

CollPlant Issues Letter to Shareholders

REHOVOT, Israel, Feb. 15, 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, is pleased to issue the following letter from its Chief Executive Officer, Yehiel Tal.



View as PDF

Dear Shareholders,

As we look toward a promising and exciting year ahead, I am proud to reflect on CollPlant's main achievements throughout 2023. We leveraged our pioneering collagen-based platform and dynamic workforce to strengthen existing business collaborations, as well as to initiate and advance new opportunities. We continued to develop products with safety and performance advantages that we believe will lead to further innovation in the fields of regenerative and aesthetic medicine. We are excited with our progress while remaining extremely focused on advancing our goal to become a global leader in these fields.

Collaborations

During 2023, we made significant progress with our development partner, AbbVie, to advance our dermal and soft tissue filler toward commercialization. Furthermore, we continue to be engaged in partnering discussions with several industry leaders seeking to leverage our rhCollagen technology and expertise in 3D bioprinting to develop therapeutics and medical applications.

AbbVie

Our long-term collaboration with AbbVie to develop a paradigm-shifting regenerative dermal and soft tissue filler continues to advance. In June of last year, we announced the achievement of an important milestone under this collaboration which triggered a \$10 million payment from AbbVie to CollPlant. Per CollPlant's agreement with AbbVie, CollPlant has the potential to receive additional milestones and option products payments, as well as receive meaningful royalties on product sales. AbbVie continues to advance the filler program which is now in clinical studies.

Stratasys

In April of last year, we announced a joint development and commercialization agreement with Stratasys Ltd. to collaborate on the development of a solution to bio-fabricate human tissues and organs using Stratasys' P3 technology-based bioprinter and CollPlant's rh-Collagen-based bioinks. The first project focuses on the development of an industrial-scale solution for CollPlant's regenerative breast implants program. The new bioprinter, based on Stratasys' precise P3[™] 3D printing technology in combination with CollPlant's flagship bioinks, is designed to enable the production of CollPlant's state of the art breast implants, which are being developed to regenerate an individual's natural breast tissue without eliciting immune response, providing a potentially revolutionary alternative for both aesthetic and reconstructive procedures.

Under the agreement, both companies have agreed to cross-promote each other's bioprinting products. Stratasys' bioprinter will be offered to customers together with CollPlant's bioinks, and similarly Stratasys' bioprinter will be offered to CollPlant's business partners and customers.

Products Pipeline

I am proud to share with you a few important highlights from this past year related to our products pipeline, which targets large commercial opportunities in both, medical aesthetics and personalized medicine markets. At the cornerstone of our success lies the many advantages of our high-performance non-animal, recombinant human (rh)Collagen.

Regenerative Breast Implants

One of our most exciting products in development is our regenerative breast implants, addressing the \$2.6 billion global breast implant market. Additionally, breast reconstruction and augmentation procedures represent the second most common plastic surgery procedure performed worldwide today. The most common breast augmentation or reconstruction procedures today are based on synthetic silicone breast implantations, an artificial substitution for natural regenerated tissue with risks of complications.

Currently, there are no commercial products that allow regeneration of soft tissues such as the breast. In the U.S. alone, hundreds of thousands of people per 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 that are comprised of the Company's proprietary plant-derived rhCollagen and other biomaterials, are expected to regenerate breast tissue without eliciting immune response, and thus may provide a revolutionary alternative for aesthetic and reconstructive procedures, including postmastectomy for cancer patients.

In January of last year, we announced the successful completion of a large animal study for our recombinant human collagen (rhCollagen)-based 3D bioprinted regenerative breast implants. The preclinical study 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. This study was followed by additional large animal studies that were intended to further optimize the implant design and composition. New tissue formation and neovascularization with no adverse tissue reactions were demonstrated confirming previous results.

Supported by these promising results, in December 2023, we initiated a large-animal study to evaluate commercial-size,3D-bioprinted, regenerative breast implants. This study will be used to obtain data that will be used to support subsequent human studies and future product commercialization.

The achievements we demonstrated to date take us another step forward in the development of a revolutionary alternative to silicone implants for aesthetic and reconstructive procedures.

Gut-on-a-Chip Tissue Model

CollPlant decided in 2022 to expand into the promising field of personalized medicine. Our lead program in this space is our gut-on-a-chip program that is addressing the need to provide therapeutic choices for inflammatory bowel diseases. Our specific focus is on ulcerative colitis, or UC.

