Kuros Biosciences

The future of spinal fusions

Kuros Biosciences

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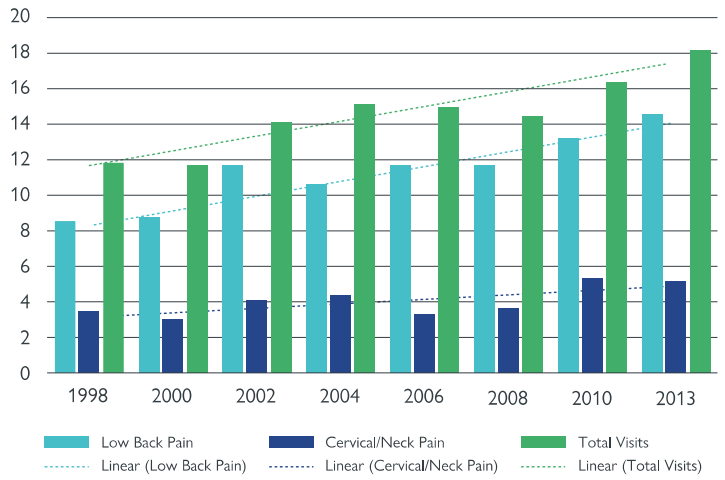
Spine-related pain is taking a huge toll on our society: more days in bed, more days off work, and at a greater financial cost to westernized healthcare than any other condition.

Physician visits have doubled over 20 years.[1]

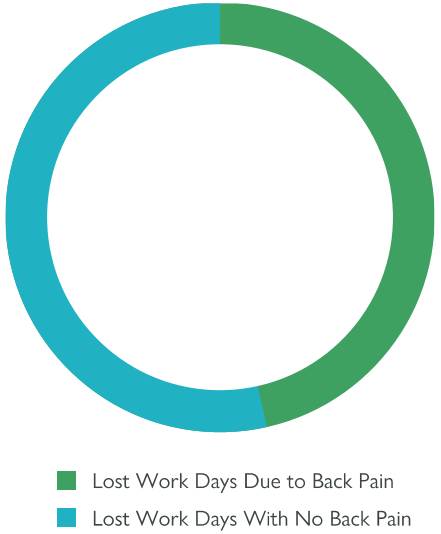
United States 1998 to 2013



Trend in physician visits back and neck pain.

The leading cause of days off work.[2]

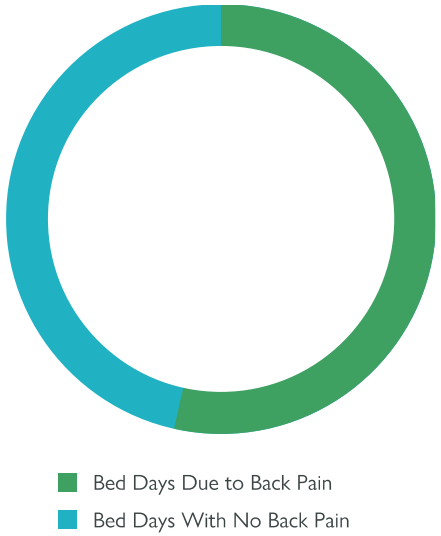
United States 2015



Share total list workdays in past 12 months with and without back pain.

More bed days than for any other condition.[3]

United States 2015



Share total bed days in past 12 months with and without back pain.

References: 1. National ambulatory medical care survey (NAMCS). 1998-2013. https://www.cdc.gov/nchs/ahcd/ahcd_questionnaires.htm. January 14, 2016. **2.** National Health Interview Survey (NHIS)_Adult sample, 2013, 2014, 2015. http://www.cdc.gov/nhis/data-questionnaires-documentation.htm. July 23, 2016. **3.** National Health Interview Survey (HIS)_Adult sample, 2013, 2014, 2015. http://www.cdc.gov/nhis/data-questionnaires-documentation.htm. July 23, 2016.

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Kuros is on a mission to ease the burden of spine-related pain through superior biologics for better spinal fusions.

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Kuros Biosciences at-a-glance

Kuros is a Swiss-headquartered biotech company, listed on the SIX Swiss Stock Exchange (Ticker: KURN) since 2016. With operations in the Netherlands and the USA, we employ a growing team of 53 people.

To deliver the ideal bone graft, you need the highest quality & quantity of scientific evidence behind it. We believe that this is a key differentiator for Kuros, given the urgent need to reduce spinal fusion failure rates. Our credentials:

A commercial & research footprint that spans 3 continents and covers more than 10 markets.

>30 biologics-related patents.

8 well-controlled Level I-III clinical trials initiated, with 3 Level I studies having been completed and meeting primary endpoints.

>150 years' combined research experience in the field of biologics for spine fusion.

>5,000 patients successfully treated worldwide with our bone graft technologies.

4 teams of internationally renowned clinical and scientific expert advisers, including 18 Key Opinion Leader (KOL) spine surgeons.

