

# Orthofix Medical and CGBio Announce Strategic Partnership Agreement for Novosis rhBMP-2 Bone Graft Solutions

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LEWISVILLE, Texas--(BUSINESS WIRE)-- **Orthofix Medical Inc.** (NASDAQ:OFIX), a global medical device company with a spine and orthopedics focus, today announced a strategic partnership agreement with CGBio, a developer of innovative, synthetic bone grafts currently used clinically in Asia for spine, orthopedic, trauma and dental applications. The two companies will work together for clinical development and commercialization of Novosis™ recombinant human bone morphogenetic protein-2 (rhBMP-2) bone growth materials and other future tissue regenerative solutions for the U.S. and Canadian markets.

This press release features multimedia. View the full release here:  
<https://www.businesswire.com/news/home/20220802005372/en/>

Under the terms of the license and distribution agreement, Orthofix will conduct clinical studies, obtain regulatory approvals, and commercialize the Novosis' rhBMP-2 technology in the U.S. and Canada. As a consideration of the agreement, CGBio will receive an upfront payment and potential development milestone payments upon achievement of regulatory milestones.

"This announcement represents the start of an exciting partnership to bring the next evolution of recombinant bone growth factor technology to the market," said Orthofix President and CEO Jon Serbousek. "Pending successful U.S. clinical trials and subsequent approvals, this surgeon-driven biologic solution will provide a moldable, flowable, bioactive rhBMP-2 bone graft material in the U.S. and fits well within our comprehensive portfolio of allografts with viable cells, demineralized fiber allografts, DBMs, synthetic scaffolds, and spinal constructs. Expanding our regenerative technology portfolio will further provide important procedural options for surgeons to enhance the clinical outcomes for their patients."

"We are pleased to collaborate with Orthofix who has a long history of success in the U.S. biologics market," said CGBio CEO Hyun Seung Yu. "The potential to bring our solutions to the U.S. and Canadian markets is exciting and

aligns well with our strategic goal of broadening the availability of our regenerative biopharmaceuticals.”

“In order to have the best clinical outcomes, it is important to have multiple options as no single bone growth solution fits all patients’ needs,” said Dr. Jeffrey Wang, Professor of Orthopaedic Surgery and Neurosurgery, Keck Medical Center at the University of Southern California (USC) and co-director of the USC Spine Center in Los Angeles. “Novosis has been well studied in Asia and a U.S. IDE clinical trial could potentially fill an unmet need for a moldable form of rhBMP-2, making this promising new technology available to more patients.”

## **About Novosis**

Novosis is a novel composite bone graft material consisting of a synthetic carrier and rhBMP-2. During surgery, it is applied to the implant site and acts as a scaffold for the formation of new bone. This combination provides a moldable handling that is unique compared to what is currently on the market. Novosis is approved for use and currently marketed in South Korea, Southeast Asia, Mexico and India with approval pending in Australia. To date approximately 50,000 patients have received a Novosis bone graft.

## **About Orthofix**

Orthofix Medical Inc. is a global medical device company with a spine and orthopedics focus. The Company’s mission is to deliver innovative, quality-driven solutions while partnering with health care professionals to improve patient mobility. Headquartered in Lewisville, Texas, Orthofix’s spine and orthopedics products are distributed in more than 60 countries via the Company’s sales representatives and distributors. For more information, please visit [www.Orthofix.com](http://www.Orthofix.com).

## **About CGBio**

CGBio is a total healthcare provider with a goal to enhance the quality of life by offering a wide range of interventional medical devices necessary for remodeling of musculoskeletal and connective tissue damage associated with diseases. Recently, CGBio has expanded its business to the field of aesthetics and face-lifting and provided essential and convenient products for use in hospitals through its excellent biomaterial-based technology and a variety of collaborations with clinical experts. CGBio has received accreditation from the American Association of Tissue Banks (AATB) for human tissue processing quality control (QC) systems.

## **Forward-Looking Statements**

This communication contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended, relating to our business and financial outlook, which are based on our current beliefs, assumptions, expectations, estimates, forecasts and projections. In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “should,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “projects,” “intends,” “predicts,”

“potential,” or “continue” or other comparable terminology. These forward-looking statements are not guarantees of our future performance and involve risks, uncertainties, estimates and assumptions that are difficult to predict, including the risks described in Part I, Item 1A under the heading Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2021 (the “2021 Form 10-K”). In addition to the risks described there, factors that could cause or contribute to such differences may include, but are not limited to: the risk that surgeons may be slow to adopt Novosis; the risk that future patient studies or clinical experience and data may indicate that treatment with Novosis does not improve patient outcomes as much as previously believed, or otherwise call into question the benefits of the use of these products to patients, hospitals and surgeons; the risk that the products may not perform as intended and may therefore not continue or achieve commercial success; the risk that competitors may develop superior products or may have a greater market position enabling more successful commercialization; the risk that insurance payers may decline to reimburse healthcare providers for the use of our products.

This list of risks, uncertainties and other factors is not complete. We discuss some of these matters more fully, as well as certain risk factors that could affect our business, financial condition, results of operations, and prospects, in reports we file from time-to-time with the SEC, which are available to read at [www.sec.gov](http://www.sec.gov). Any or all forward-looking statements that we make may turn out to be wrong (due to inaccurate assumptions that we make or otherwise), and our actual outcomes and results may differ materially from those expressed in these forward-looking statements. You should not place undue reliance on any of these forward-looking statements. Further, any forward-looking statement speaks only as of the date hereof, unless it is specifically otherwise stated to be made as of a different date. We undertake no obligation to update, and expressly disclaim any duty to update, our forward-looking statements, whether as a result of circumstances or events that arise after the date hereof, new information, or otherwise.

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