PRESS RELEASE
September 13, 2023
Gothenburg

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XVIVO intends to carry out a directed share issue

XVIVO Perfusion AB (publ) ("XVIVO" or the "Company") intends to carry out a directed share issue corresponding to approximately SEK 440 million in the Company through an accelerated bookbuilding procedure directed to Swedish and international institutional investors (the "Directed Issue"), starting immediately. XVIVO has engaged Carnegie Investment Bank AB (publ) ("Carnegie") and DNB Markets, a part of DNB Bank ASA, Sweden branch ("DNB Markets") to act as Joint Bookrunners (together the "Joint Bookrunners") in connection with the Directed Issue.

The Directed Issue

The subscription price and the number of new shares in the Directed Issue will be determined through an accelerated bookbuilding procedure, which will commence immediately following the publication of this press release and will be led by the Joint Bookrunners. Closing of the accelerated bookbuilding procedure, pricing and allocation of the new shares are expected to take place before the commencement of trading on Nasdaq Stockholm at 09:00 CEST on 14 September 2023. The timing of closing, pricing and allocation in the bookbuilding procedure are determined at the discretion of the Company and may be shortened, extended or cancelled at any time, meaning the Company may refrain, in part or in full, from carrying out the Directed Issue. The Company will announce the outcome of the Directed Issue in a press release after the bookbuilding procedure has been completed.

The interest from US clinics for XVIVO's upcoming US heart preservation trial has been significant. On July 25, 2023 the FDA granted XVIVO approval to include Donation after Circulatory Death ("**DCD**") hearts in its Investigational Device Exemption ("**IDE**") clinical trial. Expanding the clinical trial to include DCD hearts means that the Company's technology is additionally made available to approximately one third of the US donor pool.

Today, XVIVO is the European market leader within liver machine perfusion, supported by strong clinical data published in leading scientific journals. In 2022, 9,528 liver transplants were performed in the US (UNOS data). In order to become the the global market leader within abdominal machine perfusion, the Company has identified an opportunity to shorten the time to market in the US for the Liver Assist technology. This can be achieved by conducting a clinical trial to support the FDA PMA approval process for the Liver Assist in addition to the Company's heart preservation trial, meaning that the Company aims to conduct regulatory processes for both heart and liver in the US.

The net proceeds from the Directed Issue are intended to be used for:
· Increased investment in US clinical trial infrastructure and support to create an efficient FDA PMA regulatory approval process for the heart preservation technology;
· Fast-track the preparation and start of the clinical trial and FDA PMA regulatory approval process for Liver Assist; and
· Scale-up of disposable production to ensure delivery capacity and decrease in cost of goods sold.

Prior to the Directed Issue, the Company's board of directors has made an overall assessment and carefully considered the possibility to raise capital through a rights issue with preferential right for the Company's existing shareholders. The board of directors considers that the reasons for deviating from the shareholders' preferential right are (i) that a rights issue would take a significantly longer time to complete and entail a higher risk for a adverse effect on the share price, particularly in light of the current market volatility and the challenging market conditions, (ii) to diversify and strengthen the Company's shareholder base with international institutional investors, (iii) to carry out a directed share issue can be made at lower costs and with less complexity than a rights issue and in light of the current market conditions, the board of directors has assessed that a rights issue would also require external underwriting from a guarantor syndicate that would entail additional significant costs. Considering the above, the board of directors has made the assessment that a directed share issue with deviation from the shareholders' preferential right is the most favourable alternative for XVIVO, creates value for the Company and is in the best interest of the Company's shareholders. The board of directors thus considers that the reasons outweigh the main rule that new share issues are to be carried out with preferential rights for the shareholders.

Since the subscription price in the Directed Issue will been determined through an accelerated bookbuilding procedure, the board of directors assesses that the subscription price will reflect market terms and conditions.

Lock-up undertakings

In connection with the Directed Issue, the Company has agreed to a lock-up undertaking, with customary exceptions, on future share issuances for a period of 180 calendar days after the settlement date of the Directed Issue. In addition, XVIVO's board members and shareholding members of the senior management have undertaken not to, subject to customary exceptions, divest any shares in XVIVO for a period of 180 days from the settlement date of the Directed Issue.

Advisors

Carnegie and DNB Markets have been appointed Joint Bookrunners in connection with the Directed Issue. Advokatfirman Vinge acts as legal counsel to the Company and Baker McKenzie acts as legal counsel to the Joint Bookrunners.

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XVIVO Perfusion AB (publ)

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This information is information that XVIVO Perfusion AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2023-09-13 18:00 CEST.

About Us

Founded in 1998, XVIVO is the only medical technology company dedicated to extending the life of all major organs - so transplant teams around the world can save more lives. Our solutions allow leading clinicians and researchers to push the boundaries of transplantation medicine. XVIVO is headquartered in Gothenburg, Sweden, and has offices and research sites on two continents. The company is listed on Nasdaq and has the ticker symbol XVIVO. More information can be found on the website www.xvivogroup.com.