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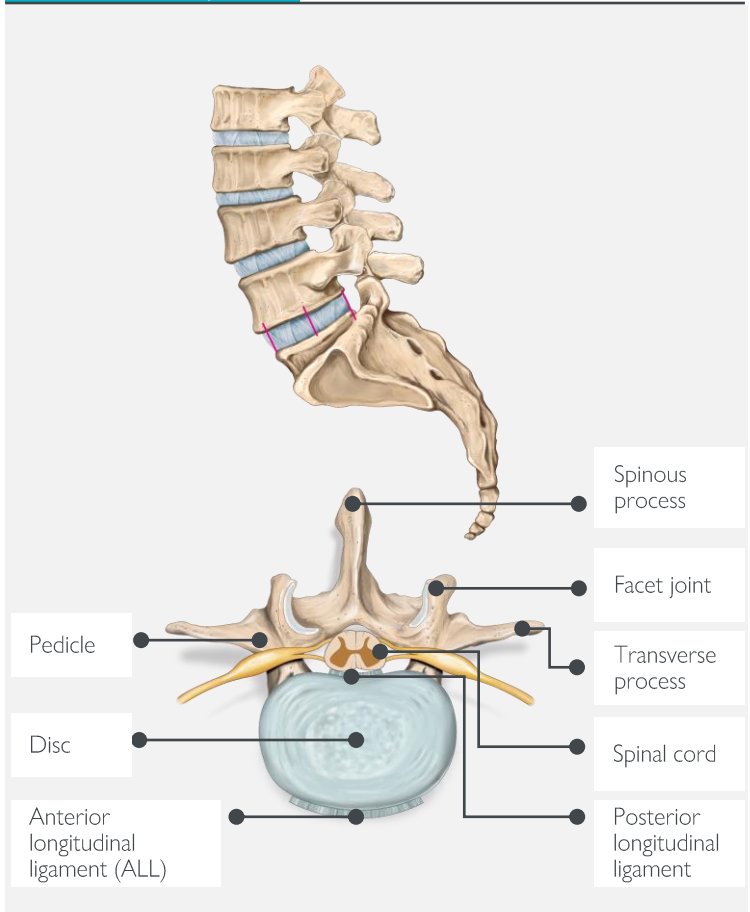
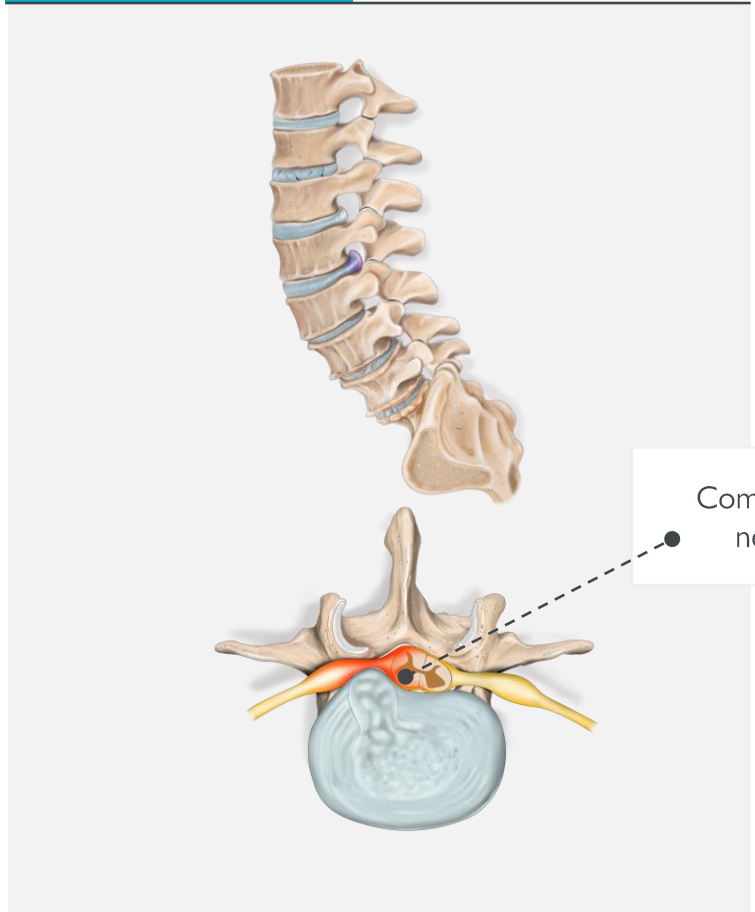
Spine-related pain

