

Bone Therapeutics

NEW **FRONTIERS**

in orthopaedics and bone diseases



2018
Business review



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Bone Therapeutics

AT A GLANCE

We focus on developing innovative products that will help patients rebuild their lives and improve their mobility.



MISSION AND STRATEGY

We aim to be a leading biotech company providing unique, innovative products addressing high unmet medical needs in the fields of orthopaedics and bone diseases.

To achieve this objective, our Company is pursuing the following strategy:

- Further advance the development of our unique, off-the-shelf, allogeneic cell therapy platform, ALLOB, through late-stage clinical development towards commercialisation.
- Further progress late-stage clinical development of our enhanced viscosupplement, JTA-004 in osteoarthritis of the knee, towards marketing authorisation.
- Advance the preclinical pipeline.
- Build R&D and commercial partnerships.

MARKET OPPORTUNITY AND COMPETITIVE ADVANTAGE

The market for orthopaedics is large and growing, characterised by limited innovation and high unmet medical needs. It is estimated that the overall market will continue to grow at a 3%¹ CAGR in the next few years, mostly driven by an ageing population.

Bone-related disorders encompass various pathologies, from orthopaedic conditions such as severe fractures to spinal issues such as degenerative disc disease. Multiple pharmaceutical, biopharmaceutical, including regenerative and cell therapy companies, and medical device companies are active in the field.

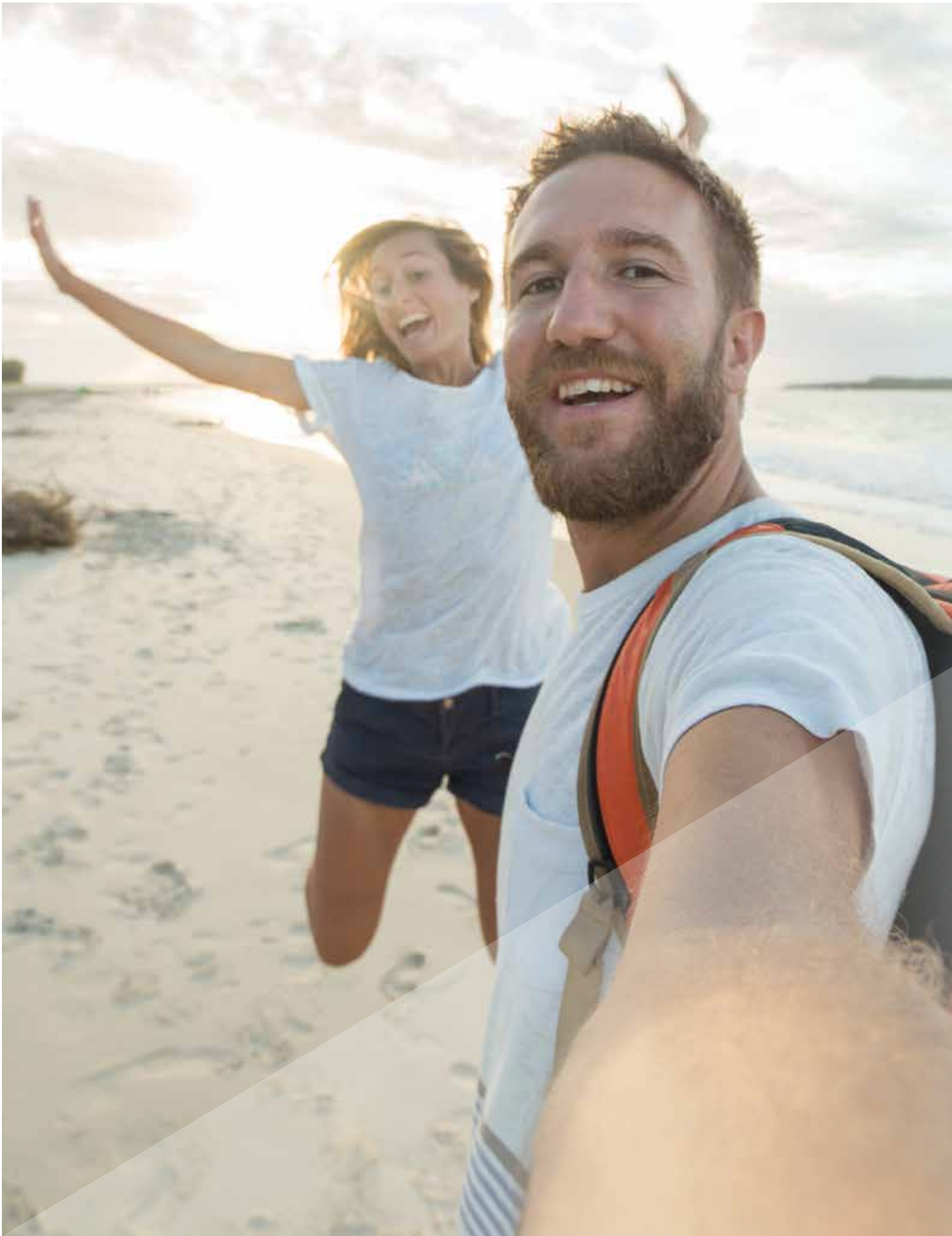
Bone Therapeutics' target markets include fracture repair, spinal implants and viscosupplementation, representing an estimated 261 million patients and a global market worth around \$22 billion in 2017.

