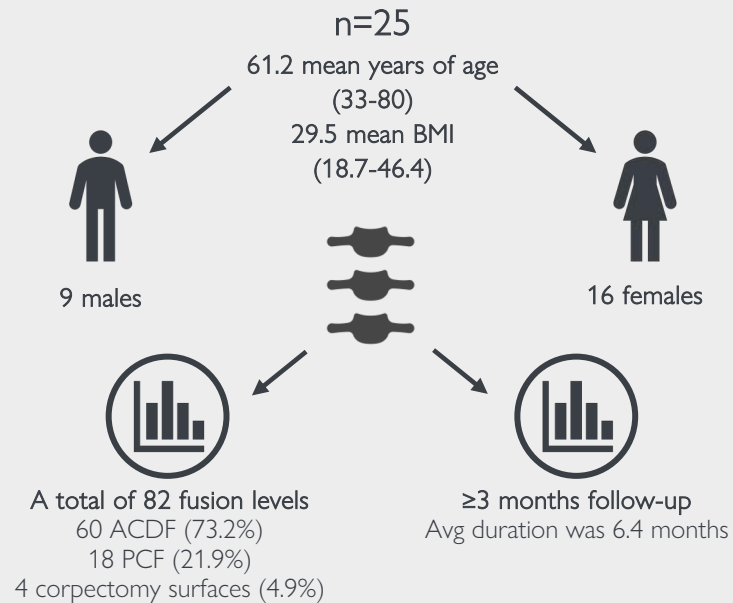
Evaluate the clinical and radiographic outcomes in patients treated over a 9-month period

COHORT

Reconstructions with posterior and anterior cervical interbody fusions, retrospective cohort study.

Clinical outcome was assessed using a modified Prolo scale and clinical evaluation at varied timepoints.

SINGLE / MULTILEVEL CERVICAL SPINE ARTHRODESIS



COMPILATION OF SUCCESSFUL FUSIONS BETWEEN 3-12 MONTHS POST-OPERATIVELY

	LEVELS			
	PCF	Corpectomy Surfaces	ACDF	Total Levels
Total	18	4	60	82
Fused	18	4	55	77
Non-Fused	0	0	5	5
Fusion %	100%	100%	92%	94%

Successful fusion was achieved within 12 months in 77 out of 82 levels (94%), of which 53 out of 82 levels (65%) fused in the first 6 months. Pseudoarthrosis was observed in 5 out of 82 levels (6.1%)





CLINICAL OUTCOME WAS ASSESSED USING A MODIFIED PROLO SCALE (0-20) AND CLINICAL EVALUATION

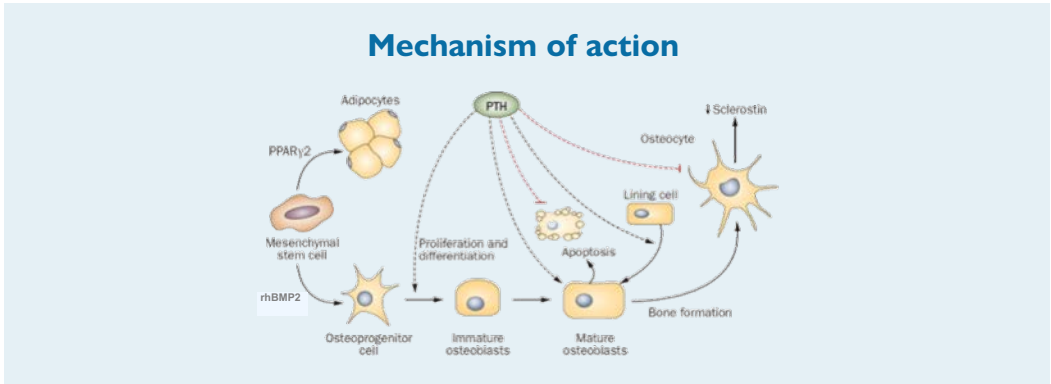


Patient reported outcomes showed a **substantial improvement** in pain and functional grade

What is Fibrin-PTH?