Important information

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This press release does not constitute or form part of an offer or solicitation to purchase or subscribe for securities in the United States. The securities referred to herein may not be sold in the United States absent registration or an exemption from registration under the US Securities Act of 1933, as amended (the "Securities Act"), and may not be offered or sold within the United States absent registration or an applicable exemption from, or in a transaction not subject to, the registration requirements of the Securities Act. There is no intention to register any securities referred to herein in the United States or to make a public offering of the securities in the United States. The information in this press release may not be announced, published, copied, reproduced or distributed, directly or indirectly, in whole or in part, within or into the United States, Australia, Canada, Hong Kong, Japan, New Zeeland, Singapore, South Africa, South Korea or in any other jurisdiction where such announcement, publication or distribution of the information would not comply with applicable laws and regulations or where such actions are subject to legal restrictions or would require additional registration or other measures than what is required under Swedish law. Actions taken in violation of this instruction may constitute a crime against applicable securities laws and regulations.

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This announcement does not identify or suggest, or purport to identify or suggest, the risks (direct or indirect) that may be associated with an investment in the new shares. Any investment decision to acquire or subscribe for shares in connection with the Directed Issue must be made on the basis of all publicly available information relating to the Company and the Company's shares. Such information has not been independently verified by the Joint Bookrunners. The Joint Bookrunners are acting for the Company in connection with the transaction and no one else and will not be responsible to anyone other than the Company for providing the protections afforded to its clients nor for giving advice in relation to the transaction or any other matter referred to herein.
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This press release does not constitute an invitation to warrant, subscribe, or otherwise acquire or transfer any securities in any jurisdiction. This press release does not constitute a recommendation for any investors' decisions regarding the Directed Issue. Each investor or potential investor should conduct a self-examination, analysis and evaluation of the business and information described in this press release and any publicly available information. The price and value of the securities can decrease as well as increase. Achieved results do not provide guidance for future results. Neither the contents of the Company's website nor any other website accessible through hyperlinks on the Company's website are incorporated into or form part of this press release.

Forward-looking statements

This press release contains forward-looking statements that reflect the Company's intentions, beliefs, or current expectations about and targets for the Company's future results of operations, financial condition, liquidity, performance, prospects, anticipated growth, strategies and opportunities and the markets in which the Company operates. Forward-looking statements are statements that are not historical facts and may be identified by words such as "believe", "expect", "anticipate", "intend", "may", "plan", "estimate", "will", "should", "could", "aim" or "might", or, in each case, their negative, or similar expressions. The forward-looking statements in this press release are based upon various assumptions, many of which are based, in turn, upon further assumptions. Although the Company believes that the expectations reflected in these forward-looking statements are reasonable, it can give no assurances that they will materialize or prove to be correct. Because these statements are based on assumptions or estimates and are subject to risks and uncertainties, the actual results or outcome could differ materially from those set out in the forward-looking statements as a result of many factors. Such risks, uncertainties, contingencies and other important factors could cause actual events to differ materially from the expectations expressed or implied in this release by such forward-looking statements. The Company does not guarantee that the assumptions underlying the forward-looking statements in this press release are free from errors and readers of this press release should not place undue reliance on the forward-looking statements in this press release. The information, opinions and forward-looking statements that are expressly or implicitly contained herein speak only as of its date and are subject to change without notice. Neither the Company nor anyone else undertake to review, update, confirm or to release publicly any revisions to any forward-looking statements to reflect events that occur or circumstances that arise in relation to the content of this press release, unless it is not required by law or Nasdaq Stockholm's Rulebook for Issuers.

Information to distributors

Solely for the purposes of the product governance requirements contained within: (a) EU Directive 2014/65 /EU on markets in financial instruments, as amended ("MiFID II"); (b) Articles 9 and 10 of Commission Delegated Directive (EU) 2017/593 supplementing MiFID II; and (c) local implementing measures (together, the "MiFID II Product Governance Requirements"), and disclaiming all and any liability, whether arising in tort, contract or otherwise, which any "manufacturer" (for the purposes of the MiFID II Product Governance Requirements) may otherwise have with respect thereto, the shares in the Company have been subject to a product approval process, which has determined that such shares are: (i) compatible with an end target market of retail investors and investors who meet the criteria of professional clients and eligible counterparties, each as defined in MiFID II; and (ii) eligible for distribution through all distribution channels as are permitted by MiFID II (the "Target Market Assessment"). Notwithstanding the Target Market Assessment, Distributors should note that: the price of the shares in the Company may decline and investors could lose all or part of their investment; the shares in the Company offer no guaranteed income and no capital protection; and an investment in the shares in the Company is compatible only with investors who do not need a guaranteed income or capital protection, who (either alone or in conjunction with an appropriate financial or other adviser) are capable of evaluating the merits and risks of such an investment and who have sufficient resources to be able to bear any losses that may result therefrom. The Target Market Assessment is without prejudice to the requirements of any contractual, legal or regulatory selling restrictions in relation to the Directed Issue. Furthermore, it is noted that, notwithstanding the Target Market Assessment, the Joint Bookrunners will only procure investors who meet the criteria of professional clients and eligible counterparties.

For the avoidance of doubt, the Target Market Assessment does not constitute: (a) an assessment of suitability or appropriateness for the purposes of MiFID II; or (b) a recommendation to any investor or group of investors to invest in, or purchase, or take any other action whatsoever with respect to the shares in the Company.

Each distributor is responsible for undertaking its own target market assessment in respect of the shares in the Company and determining appropriate distribution channels.

This is a translation of the Swedish version of the press release. In case of discrepancies, the Swedish wording shall prevail.

Attachments

XVIVO intends to carry out a directed share issue