ALLOB is the Company's allogeneic cell therapy platform consisting of human allogeneic bone-forming cells derived from cultured bone marrow mesenchymal stem cells (MSC) from healthy adult donors.

We have focused our efforts on the development of our allogeneic cell therapy platform, which, in comparison to an autologous approach, offers numerous advantages in product quality, injectable quantity, production costs and supply chain. In addition, our proprietary cell therapy manufacturing process is optimised to allow commercial distribution of our cryopreserved cell therapy product, a major competitive advantage in the industry.

In addition to our cell therapy product pipeline, we are developing an enhanced viscosupplement for the treatment of osteoarthritis of the knee, JTA-004. Viscosupplements are injectable solutions containing hyaluronic acid (HA), a main component of the synovial fluid in the knee joint, and aim to provide added lubrication and protection to the cartilage of the arthritic joint. In addition to HA, JTA-004 also contains an analgesic and anti-inflammatory agent and an enriched protein solution. Due to its unique composition, JTA-004 showed distinct advantages over other viscosupplements supported by strong clinical results in a first efficacy study in patients.

1 Based on the Orthopedic Industry Annual Report published in April 2017 by Orthoworld.



MESSAGE FROM THE CHAIRMAN AND THE CEO

A year of significant progress across
all areas of our business



Chairman and CEO / Jean Stéphane and Thomas Lienard



CHAIRMAN

JEAN STÉPHENNE

“Bone Therapeutics is about excellent science combined with smart business”

Dear Shareholders,

2018 has been a year of significant progress across all areas of our business.

Our allogeneic cell therapy platform, ALLOB, delivered positive efficacy and safety results in patients with delayed-union fractures, supporting its progression into the next stage of clinical development. Treatment with ALLOB in this patient population resulted in a strong improvement in fracture healing and in clinical parameters. In addition, treatment with ALLOB was generally well-tolerated.

We also completed the recruitment of the Phase IIa study with ALLOB in patients undergoing a spinal fusion procedure and look forward to revealing top line data later this year.

We are very proud of the implementation of our improved and optimised production process for ALLOB, which will deliver consistency, scalability,

cost-effectiveness and ease of use, all of which are critical factors for the development and commercialisation of a successful cell therapy product. This is a major achievement for our Company and offers an important competitive advantage in the industry.

With this optimised process, one bone marrow donation will allow the production of the doses needed to treat 100,000 patients. Moreover, the final product will be cryopreserved to allow ease of shipment and local storage in a hospital setting. This process will therefore substantially reduce overall production costs and simplify supply chain logistics, which improves patient accessibility and facilitates global commercialisation. We plan to implement this process for all our future clinical programmes with ALLOB.

In addition to the achievements with our cell therapy platform, ALLOB, we also made significant progress with our second pillar, our enhanced viscosupplement, JTA-004, in patients with painful knee osteoarthritis. The results of the Phase IIb study demonstrated a better pain relief at six months compared to the leading viscosupplement currently on the

CEO

THOMAS LIENARD

“Our ambition is to focus on rebuilding people’s lives by being the leader in orthobiologics”



market. JTA-004 was generally well tolerated across all administered doses.

This year was also marked by the discontinuation of the development of PREOB, our historical autologous product. The interim analysis revealed that the control group performed better than originally anticipated, hence the study would not have been able to demonstrate a superiority of PREOB vs. control. Based on the preclinical data, manufacturing and intellectual property experience with PREOB, the Company generated the knowledge to develop ALLOB, its patented allogeneic cell therapy platform. ALLOB’s optimised production process significantly increases the production yield, substantially reducing production costs, and the product is delivered to physicians in a ready-to-use cryopreserved formulation, to the benefit of patients.

2019 will further build on the successes of 2018. With the appointments of Linda Lebon as Chief Regulatory Officer, Benoit Moreaux as Chief Scientific and Technology Officer and Olivier Godeaux as Chief Medical Officer, we now have the right team in place to further exploit our innovative platform and advance our product

pipeline to drive long term growth. Later this year, we expect to file clinical trial applications in Europe and the US to allow the start of late-stage clinical development of ALLOB in patients with delayed-union fractures and with JTA-004 in patients with knee osteoarthritis. We also expect to announce the results from the Phase IIa study of ALLOB in patients undergoing a spinal fusion procedure.

On behalf of the Board and the management team, we would like to thank everyone who works for, and with, Bone Therapeutics. Our employees have shown loyalty, commitment, hard work and dedication. We also thank you, our patients, partners and shareholders for the trust you have placed in us. We will continue to work hard to deliver on that trust, and will keep you informed on the progress we make.