Two most common ailments

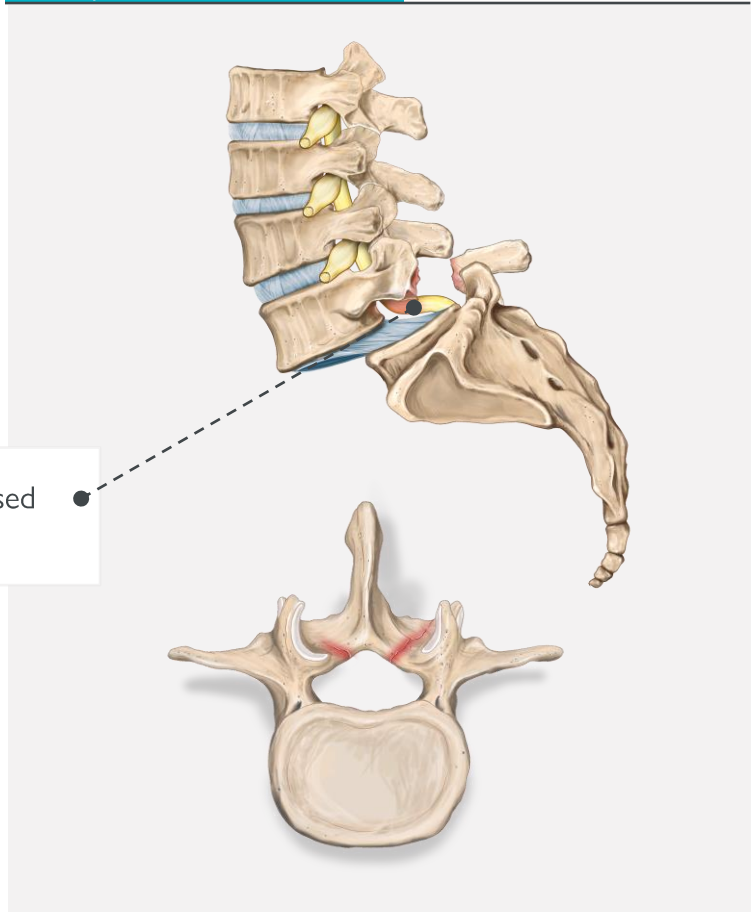
Normal spine



Herniated disc



Displaced vertebra



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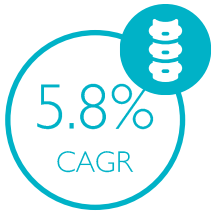
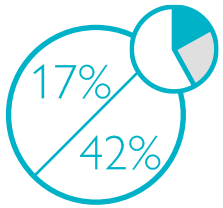
Spinal fusion surgery

The challenge & opportunity



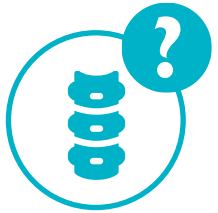
The number of spinal fusion surgeries conducted worldwide is growing.



However, the failure rate for current surgical treatment is 17% - which jumps to 42% for patients with poor health.[1-3]

In fact, the re-operation rate for spine fusions is 10%: so 1 in 10 patients need a second operation to resolve their spine-related pain.[4]

This is bad news for patients, insurers, and medical organizations – where revision surgery barely meets the threshold of cost-effectiveness at $118k/QALY.[5]



Hence, surgeons, medical organizations and insurers are becoming more discerning about the products approved for these procedures.

Already, we are seeing a reimbursement storm as insurers refuse claims for unproven and off-label products.

Bone grafts are essential to improving fusion rates: in fact, the most effective ones can improve the chance of success by up to 60%.[2,6,7]

Bone grafts supported by high-quality Level I clinical studies will ultimately become the solution of choice of surgeons, providers, and insurers.

References: 1. Medtech 360 report "Orthopedic Biomaterials Market Analysis 2017". **2.** Hsu, et al. *GSJ.* 2012;2:239–248. **3.** Company estimates based on Pearldiver Mariner database. **4.** Mabud, et al. *Clin Spine Surg.* 2017;30:E1376–E1381. **5.** Adogwa, et al. *J Spinal Disord Tech.* 2015;28(3):101–5. **6.** Chun, et al. *Neurosurgical Focus.* 2015;39(4):E10. **7.** Morris, et al, *ESJ.* 2018;27:1856–1867.

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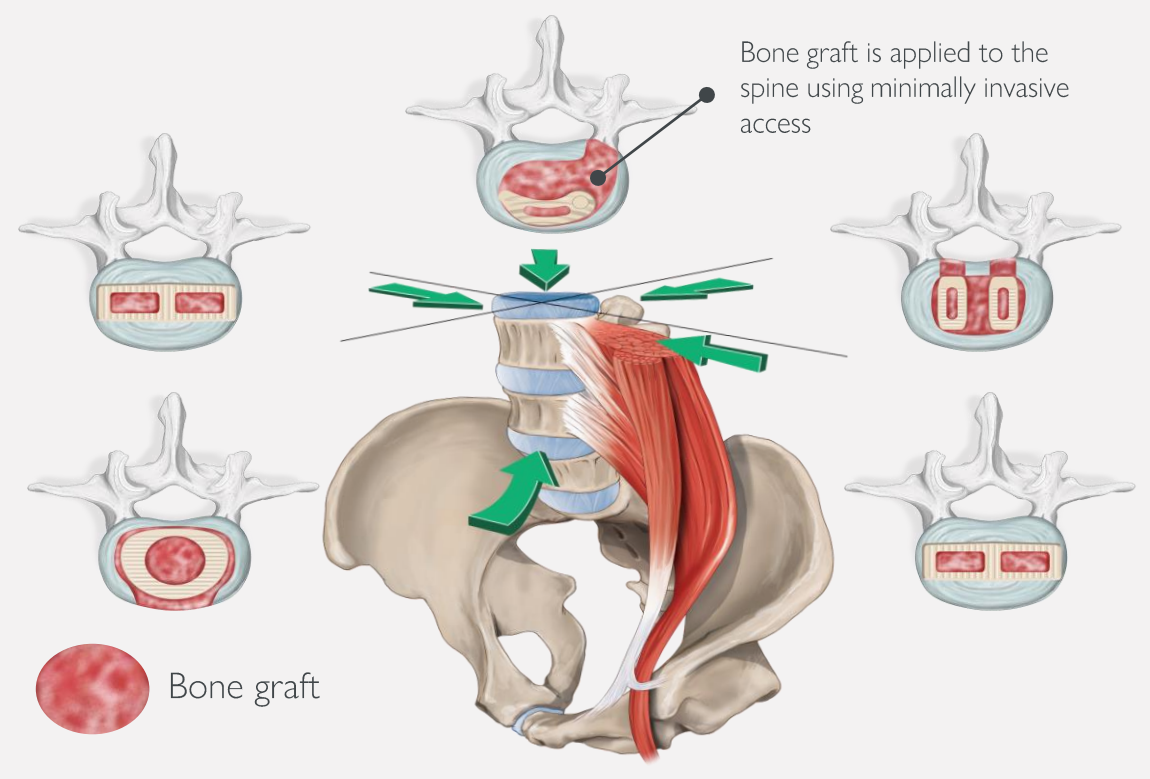
Spinal fusion surgery

