Translation of Immediate Report Filed by Elron on March 30, 2022 with the Israeli Securities Authority

Tel-Aviv, March 30, 2022 – Elron Ventures Ltd. ("Elron") (TASE: ELRN) hereby announces further to Section 23, and in particular Section 23.15, of "Part I – Description of Corporation's Business" in Elron's annual periodic report for 2021 with regard to the investment and option transaction for the sale of CartiHeal (2009) Ltd. ("CartiHeal") to Bioventus (the "Transaction"), that CartiHeal updated that it received the FDA approval for the Agili-C implant. Attached is the FDA report as it was sent to CartiHeal.

Accordingly, CartiHeal submitted its position to Bioventus that it believes in good faith that the Regulatory Approval Milestone stipulated in the Transaction documents for the consummation of the Transaction, has been achieved.

There is no assurance as to the Transaction's consummation or the timing thereof.

CartiHeal is 27% held by Elron (25% on a fully diluted basis).

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March 29, 2022

CartiHeal Ltd.
% Janice M. Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, Floor 23
Philadelphia, Pennsylvania 19103

Re: P210034
Trade/Device Name: Agili-C™
Product Code: QRU
Filed: September 30, 2021
Amended: November 30, 2021

Dear Janice M. Hogan:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Agili-C™.

The Agili-C™ scaffold is indicated for the treatment of an International Cartilage Repair Society grade III or above knee-joint surface lesion(s), with a total treatable area of 1-7cm^2, without severe osteoarthritis (Kellgren-Lawrence grade 0-3).

We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below. Although this letter refers to your product as a device, please be aware that some approved products may instead be combination products. The Premarket Approval Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm identifies combination product submissions.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). The device is further restricted under section 515(d)(1)(B)(ii) of the act insofar as the labeling must specify the specific training or experience practitioners need in order to use the device. FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices.

Expiration dating for this device has been established and approved at five years. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(7).

Continued approval of the PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. This report, identified as "Annual Report" and bearing the applicable PMA reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.84.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the PMA device, the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

In addition to the Annual Report requirements, you must provide the following data in post-approval study (PAS) reports for the PAS listed below.

- "A Post Approval Multicenter, Open-label, Randomized, Controlled Trial of Agili-C™ vs. Surgical Standard of Care for the Treatment of Joint Surface Lesions of the Knee" will be conducted in accordance with protocol CLN0021-US Rev 8 dated January 25, 2022. The study will consist of all living subjects who were enrolled in the IDE study, "A Prospective Multicenter Open-label Randomized Controlled Trial of Agili-C™ vs. Surgical Standard of Care for the Treatment of Joint Surface Lesions of the Knee". Subject follow-up will continue for all cohorts based on the timelines and assessments stipulated in the IDE protocol. The objective of this PAS is to characterize the clinical outcomes annually through 5 years post-procedure. Data will be collected per the study protocol, including, but not limited to, the following key safety and effectiveness endpoints: Adverse events, including serious adverse events, reoperations and revisions, up to 60 months – safety endpoints; Change from baseline to 60 months in the average overall Knee Injury and Osteoarthritis Outcome Score (KOOS) – (Pain, Symptoms, QOL, ADL & Sports) – primary endpoint; Change from baseline to 60 months in KOOS Pain subscore, KOOS QOL subscore, KOOS ADL subscore, KOOS Symptoms subscore, KOOS Sports subscore, and Overall KOOS responder rate (defined as an increase from baseline to 60 months of ≥ 30 points on overall KOOS) – confirmatory secondary endpoints; Change from baseline at 36, 48 and 60 Months in IKDC Subjective Knee Evaluation, Tegner score, SF-12 v2 Physical Component Summary score and Mental Health Component Summary, and analyses of various subgroups – additional secondary endpoints. The statistical analyses will be conducted using the same statistical models that were used in the analyses in the pivotal trial. Interim analyses will be submitted in interim reports in October 2022 and annually thereafter until study completion, with a final report in Quarter 2, 2025.