Sincerely,

Jean Stéphane, Chairman

Thomas Lienard, CEO

CORPORATE HIGHLIGHTS

- Appointed Linda Lebon as **Chief Regulatory Officer.**

- Further strengthened the Board of Directors with the **appointments of Jean Stéphane as Chairman, Jean-Luc Vandebroek as Executive Director and Claudia D'Augusta as Independent Director.**

FINANCIAL HIGHLIGHTS

- **Operating loss for the period amounted to € 11.5 million, compared to € 12.3 million for the full year 2017.**

- **Revenue and operating income of € 5.1 million, up 20.5% compared to 2017.**

- Lower than anticipated net cash burn of **€ 13.9 million vs guidance of € 15-16 million.**

- Year-end cash position of **€ 8.2 million compared to € 8.4 million year-end 2017.**

- Secured a total of € 19.45 million in committed funds following **the successful private placement of convertible bonds.**



2018

in brief

CLINICAL AND OPERATIONAL HIGHLIGHTS

- **Achieved positive final results** for the Phase I/IIa study of ALLOB in 21 patients with delayed-union fractures.
- **Completed patient recruitment** in the ALLOB Phase IIa lumbar spinal fusion study.
- **Optimised the ALLOB manufacturing process to improve consistency, scalability, cost effectiveness and ease of use**, factors critical for the successful development of a commercial cell therapy product.
- **Demonstrated additional evidence of the potent osteogenic properties of the allogeneic cell therapy platform**, presented at the Annual Meeting of the European Orthopaedic Research Society (EORS).
- **Reported positive Phase IIb efficacy results with JTA-004** in knee osteoarthritis, showing a superior improvement in pain relief compared to a leading viscosupplement.
- **Pipeline focused on the clinical development of ALLOB and JTA-004.**

Post-period

EVENTS



PARTNERSHIP UPDATE

PREOB COLLABORATION WITH ASAHI KASEI

- Achieved a regulatory milestone as part of its PREOB collaboration with Asahi Kasei, triggering a €1 million success fee.
- In parallel, Asahi Kasei and the Company are reviewing their options regarding the future of the PREOB licensing agreement, following termination of the PREOB study in osteonecrosis of the hip in Europe.

PIPELINE UPDATE

DEMONSTRATED ADDITIONAL EVIDENCE OF PREOB PHASE III STUDY RESULTS

- Subsequent analysis of the unblinded interim data of the Phase III PREOB study in patients with hip osteonecrosis demonstrated that PREOB had a clinical effect, which was in line with the previous reported results from the Phase II study. However, this analysis also revealed that the control group, which consisted of core decompression alone, performed much better than was originally anticipated from historical clinical studies. This could be related to improvements of the core decompression techniques in recent years, and hence may have led to a reduced difference in responder rate between the control arm and PREOB group.

SCIENTIFIC PRESENTATION

ANNUAL MEETING OF THE ORTHOPAEDIC RESEARCH SOCIETY

- Further demonstrated the potent osteogenic properties of its allogeneic cell therapy product at the Annual Meeting of the Orthopaedic Research Society (ORS).

STRENGTHENED EXECUTIVE MANAGEMENT TEAM

APPOINTMENT OF CSTO AND CMO

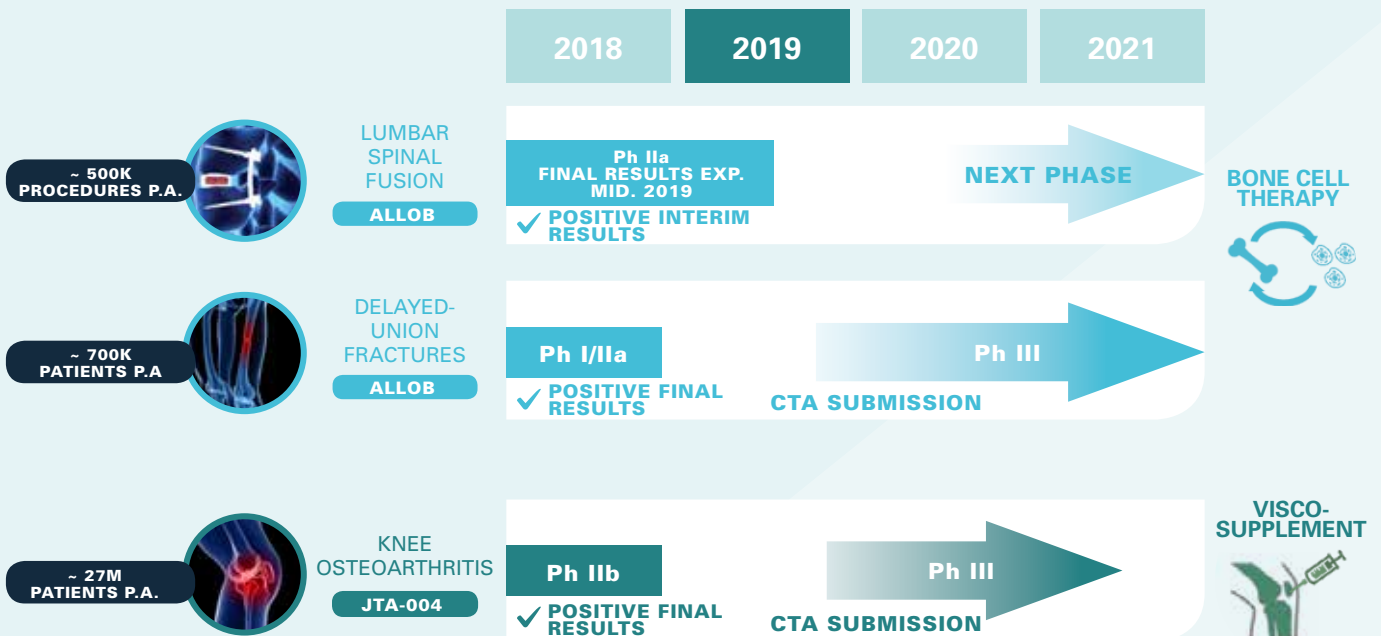
- Appointment of Benoit Moreaux as Chief Scientific & Technology Officer (CSTO). Benoit will lead preclinical activities and clinical and commercial manufacturing operations.
- Appointment of Olivier Godeaux as Chief Medical Officer (CMO). Olivier will be responsible for the development and execution of the Company's clinical development strategy, advancing its late-stage products through clinical development towards commercialisation, while playing a crucial role in interactions with regulatory authorities, clinical experts and key opinion leaders.