Two main types of surgery

Anterior column

770k lumbar bone grafts per annum in the US[1]

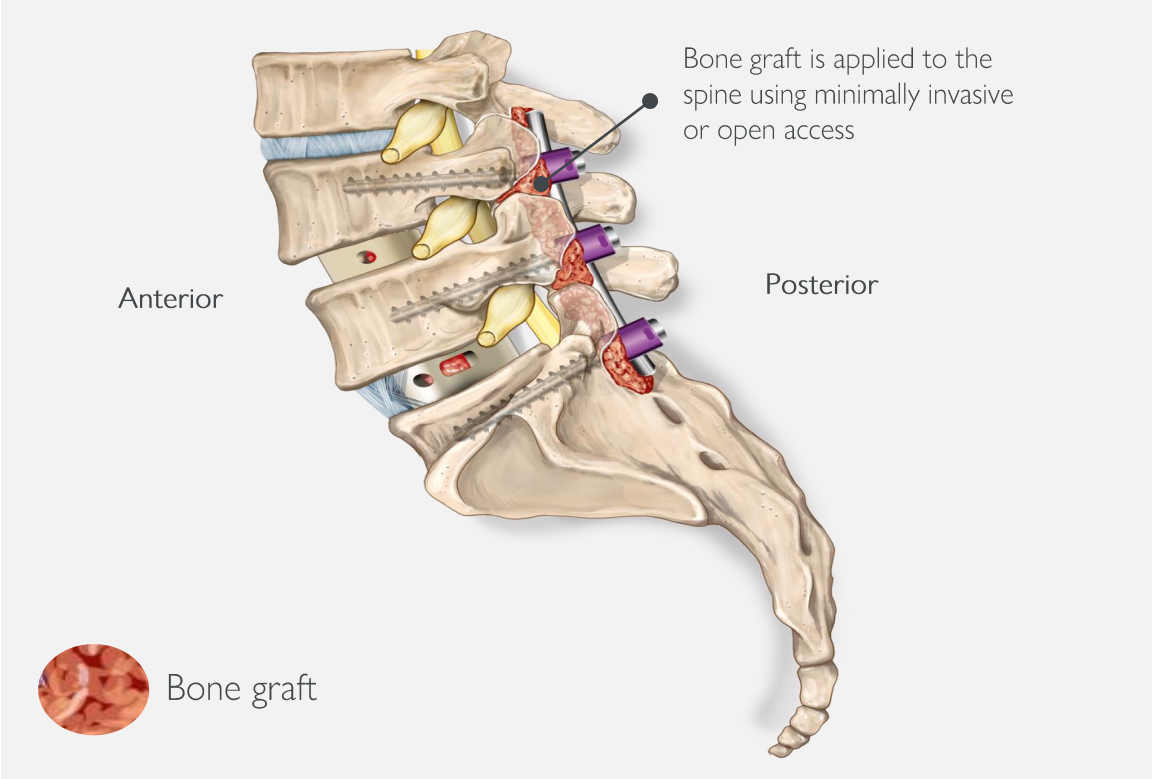
Today's competitive landscape shows solutions that deliver high safety or efficacy…but rarely both. And none that are suitable for truly non-invasive surgical approaches.



Posterior column

640k lumbar bone grafts per annum in the US[1]

There is a clear market opportunity for a product that increases fusion rates, is backed by high quality clinical data, but provided at a lower price point.



References: 1. Company estimates based on proprietary quantitative market research study of 100 US spine surgeons