Drug-biologic combination - Parathyroid hormone (PTH) and fibrin

			
<p>Mechanism of action</p> <ul style="list-style-type: none"> ✓ PTH promotes bone formation ✓ Controlled & targeted release of PTH 	<p>Indications</p> <ul style="list-style-type: none"> ✓ Interbody lumbar spinal fusion (focus area) ✓ Use with FDA cleared cages¹, incl. Kuros TLIF cage 	<p>Benefits & positioning</p> <ul style="list-style-type: none"> ✓ Effective with superior safety and handling vs Infuse² ✓ Proven safety profile of PTH (Lilly's blockbuster drug Forteo[®]) ✓ Excellent flowability & setting: ideal for open or minimally invasive surgery 	<p>Development stage</p> <ul style="list-style-type: none"> ✓ De-risked: safe & effective in trauma p2 trials (~400 patients) ✓ Phase 2 spinal fusion trial enrollment initiated[#] <p>Next value inflection</p> <ul style="list-style-type: none"> ✓ Phase 2 read-out end 2021/early 2022*



Market opportunity est. USD 2bn by 2030³

Indication	2016 - Market Size US + EU	2030 - Market Size US + EU
Spinal Fusion (Focus area)	USD 1,402m	USD 1,979m
Growth factors (in spinal fusion)	USD 500m	USD 1b
Total Bone Graft Mkt Size	USD 2,191m	USD 3,381m

3D Animation: <http://kurosbio.com/resources/fibrin-pth-kur-113-3d-animation/>

1: Dependent on FDA feedback
 2: Off-label product use
 3: Company estimates based on Medtech 360 reports (US/EU) "Orthopedic Biomaterials Market Analysis 2017"
[#] Fibrin-PTH (KUR-113) is an investigational drug/biologic combination product candidate. Fibrin-PTH (KUR-113) has been evaluated in animals for use in lumbar interbody fusion. The safety & efficacy of Fibrin-PTH (KUR-113) has not yet been evaluated for spinal fusion in humans
 *Dependent on COVID-19 & start of elective surgeries

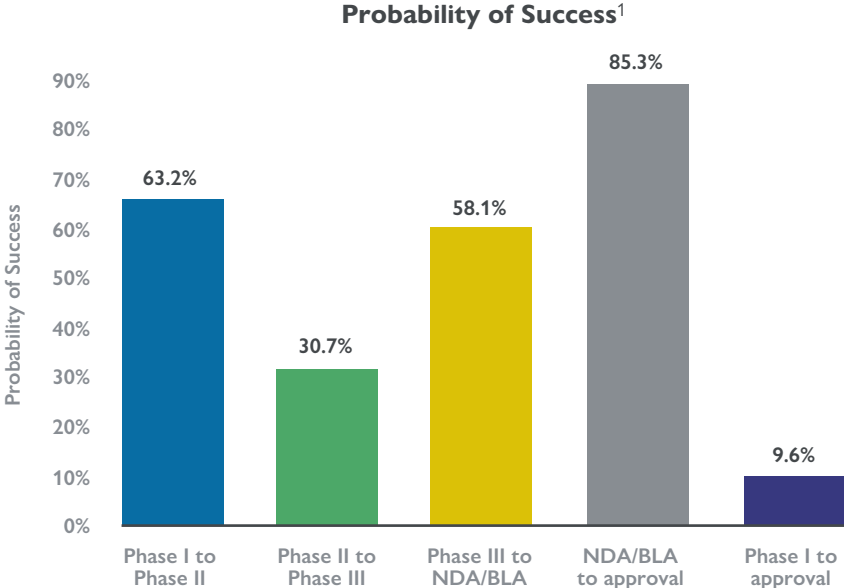
Fibrin-PTH is significantly de-risked

Phase transition success & likelihood of approval (LoA)

Fibrin-PTH is significantly de-risked:

- Successful completion of two Phase 2 studies (safety/efficacy in nearly 400 patients) related to bone repair in the trauma field (Tibial Plateau Fractures/Tibial Shaft Fractures phase 2b)
- Safety profile of PTH (Forteo, Lilly’s \$1.7b blockbuster drug)

	All diseases, all modalities ¹	Fibrin-PTH (Spine) ²
Phase I to II	63,2%	
Phase II to III	30,7%	90,0%
Phase III to NDA/BLA	58,1%	75,0%
NDA/BLA to approval	85,3%	90,0%
LOA from Phase I	9,6%	
LOA from Phase II	15,2%	60,8%



1: BIO Industry Analysis, Biotechnology Innovation Organization, "Clinical Development Success Rates 2006-2015"
 2: Based on company estimates

Kuros Biosciences – patent portfolio

Extensive patent portfolio to protect its products

- Kuros has a broad patent portfolio with >100 granted patents and a number of additional patent applications
- Patents are focused in the main markets of US and Europe but also include other markets such as China, Australia and Canada
- Current granted patents have valid claims until 2036 with patent applications which, if granted, would give coverage until 2039

Patent families related to:	Approx. expiry of granted patents	Approx. expiry of pending if granted
Fibrin-PTH	2031	2039
MagnetOs	2036	2036



Kuros Biosciences

Kuros Biosciences AG is a limited liability company registered in Switzerland. Registered address: Wagistrasse 25, 8952 Schlieren, Switzerland.
Register of commerce number CHE-104.785.642