Outlook

2019

During 2019, the Company will continue to execute on its business strategy and advance its core assets, ALLOB and JTA-004, through late-stage clinical development. In addition, disciplined cost and cash management will remain a key priority for the Company.

CLINICAL OUTLOOK 2019



KEY EXPECTED DEVELOPMENTS FOR 2019:

- To report top line data from the Phase IIa study with ALLOB in patients undergoing a lumbar spinal fusion procedure.
- To submit a clinical trial application (CTA) with the regulatory authorities in Europe and the US to allow the start of a Phase III clinical trial for ALLOB in patients with delayed-union fractures, using its proprietary, optimised production process.
- To submit a CTA with the regulatory authorities in Europe and the US for the Phase III programme with JTA-004 in patients with knee osteoarthritis.
- Net cash burn for the full year 2019 is expected to be in the range of € 13-14 million.
- The Company expects to have sufficient cash to carry out its business objectives until the end of 2019, taking into account the € 5.18 million to be received under the convertible bond programme.

ADVANCING INNOVATION IN ORTHOPAEDIC CARE

2 PRODUCTS ENTERING PHASE III END 2019

ALLOB



BONE CELL THERAPY

- **Differentiated, active bone-forming cells**
- **Allogeneic** (from donor bone marrow)
- **Injectable** (minimally invasive)
- **Economical, large-scale manufacturing**
- **Off-the-shelf** (ready to use)
- Market :
 - Delayed-union fractures (~ 700K patients p.a)
 - Spinal fusion procedures (~ 500K patients p.a.)

JTA-004



VISCO-SUPPLEMENT

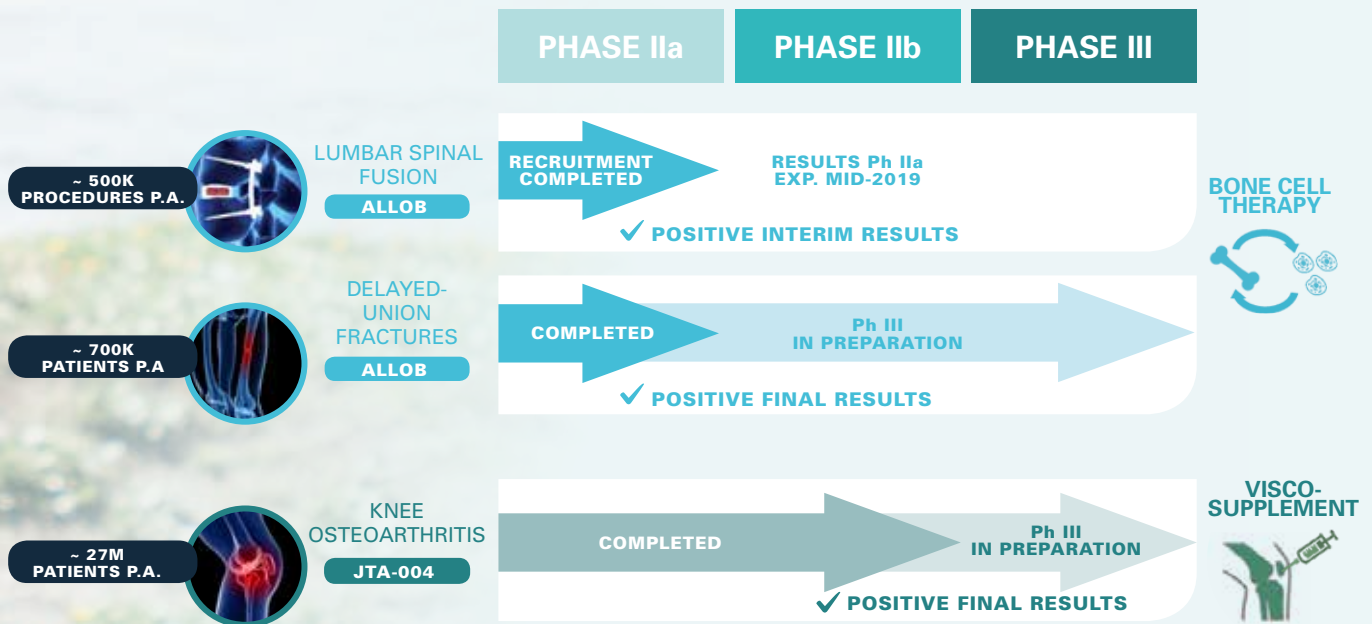
- **Patented composition of 3 active substances**
- Convenient, **single injection**
- **Analgesic & lubricating** properties
- **Better pain reduction vs market leader**
- **Simple manufacturing process**
- Market :
 - Symptomatic knee osteoarthritis (~ 27M patients p.a. in EU/USA/JAP)