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Kuros solutions

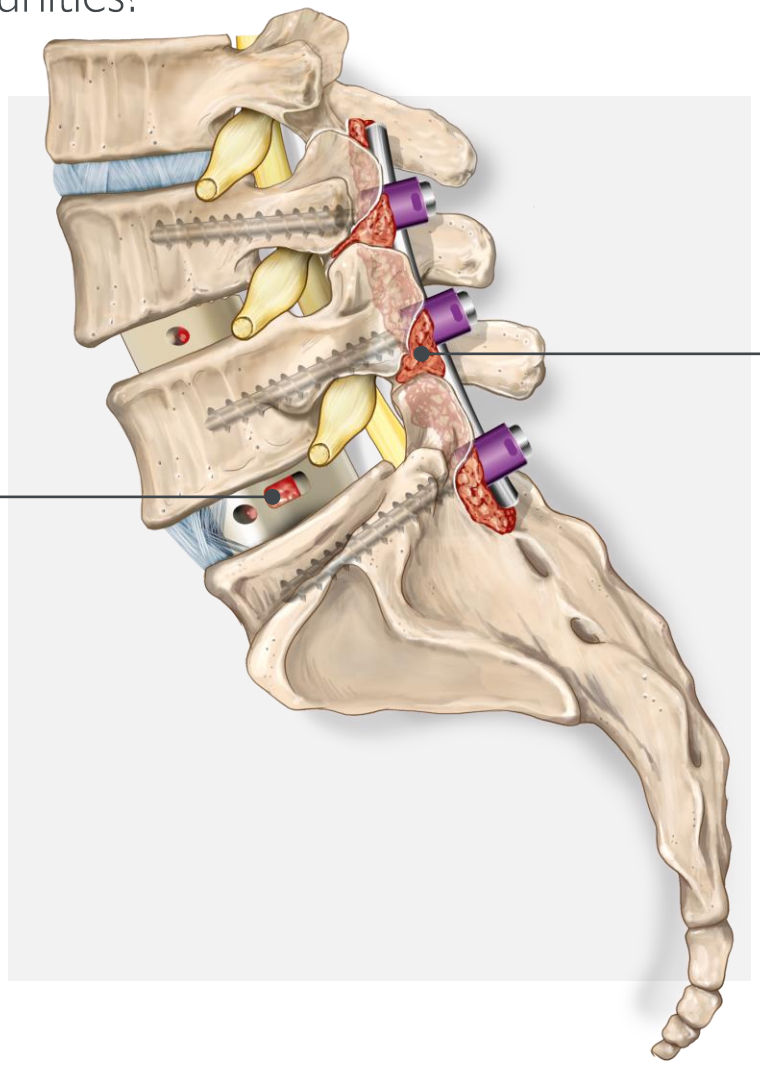
How do we address these two opportunities?

Anterior column reconstruction

Fibrin-PTH (KUR-113): Phase II

The first ever investigational drug-biologic candidate to be evaluated for spinal fusion; and the first to be compatible with truly non-invasive surgical procedures.

- 2022 — Phase 2 enrolment complete
- 2023 — Phase 2 results
- 2023 — Phase 3 study start



Posterior column reconstruction

MagnetOs: Launched

A bone graft that unlocks previously untapped potential to stimulate stem cells and form new bone, even in soft tissue, throughout the graft for an efficient and predictable fusion.*†[1-4]

- 2022 — 2 new EU country launches planned
- 2022 — US launch MagnetOs Easypack Putty/Flex Matrix
- 2023 — 2x new clinical studies planned
- 2022 — 510(k) – MagnetOs Flex Matrix/Granules standalone PLF
- 2023 — EU launch MagnetOs Flex Matrix

References: 1. Van Dijk, et al. *eCM.* 2021;41:756-73. **2.** Duan, et al. *eCM.* 2019;37:60-73. **3.** Van Dijk, et al. *JOR Spine.* 2018;e1039. **4.** Van Dijk, et al. *J Biomed Mater Res. Part B: Appl Biomater.* 2019;107(6):2080-2090. *Results from in vivo laboratory testing may not be predictive of clinical experience in humans.
For important safety and intended use information please visit kurosbio.com. †MagnetOs is not cleared by the FDA or TGA as an osteoinductive bone graft.

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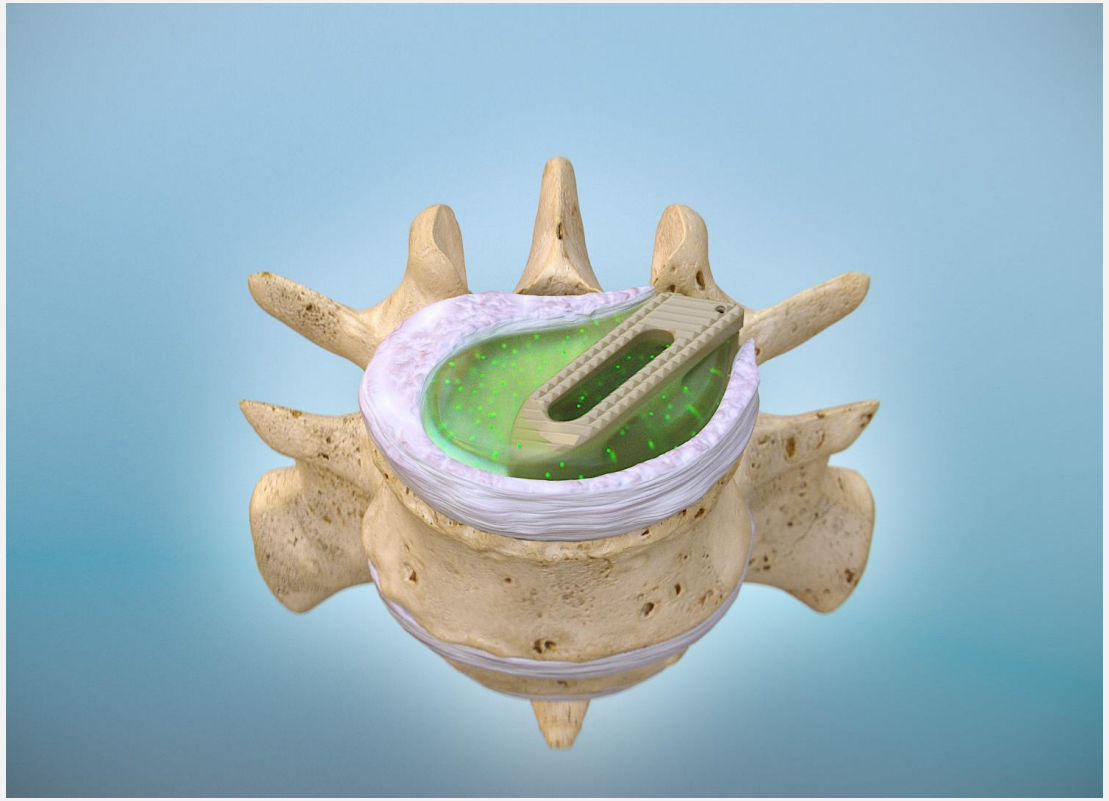
Fibrin-PTH (KUR-113)