Each PAS report should be submitted to the address below identified as a "PMA Post-Approval Study Report" in accordance with how the study is identified above and bearing the applicable PMA reference number.

Due to the ongoing COVID-19 pandemic, the Agency has been unable to conduct pre-approval inspections of the site involved in the manufacture of the Agili-C™ device. In lieu of the pre-approval inspection, the Agency has requested and considered additional information that would help it understand the adequacy of your Quality Systems and how they contribute to your device's safety. The Agency has determined that there is sufficient Good Manufacturing Practices (GMP) information to support approval of your PMA at this time. However, approval is contingent upon the condition that CartiHeal Ltd. should be readily available for a FDA GMP inspection with no other hindering factors when the affected sites are in a "Green" or "Yellow" zone and ORA resources are available to conduct an inspection. Furthermore, if upon inspection by FDA, the sites are deemed as not in compliance with the requisite FDA Current Good Manufacturing Practices (CGMPs) as outlined in 21 CFR 820, FDA has the authority to withdraw the approval of the PMA in accordance with 21 CFR 814.82(c).

Be advised that failure to comply with any post-approval requirement, including GMP inspection and Post-Approval Study reporting as outlined above, constitutes grounds for FDA withdrawal of approval of the PMA in accordance with 21 CFR 814.82(c) and 814.46(a)(2).

Be advised that the failure to conduct any such study in compliance with the good clinical laboratory practices in 21 CFR part 58 (if a non-clinical study subject to part 58) or the institutional review board regulations in 21 CFR part 56 and the informed consent regulations in 21 CFR part 50 (if a clinical study involving human subjects) may be grounds for FDA withdrawal of approval of the PMA in accordance with 21 CFR 814.46(a)(3)-(4).

Be advised that protocol information, interim and final results will be published on the Post Approval Study Webpage https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma_pas.cfm.

In addition, the results from any post approval study should be included in the labeling as these data become available. Any updated labeling must be submitted to FDA in the form of a PMA Supplement. For more information on post-approval studies, see the FDA guidance document entitled, "Procedures for Handling Post-Approval Studies Imposed by PMA Order" (https://www.fda.gov/media/71327/download).

This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final Unique Device Identification (UDI) rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR 830 Subpart E). Additionally, 21 CFR 814.84 (b)(4) requires PMA annual reports submitted after September 24, 2014, to identify each device identifier currently in use for the subject device, and the device identifiers for devices that have been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013. Combination Products may also be subject to UDI requirements (see 21 CFR 801.30). For more information on these requirements, please see the UDI website, https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-udi-system.

Before making any change affecting the safety or effectiveness of the PMA device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39. All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21

CFR 814.39. For more information, please refer to the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" https://www.fda.gov/media/81431/download.

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52 for devices or post-marketing safety reporting (21 CFR 4, Subpart B) for combination products, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems and on combination product post-marketing safety reporting is available at (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products).

In accordance with the recall requirements specified in 21 CFR 806.10 for devices or the post-marketing safety reporting requirements (21 CFR 4, Subpart B) for combination products, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls.

CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading. CDRH will notify the public of its decision to approve your PMA by making available, among other information, a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet Home Page located at https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/pma-approvals. Written requests for this information can also be made to the Food and Drug Administration, Dockets Management Branch, (HFA-305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by submitting a petition for review under section 515(g) of the act and requesting either a hearing or review by an independent advisory committee. FDA may, for good cause, extend this 30-day filing period.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with a copy of all final labeling. Final labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final labeling is identical to the labeling approved in draft form. If the final labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning this approval order, please contact Pooja Panigrahi, Ph.D., at 240-402-1090 or Pooja.Panigrahi@fda.hhs.gov.

Sincerely,

Raquel A. Peat -S

CAPT Raquel Peat, Ph.D., M.P.H., USPHS
Director
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health