A UNIQUE TECHNOLOGY PLATFORM

and late-stage product pipeline

LATE-STAGE CLINICAL PIPELINE FOR ORTHOPAEDIC CONDITIONS WITH HIGH UNMET NEEDS IN BONE DISORDERS



ALLOB

Differentiated, active bone-forming cells



ALLOB is the Company's allogeneic product that consists of human allogeneic bone-forming cells derived from cultured bone marrow mesenchymal stem cells (MSC) of healthy adult donors. A bone marrow aspirate is performed from the iliac crest of the donor, after which the cells are isolated, expanded and differentiated. The active part of the product thus comprises human allogeneic bone-forming cells. ALLOB has been classified as Tissue Engineered Product (non-combined) by the EMA under the Advanced Therapy Medicinal Products (ATMP) classification 1394/2007. The manufacturing process is performed under strict GMP rules and procedures to ensure aseptic manufacturing, full traceability, and quality control.

ALLOB cells express master osteoblast genes, mesenchymal and bone matrix adhesion

markers and display bone-forming properties. The cells are able to adhere, synthesize and mineralize new bone matrix.

Bone Therapeutics has established an optimised, competitive production process to allow successful, commercial scale manufacturing of ALLOB with improved consistency, scalability, cost effectiveness and ease of use, factors critical for the successful development of a commercial cell therapy.

Bone Therapeutics is developing ALLOB for the treatment of patients undergoing a spinal fusion procedure and patients with delayed-union fractures.

ACHIEVEMENTS IN 2018

Positive final results, supporting the progression into the next phase of clinical development in this indication

NEXT STEPS:

CTA submission expected in H2 2019 to start a Phase III study in EU and US

DELAYED UNION FRACTURES

POSITIVE PHASE I/IIa RESULTS AND START OF PHASE III STUDY EXPECTED BY END 2019

To assess its potential in treating severe unhealed fractures, ALLOB was being evaluated in a Phase I/IIa study in patients with delayed-union fractures.

This Phase I/IIa study was a six-month open-label trial to evaluate the safety and efficacy of ALLOB in the treatment of delayed-union fractures of long bones. 21 patients with a fracture that had failed to consolidate after a minimum of three, and a maximum of seven months, received a single percutaneous administration of ALLOB directly into the fracture site (i.e. through a minimally invasive implantation procedure). Fracture healing of ALLOB-treated patients was assessed through clinical evaluation (e.g. general health status and pain) and radiological evaluation (based on CT-scan).

In **September 2018**, after completion of the six-month follow-up period, the Company announced positive final results. The data showed that at six months, all patients treated with ALLOB met the primary endpoint, and treatment with ALLOB was well tolerated.

DELAYED-UNION FRACTURES

- Delayed-union: failure to achieve bone union within an adequate period of time (3-7 months)
- There are about 700,000 patients per year in the US, Europe and Japan
- Currently a 'wait and see' approach is adopted for delayed-union fractures, delaying a patient's return to normal life

Sources: Kanakaris et al. Injury 2007 (38S) S77-S84; Company estimates detailed in the prospectus, dated 20 January 2015.

Radiological evaluation of fracture healing showed an improvement of, on average, 4 points on the TUS (Tomographic Union Score) scale, twice the required minimum of 2 points. The health status of patients, as measured by the Global Disease Evaluation (GDE) score, improved by, on average, 48%, compared to the predetermined minimum of 25%, and there was a statistically significant reduction in pain at the fracture site of 61% on average.

