

CollPlant Biotechnologies Begins Preclinical Trial with Commercial-Size, Regenerative Breast Implants

- The current market for breast implants is estimated at \$2.6 billion a year
- CollPlant expects the study to conclude by the first half of 2024
- CollPlant plans to use findings from this study and successive studies during 2024 for further optimization of the implant design towards a GLP preclinical pivotal study with commercial size implants

REHOVOT, Israel, Jan. 2, 2024 /PRNewswire/ -- CollPlant Biotechnologies (NASDAQ: CLGN), a regenerative and aesthetics medicine company developing innovative technologies and products based on its non-animal-derived collagen for tissue regeneration and organ manufacturing, today announced its initiation of a pre-clinical trial to evaluate commercial-size, 3D-bioprinted, regenerative breast implants. Currently, there are no commercial products that allow regeneration of soft tissues such as the breast.



"We are very happy with the progress of our regenerative breast implants program thus far, and the initiation of this important study," said CollPlant's Chief Executive Officer, Yehiel Tal. "CollPlant's breast implants in development are unique in that they are designed to regenerate breast tissue as well as have inherent safety advantages. This would be paradigm-shifting in a market that has maintained such a large demand yet has seen increasing issues with safety over the last few decades. A primary goal of this study is to obtain data which would then support the optimization of the implant design and apply this design to a pivotal large-animal study that is intended to be the subject of discussions with the FDA."

In the U.S. alone, hundreds of thousands of people each year experience adverse events

that range from autoimmune symptoms to the very serious breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). CollPlant's breast implants, comprised of the Company's proprietary plant-derived rhCollagen and other biomaterials, are expected to regenerate breast tissue without eliciting immune response and therefore may provide a revolutionary alternative for aesthetic and reconstructive procedures, including postmastectomy for cancer patients.

In January 2023, CollPlant announced positive results from its first large-animal study, which demonstrated progressive stages of tissue regeneration after three months, as highlighted by the formation of maturing connective tissue and neovascular networks within the implants, with no adverse events reported.

About CollPlant

CollPlant is a regenerative and aesthetic medicine company focused on 3D bioprinting of tissues and organs, and medical aesthetics. The Company's products are based on its rhCollagen (recombinant human collagen) produced with CollPlant's proprietary plant based genetic engineering technology. These products address indications for the diverse fields of tissue repair, aesthetics, and organ manufacturing, and are ushering in a new era in regenerative and aesthetic medicine.

In 2021 CollPlant entered into a development and global commercialization agreement for dermal and soft tissue fillers with Allergan, an AbbVie company, the global leader in the dermal filler market.

For more information about CollPlant, visithttp://www.collplant.com.

Forward-Looking Statements

This press release may include forward-looking statements. Forward-looking statements may include, but are not limited to, statements relating to CollPlant's objectives plans and strategies, as well as statements, other than historical facts, that address activities, events or developments that CollPlant intends, expects, projects, believes or anticipates will or may occur in the future. These statements are often characterized by terminology such as "believes," "hopes," "may," "anticipates," "should," "intends," "plans," "will," "expects," "estimates," "projects," "positioned," "strategy" and similar expressions and are based on assumptions and assessments made in light of management's experience and perception of historical trends, current conditions, expected future developments and other factors believed to be appropriate.

Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statements. Many factors could cause CollPlant's actual activities or results to differ materially from the activities and results anticipated in forward-looking statements, including, but not limited to, the following: the Company's history of significant losses, its need to raise additional capital and its inability to obtain additional capital on acceptable terms, or at all; the Company's expectations regarding the timing and cost of commencing pre-clinical and clinical trials with respect to breast implants, tissues and organs which are based on its rhCollagen based Biolnk and other products for medical aesthetics, and specifically the Company's ability to initiate its next large-animal study for its

breast implants in a timely manner, or at all; the Company's ability to obtain favorable preclinical and clinical trial results; regulatory action with respect to rhCollagen based Biolnk and medical aesthetics products including but not limited to acceptance of an application for marketing authorization review and approval of such application, and, if approved, the scope of the approved indication and labeling; commercial success and market acceptance of the Company's rhCollagen based products, in 3D bioprinting and medical aesthetics; the Company's ability to establish sales and marketing capabilities or enter into agreements with third parties and its reliance on third party distributors and resellers; the Company's ability to establish and maintain strategic partnerships and other corporate collaborations, including its partnership with AbbVie and its ability to continue to receive milestone and royalties payments under the AbbVie agreement; the Company's reliance on third parties to conduct some or all aspects of its product manufacturing; the scope of protection the Company is able to establish and maintain for intellectual property rights and the Company's ability to operate its business without infringing the intellectual property rights of others; current or future unfavorable economic and market conditions and adverse developments with respect to financial institutions and associated liquidity risk; the impact of competition and new technologies; general market, political, and economic conditions in the countries in which the Company operates, including, with respect to the Israel- Hamas war, projected capital expenditures and liquidity, changes in the Company's strategy, and litigation and regulatory proceedings. More detailed information about the risks and uncertainties affecting CollPlant are contained under the heading "Risk Factors" included in CollPlant's most recent annual report on Form 20-F filed with the SEC, and in other filings that CollPlant has made and may make with the SEC in the future. The forward-looking statements contained in this press release are made as of the date of this press release and reflect CollPlant's current views with respect to future events, and CollPlant does not undertake and specifically disclaims any obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.

Contacts

CollPlant:

Eran Rotem
Deputy CEO & CFO
Tel: + 972-73-2325600
Eran@collplant.com

Investors:

LifeSci Advisors
John Mullaly
jmullaly@lifesciadvisors.com

Photo: https://mma.prnewswire.com/media/2309446/CollPlant breast implants.jpg

Logo: https://mma.prnewswire.com/media/2217353/CollPlant Logo.jpg



C View original content: https://www.prnewswire.com/news-releases/collplant-biotechnologies-begins-preclinical-trial-with-commercial-size-regenerative-breast-implants-302024360.html

SOURCE CollPlant