In pursuit of the first drug-biologic combination for spinal fusion

- Fibrin-PTH combines the well-established mechanism of the bone growth factor parathyroid hormone (PTH) with the natural healing matrix known as fibrin.*
- Once implanted, Fibrin-PTH promotes spinal fusion by increasing the number and lifespan of bone-forming cells in the fusion space inside the spine.
- This is also the first drug-biologic candidate to be compatible with narrow gauge cannulas for truly non-invasive surgical procedures.
- Now undergoing a Phase 2 clinical trial in the US as part of a de-risked pre-market clinical program.
- Ultimately, this product has the potential to be a genuine game changer once commercially available.



>> https://kurosbio.com/fibrin-pth/

*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.

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STRUCTURE Fibrin-PTH Phase II:
First drug-biologic candidate in trials for spinal fusion

Design

- Prospective, randomized controlled single-blind multi-center study which intends to demonstrate safety and efficacy of Fibrin-PTH (KUR-113) versus local autograft.
- 50 patients in two stages (2 dose levels vs local autograft).

Treatment

- Single-level TLIF with Fibrin-PTH or local autograft added in and around any static FDA cleared monoblock PEEK cage.
- PLF (fixation plus MagnetOs Putty).

Primary endpoint

- Radiological fusion determined by CT-scans and assessed by IREP at 12 months.

Study sites and PIs

- 14 study sites.
- Includes strategic research centers such as UCSD, BWH, HSS, UPenn, Cedars Sinai, Northwestern, Medstar.

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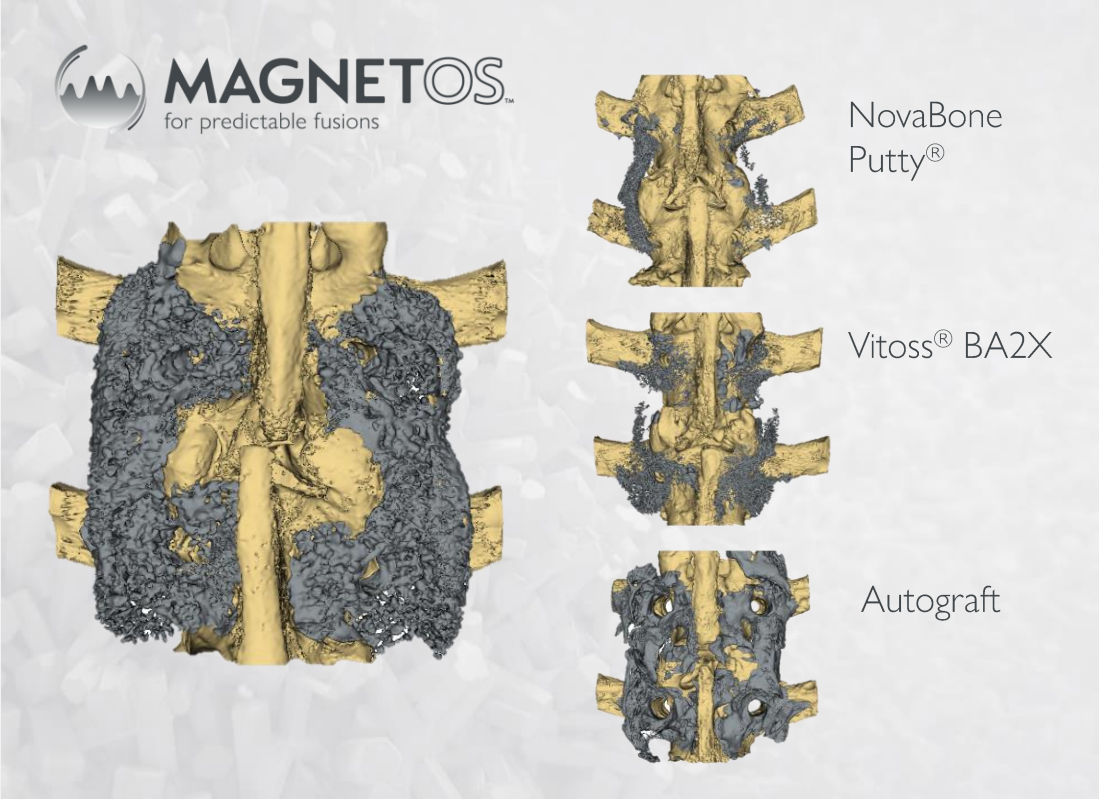
MagnetOs



>> https://kurosbio.com/magnetos/

NeedleGrip™: Getting a grip on non-unions

- MagnetOs isn't like other bone grafts. It grows bone even in soft tissue thanks to our unique NeedleGrip surface technology which provides traction for our body's vitally important 'pro-healing' immune cells (M2 macrophages).*†[1,2]
- This in turn, unlocks previously untapped potential to stimulate stem cells - and form new bone throughout the graft.*[3-5]
- The growing body of science behind NeedleGrip is called *osteoimmunology*. But for surgeons and their patients it means one thing: a more efficient and predictable fusion.*‡[5]
- MagnetOs has already been successfully used in over 5,000 surgeries worldwide.
- New product developments provide a more complete portfolio of peri-operative solutions to surgeons wanting to have access to the therapeutic benefits of MagnetOs bone graft and its NeedleGrip surface technology.