LUMBAR SPINAL FUSION

PHASE IIa ONGOING WITH TOPLINE RESULTS EXPECTED MID-2019

This proof-of-concept Phase IIa study is designed to evaluate the safety and efficacy of ALLOB in addition to standard of care, which consists of the implantation of an interbody cage with bioceramic granules into the spine to achieve fusion of the lumbar vertebrae. The combination of ALLOB with the micro-granules has the potential to enhance bone growth (as demonstrated in preclinical studies), bringing advantages in stability and structure. The primary endpoints of the study include radiological assessments to evaluate lumbar fusion progression, clinical assessments to evaluate improvement in physical condition, and safety.

In **September 2017**, the Company reported positive interim efficacy and safety results for the first 15 patients enrolled in the study. In addition to evidence of successful fusion as shown by radiological data collected over a 12-month follow-up period, the interim results revealed substantial clinical improvement in function (55% improvement on the Oswestry Disability Index) and a strong reduction in back and leg pain (59% and 90% respectively). Treatment with ALLOB was well tolerated in all patients.

SPINAL FUSION

- Gold-standard surgery for treating a broad spectrum of degenerative spine disorders
- Aims to relieve pain and improve function
- Consists of bridging two or more vertebrae with the use of a cage and graft material
- Up to 25% of patients not satisfied with surgery
- Each year over 1 million spinal fusion procedures are performed in the US, Europe and Japan of which over 0.5 million at lumbar level

Sources: Park et al. Bulletin of the Hospital for Joint Disease 2013 (71) 39-48; Rajaei et al. The Bone and Joint Journal 2014 (96) 807-816. Company estimates detailed in the prospectus dated 20 January 2015.

ACHIEVEMENTS IN 2018

recruitment of

32 patients
completed in February 2018

NEXT STEPS:

Report final efficacy and safety results,
expected mid-2019

In **February 2018**, the Company announced that it had completed recruitment of 32 patients. Following the 12-month follow-up period, top line efficacy and safety results are expected mid-2019.



Spinal fusion / Over 500,000 lumbar spinal fusions are performed each year in Europe and the US and the market is growing at a rate of 5% per year.



Delayed-Union Fractures / There are about 700,000 patients per year in the US, Europe and Japan.

OPTIMISED, PROPRIETARY ALLOGENEIC MANUFACTURING PROCESS IMPLEMENTED

Production consistency, scalability, cost effectiveness and ease of use of the end product are critical success factors in the development and commercialisation of cell therapies, offering major competitive advantages in the industry.

In order to build its competitive edge, the Company has focused its capabilities and investments to implement an optimised ALLOB manufacturing process.

The optimised production process significantly increases the production yield, generating 100,000 doses of ALLOB per bone marrow donation. Additionally, the final ALLOB product

can be cryopreserved, enabling easy shipment and storage in a frozen form in a hospital setting, making it readily available for patients in need. The optimised production process will therefore significantly reduce overall production costs, and the final product will be delivered to physicians in a ready-to-use cryopreserved formulation, all to the benefit of patients.

Bone Therapeutics believes the optimised manufacturing process is essential for the future commercial success of ALLOB. In order to avoid process changes in later phases of development, improve cost effectiveness and streamline ALLOB's route to market, the Company will implement this optimised production process in all future clinical trials with ALLOB.

JTA-004

Patented, enhanced viscosupplement composed of three active substances



In addition to its ALLOB cell therapy platform, Bone Therapeutics is also developing an enhanced viscosupplement, JTA-004, for the treatment of pain in the knee. JTA-004 is a patented, non-cellular viscosupplement product that is currently being evaluated for the treatment of pain in knee osteoarthritis (KOA).

Viscosupplements are injectable solutions containing hyaluronic acid (HA), a main component of the synovial fluid of the knee joint, and aim to provide added lubrication and protection to the cartilage of the arthritic joint. In addition to HA, JTA-004 also contains an analgesic and anti-inflammatory agent and an enriched protein solution.

Due to its unique composition, JTA-004 showed distinct advantages over other viscosupplements in a first efficacy study in patients.

KNEE OSTEOARTHRITIS

POSITIVE PHASE IIB RESULTS AND START OF PHASE III EXPECTED BY END 2019

To evaluate the efficacy and safety of JTA-004, the Company initiated a Phase IIb study in patients with moderate symptomatic knee osteoarthritis.

This Phase IIb study was a prospective, multicentre, randomised, double-blind, controlled study whereby 164 patients were randomly assigned to receive either one of the three doses of JTA-004, or the reference product, hylan G-F 20, the global market leader in viscosupplements. The main objective of the study was to demonstrate superiority of a single intra-articular injection with JTA-004

ACHIEVEMENTS IN 2018

Positive results from a first efficacy study, supporting the progression to the next phase of clinical development in this indication

NEXT STEPS:

CTA submission expected in H2 2019 to start the Phase III programme in EU and US

KNEE OSTEOARTHRITIS (KOA)

KOA is the most common chronic joint condition. The protective cartilage in the knee joint progressively breaks down resulting in joint pain, swelling, stiffness and limited range of motion.