We are developing a bioprinted human intestine model that can be used in drug discovery and personalized treatment of UC. The 3D bioprinted model is designed to emulate the human intestine tissue in order to allow medical professionals to identify drug targets and personalized therapeutic responses that can lead to improved patient outcomes.

We remain extremely excited about the prospects for this program and plan to provide an update with the next steps for this program as we enter the next phase of development.

Intellectual Property

In November of last year, we announced that the U.S. Patent and Trademark Office has granted a patent that covers CollPlant's photocurable dermal filler product candidate, being developed for the aesthetics market.

The U.S. Patent (No. 11,801,329) is directed, among other things, to a method of filling tissue space under the epidermis by introducing a polymerizable filler solution into the tissue

space and applying external light to induce in-situ polymerization. This newly issued patent is related to CollPlant's photocuring technology and serves as the basis of our photocurable dermal filler product pipeline currently under development. The polymerizable solution injected into the tissue space is comprised of a chemically modified recombinant human collagen (rhCollagen) and other constituents such as hyaluronic acid.

This patent represents an integral part of the Company's strategy to expand the uses for its novel, rhCollagen technology into new, high-value markets. The U.S. is one of CollPlant's strategic target markets, and we see the strengthening of our intellectual property in this territory as a significant achievement.

In addition to its superior skin lifting capacity, the photocurable filler is designed to enable tissue regeneration and tissue contouring ability. This issued patent expiring in 2039 provides coverage for a regenerative photocurable dermal filler with contouring capabilities and we believe this will strengthen our position in the market for many years to come.

Corporate Responsibility

Our rhCollagen production process utilizes plant-based genetic engineering technology. This approach eliminates the need for traditional animal-derived collagen sources, reducing the environmental strain associated with traditional methods and promoting more ethical and sustainable practices.

In the second quarter of 2023, CollPlant hired a dedicated expert to lead our Environment, Social and Governance (ESG) effort. Our goal was to identify CollPlant's strengths in the areas of ESG that are already in line with our mission and communicate these practices to business partners and the public.

In line with this initiative, in September last year, CollPlant announced that it joined the United Nations Global Compact, the world's largest initiative for sustainable and responsible corporate governance. As a new participant of this voluntary leadership platform, CollPlant strengthens its commitment to operate sustainably as it is also producing sustainable alternatives to the regenerative and aesthetics medicine products and technologies that currently exist.

Consistent with our mission of helping people live longer, healthier lives through regenerative medicine, we are committed to supporting a more sustainable ecosystem that benefits all stakeholders, including patients, our employees, and our shareholders.

In Closing

Tissue and organ shortage is a major medical challenge arising from a combination of donor scarcity and patient rejection. As technologies evolve with 3D bioprinting technology, we believe this will enable CollPlant to address the challenge by utilizing our rhCollagen to help to create an unlimited supply of tissues and organs.

Additionally, as we develop tissue models that can mimic a variety of human disease conditions, this will be a driver for our strategic expansion into personalized medicine.

In 2024, we plan to further advance and expand our diverse portfolio of innovative products and value-creating partnerships, alongside our commitment to support a more sustainable

and equitable world.

Especially this challenging year, I would like to thank our employees – who continue to show an unwavering commitment to improving patients' lives - for their dedication and passion, which has launched us to the next level of performance and closer towards becoming the leaders in regenerative medicine.

Finally, and importantly, I would also like to thank my fellow shareholders for their continued trust and support for CollPlant's mission to become a global leader in regenerative and aesthetic medicine.

With Appreciation and Optimism,

Yehiel Tal

Chief Executive Officer, CollPlant Biotechnologies

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, visit: http://www.collplant.com.

Forward-Looking Statements

This communication 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 develop a printing solution for its breast implants program, or at all; the Company's ability to obtain favorable pre-clinical 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.

Contact at CollPlant:

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

Photo - https://mma.prnewswire.com/media/2341117/Yehiel_Tal_CollPlant_CEO.jpg
Logo - https://mma.prnewswire.com/media/2217353/CollPlant_Logo.jpg



C View original content to download multimedia https://www.prnewswire.com/news-releases/collplant-issues-letter-to-shareholders-302063006.html

SOURCE CollPlant