References: 1. Duan, et al. *eCM*. 2019;37:60-73. **2.** Van Dijk, et al. *eCM*. 2021;41:756-73. **3.** Van Dijk, et al. *JOR Spine*. 2018;e1039. **4.** Van Dijk, et al. *J Biomed Mater Res. Part B: Appl Biomater*. 2019;107(6):2080-2090. *Results from in vivo laboratory testing may not be predictive of clinical experience in humans. For important safety and intended use information please visit kurosbio.com. †MagnetOs is not cleared by the FDA or TGA as an osteoinductive bone graft. ‡MagnetOs has been proven to generate more predictable fusions than two commercially available alternatives in an ovine model of posterolateral fusion. Vitoss is a registered trademark of Stryker Corp. Novabone Putty is a registered trademark of Novabone Products LLC.

Kuros Biosciences

Expand the depth and breadth of our commercial footprint,

by doubling our US sales team and expanding new territories

United States

- Direct sales team that spans 50 states.
- Supported by growing network of independent agents & distributors.
- Sales in all major metropolitan areas.
- Accounts include prestigious names across the country such as: HSS (NY), Northwestern (Chicago), Medstar (DC), UCSD (CA).

International

- Launched MagnetOs in 11 new EU countries and 1 APAC country within the space of 12 months.
- EU distributors in Switzerland, The Netherlands, UK, France, Italy, Spain, Austria, Denmark, Norway, Sweden, Finland, and Greece.
- Portugal expected to close in H1, 22.
- Augmented pricing granted and product launched in Australia.

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Management overview

Executive Management

Joost de Bruijn
Chief Executive Officer

Michael Grau
Chief Finance Officer

Extended Leadership Team

John Griffin
SVP & President US Sales

Charlie Campion
SVP Marketing & International Sales

James Ryaby
SVP, Clinical and Medical Affairs

Philippe Saudan
Chief Development Officer

Alistair Irvine
Chief Business Officer

Florence de Groot
Head of Development

Marcel Borger
Head of Quality & Regulatory Affairs

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Company overview

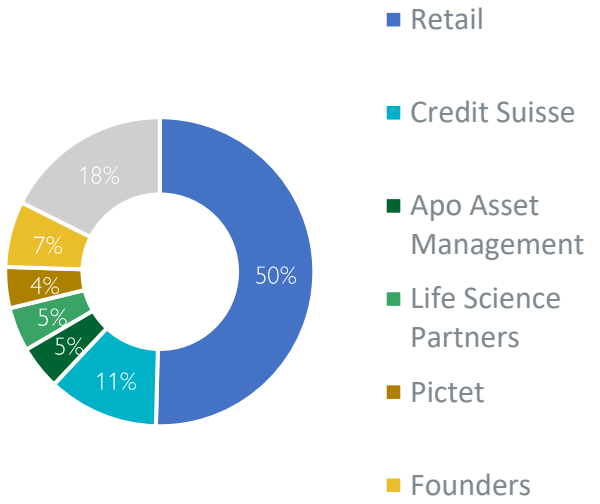
Locations

Boston (US)
- Sales & Marketing
- Medical Education
- Clinical development

Bilthoven (NL)
- MagnetOs manufacturing hub
- Clinical development & R&D
- Marketing & International sales
- Regulatory affairs
- Quality management
- Logistics

Schlieren (CH)
- Financial head office
- Fibrin-PTH development hub
- Business Development

- Listed on the SIX Swiss Stock Exchange (Ticker: KURN)
- HQ in Switzerland, operational base in the Netherlands, Sales office in USA
- 53 Employees



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Company timeline

March 2000
Founded as a spin-off of Swiss Federal Institute of Technology in Zurich

May 2016
Listed on Swiss Exchange

January 2017
Acquired Xpand Biotechnology in 2017 to strengthen the biologics platform

May 2017
First patient treated with MagnetOs (EU)

February 2018
US registration and virtual office established

June 2018
First patient treated with MagnetOs (US)

July 2019
Signing of first APAC distributor

Sept 2019
Full commercial launch of MagnetOs (US)