- Currently, there is no cure for KOA
- Treatments focus on relieving and controlling pain and symptoms, preventing disease progression, minimizing disability, and improving quality of life
- Ultimately, severe KOA leads to highly invasive surgical interventions such as total knee replacement
- Most prevalent joint disorder with 27 million cases in EU, US and JP per year

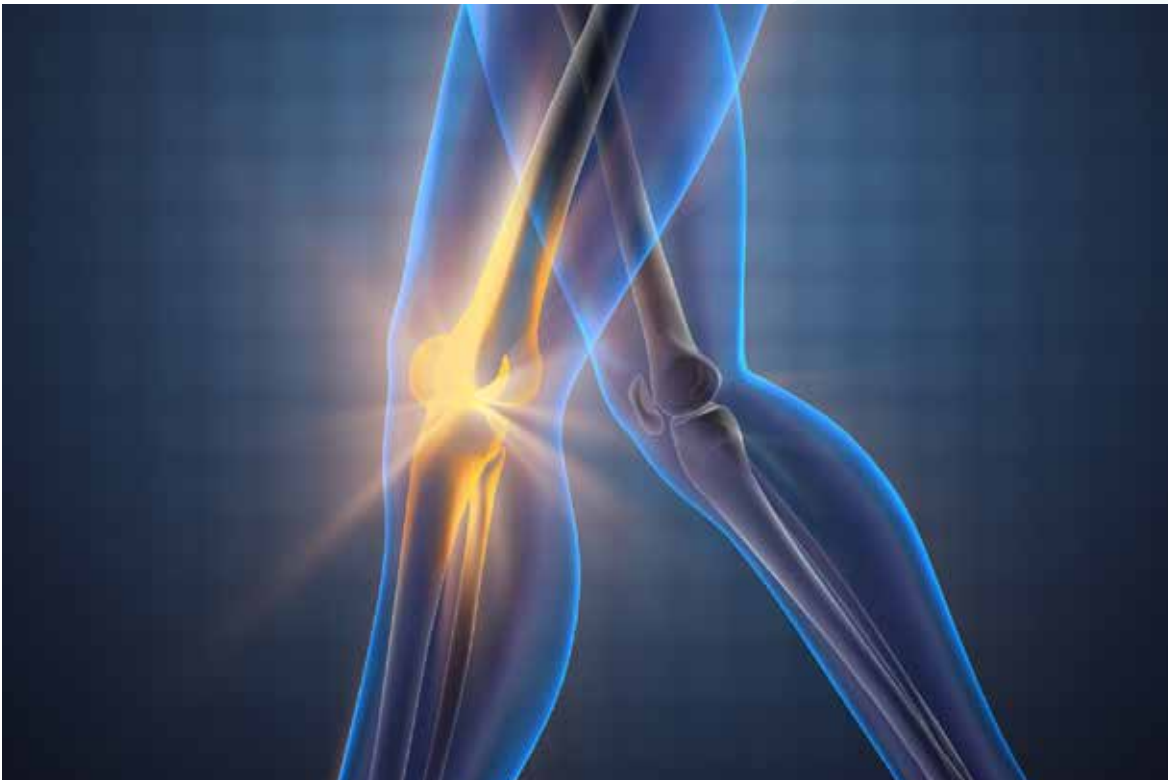
compared to the reference product.

The primary endpoint of the study was the mean change in WOMAC® VA 3.1 pain subscale score (ranging between 0 and 100 mm) between baseline and six months after treatment.

In October 2018, the Company announced positive results from this study. At six months post administration, patients in the pooled JTA-004 group showed a 26.1 mm mean improvement vs. 15.6 mm for the reference

group, demonstrating a statistically significant superior pain reduction for patients in the pooled JTA-004 group compared to the leading viscosupplement on the market. In addition, the single intra-articular injection of JTA-004 was generally well tolerated.

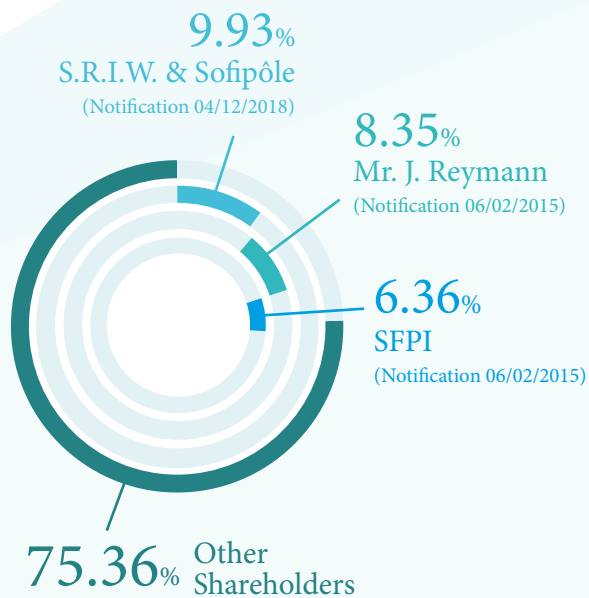
JTA-004 is a patented, non-cellular viscosupplement product for the treatment of pain in knee osteoarthritis (KOA), which Bone Therapeutics has been developing in parallel with its core cell therapy pipeline and addressing its mission of bringing innovative solutions to orthopaedic conditions.



Investor

RELATIONS

SHAREHOLDER STRUCTURE



FINANCIAL CALENDAR 2019

7 May 2019	Q1 2019 Business Update
12 June 2019	Annual General Meeting
30 August 2019	Half-year Results 2019
6 November 2019	Q3 2019 Business Update

ANALYST COVERAGE

Broker	Analyst
Bryan, Garnier & Co	Hugo Solvet
KBC Securities	Sandra Cauwenberghs
Kepler Cheuvreux	Arsene Guekam

SHAREPRICE EVOLUTION 2018



KEY EXPECTED DEVELOPMENTS FOR 2019

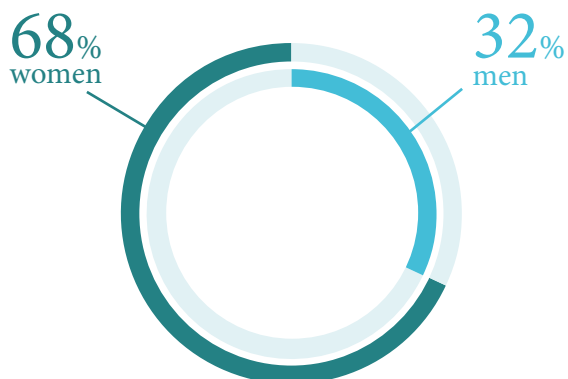
- To report top line data from the Phase IIa study with ALLOB in patients undergoing a lumbar spinal fusion procedure.
- To submit a clinical trial application (CTA) with the regulatory authorities in Europe and the US to allow the start of a Phase III clinical trial for ALLOB in patients with delayed-union fractures, using its proprietary, optimised production process.
- To submit a CTA with the regulatory authorities in Europe and the US for the Phase III programme with JTA-004 in patients with knee osteoarthritis.



THE TEAM

at December 31, 2018

The scientific fields of specialization include cell and molecular biology, pharmaceutical sciences, veterinary medicine, physiology, life sciences, biomedical sciences.



16%
obtained a Ph.D

30%
obtained a Master's degree

The staff is represented by	5 nationalities
Average age is	34 years
Number of interns who worked with us throughout 2018	12
Number of external collaborators	12



OUR VALUES

DARE

...DARE TO FREE YOURSELF FROM PRECONCEIVED IDEAS, BE CURIOUS AND DYNAMIC, QUESTION YOUR THEORIES AND BE DRIVEN BY A POSITIVE ENERGY...

DRIVEN BY PASSION

...LET YOURSELF BE DRIVEN BY A POSITIVE EMOTION AND A SENSE OF PURPOSE... BE CARRIED AWAY BY YOUR PASSION FOR SCIENCE, LIFE...

OPENNESS

...WELCOME CHANGE IN A POSITIVE WAY, BE OPEN TO INNOVATION AND OTHERS, COMMIT TO ADVANCING SCIENCE AND PROGRESS....

CARE

...TAKE CARE OF YOUR COLLEAGUES, TAKE THE WELL-BEING OF PATIENTS AND CARERS TO HEART, FOR A RENEWED QUALITY OF LIFE FOR ALL, WITH RESPECT AND COMMITMENT...

Financial

HIGHLIGHTS

- Revenue and operating income of € 5.1 million, up 20.5% compared to 2017
- Operating loss for the period amounted to € 11.5 million, compared to € 12.3 million for the full year 2017
- Lower than anticipated net cash burn of € 13.9 million vs € 15-16 million previously guided
- Year-end cash position of €8.2 million compared to €8.4 million year-end 2017
- Secured a total of €19.45 million in committed funds following the successful private placement of convertible bonds
- The Company expects to have sufficient cash to carry out its business objectives until the end of 2019, taking into account the € 5.18 million to be received under the convertible bond programme.

(€ million)	FY 2018	FY 2017
Revenues and operating income	5.08	4.21
Operating expenses	(16.54)	(16.51)
R&D	(12.88)	(13.12)
G&A	(3.66)	(3.39)
Operating result	(11.47)	(12.29)
Net financial result and taxes	(2.67)	(0.48)
Net result	(14.14)	(12.77)
Net cash flow	(0.24)	(11.89)
Operating activities	(12.90)	(11.02)
Investing activities	(0.30)	(0.42)
Financing activities	12.96	(0.46)
Cash position at 31 December	8.17	8.41



BONE THERAPEUTICS S.A.

Rue Auguste Piccard, 37
6041 Gosselies
Belgium
Phone: +32 (0) 71 12 10 00
www.bonetherapeutics.com

Thomas Lienard, Chief Executive Officer
Jean-Luc Vandebroek, Chief Financial Officer

Gunther De Backer, Head of Corporate Communications and Investor Relations

investorrelations@bonetherapeutics.com



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