August 2020
First patient treated with Fibrin-PTH (KUR-113) in the spine

July 2021
First human data for MagnetOs published

July 2021
Launch of MagnetOs in nine European countries

August 2021
US office opened in Boston

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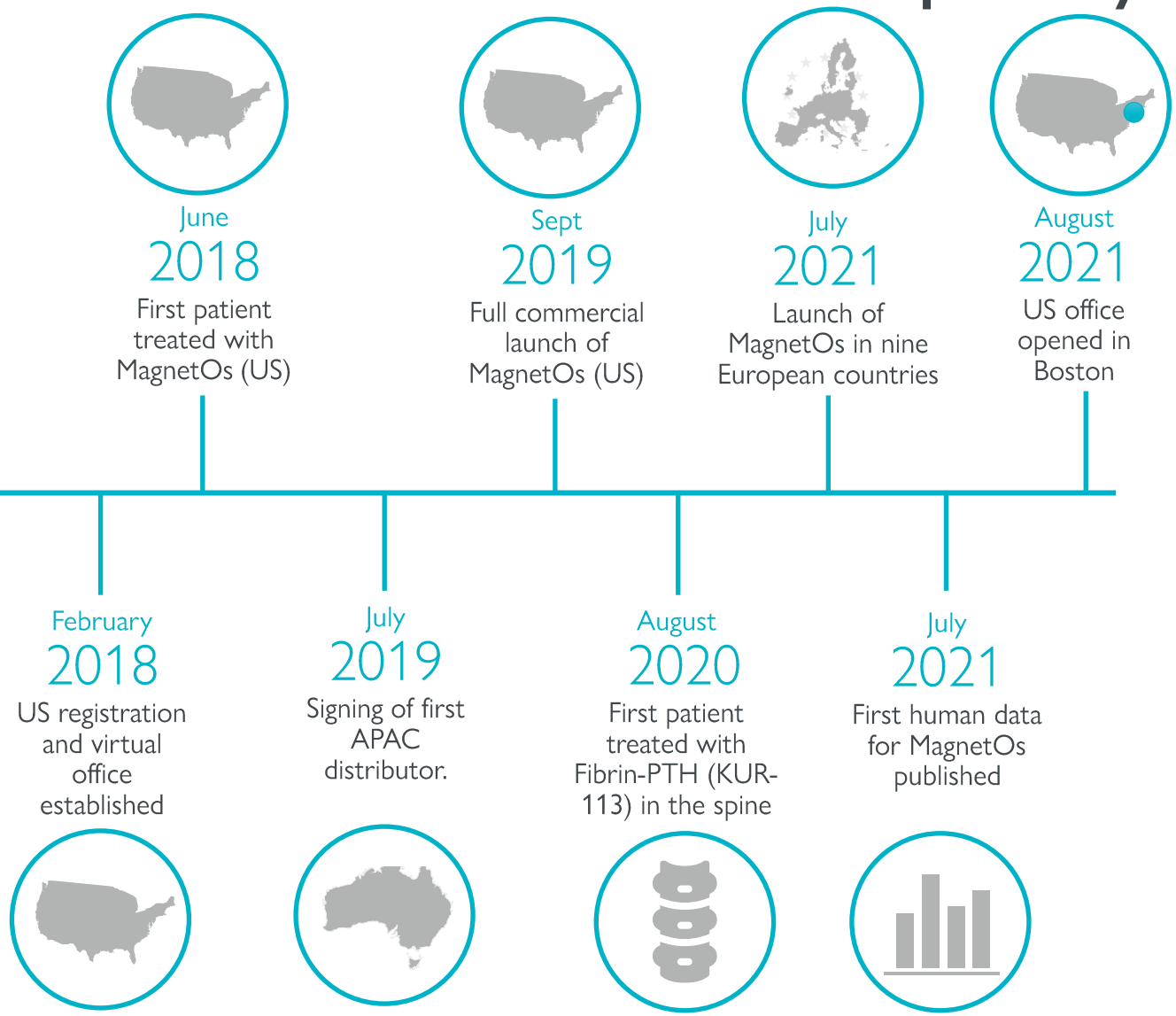
Our transformation over the past 3 years



- Transitioned from research/B2B to science-focused commercial organization.
- Strategically focused on a high-value market segment.
- Defocused non-core workstreams and products.
- Established a physical presence in our core market of the USA.

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Strategic plan for growth:

4 key value drivers

01 **Expand depth and breadth of our commercial footprint** by doubling our US sales team and expanding new territories.

02 **Phase II clinical trial for Fibrin-PTH** (STRUCTURE study): the first drug-biologic candidate to be approved for an open IND by FDA for spinal fusion.

03 **Make the unpredictable…predictable,** through an unprecedented quality and quantity of clinical research (*Project FUSION*).

04 **Maximize the efficiency of clinical programs** and feeding our NPD strategy (*Project ENGAGE*).

	2022	2023	2024
Regulatory	• 510(k) – MagnetOs Flex Matrix • 510(k) – MagnetOs Granules indication expansion	• CE mark – MagnetOs Flex Matrix	
Clinical	• MagnetOs – 3x clinical studies • Fibrin-PTH – Phase 2 enrolment complete • Fibrin-PTH – Publication of non-spine orthopedic data	• MagnetOs – 2x clinical studies • Fibrin-PTH – Phase 2 results • Fibrin-PTH – Phase 3 start	• MagnetOs – 2x clinical studies • Fibrin-PTH – Publication of Phase 2 data
Commercial	• EU – 2x new markets • US – Launch MagnetOs Easypack Putty • US – Launch MagnetOs Flex Matrix	• EU – Launch MagnetOs Flex Matrix	

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In summary…

The biggest crisis facing the healthcare economy is spine-related pain, with the number of procedures growing every year.

Bone grafts are an essential part of the solution, but current fusion rates are unacceptable and unsustainable.

Kuros is primed to meet this clinical need in both the anterior and posterior columns of the spine.

We achieve this through superior biologics for spinal fusion, supported by the greatest quality and quantity of clinical data.

Kuros is strategically positioned to create significant value and returns for investors.

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Thank you

PROMO/KUR/GL/055-21/R01

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The future of spinal fusions

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