

ASX RELEASE

Volpara Receives New FDA 510(k) Clearance

Wellington, NZ, 24th September 2018: [Volpara Health Technologies](#) ("Volpara"; ASX: VHT), a medical technology company whose AI imaging algorithms assist the early detection of breast cancer, announced today that the company has received a new FDA 510(k) clearance for technologies used in Volpara®Enterprise™ software and the Volpara®Density™ clinical application. This sets the stage for the introduction of the Volpara®Live!™ system, the first real-time decision support product for mammography designed to use quality control feedback to improve breast care for women whilst improving the financial performance of breast imaging clinics.

The new clearance (K182310) expands the types of information that Volpara algorithms can provide to clinicians. For instance, Volpara can now refine breast density scoring when there is an area of the breast that is especially dense, and provide an overall sensitivity score for the exam (based on the results of the many international clinical trials that have used the VolparaDensity clinical application)—an industry first. The clearance also expands the list of x-ray systems compatible with the VolparaDensity clinical application.

Dr Ralph Highnam, Volpara CEO, said: "These new features show Volpara's continuing leadership and commitment to the breast density space. They clearly demonstrate our ever-growing customer focus, driving revenue for our SaaS business (with minimal churn) and exponential growth of our cloud-based Big Data."

The new clearance also covers a new type of output, which advises the radiographer of any image quality issues soon after the image is acquired. This allows the radiographer to evaluate whether a retake is necessary before the woman leaves the clinic. This new technology, to be marketed as the VolparaLive! system, opens a new, untapped product market area for Volpara.

Dr Highnam added: "Over the last two years we have learned a great deal from VolparaEnterprise customers and the Big Data in our cloud. Through our refined understanding of quality in mammography, and our ability to automatically and objectively measure performance, we have uncovered new ways that we can help improve mammography. The VolparaLive! system will be our first commercialisation path for this newfound knowledge and falls in step with the recent introduction of the FDA EQUIP initiative, which mandates that all mammography facilities have a renewed focus on quality.

"The VolparaLive! system is a natural, customer-led extension of our product line and will see us increase our price per woman (ARPU) while continuing to retain high gross margins. We look forward to completing the development of the VolparaLive! system and introducing it to customers in late November at Chicago's RSNA 2018."

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About Volpara Health Technologies Limited (ASX: VHT)

VHT is a MedTech SaaS company founded in 2009 on research originally conducted at Oxford University. VHT's clinical applications for screening clinics provide feedback on breast density, compression, dose and quality, while its enterprise-wide software, VolparaEnterprise, provides role specific dashboards and wide-ranging benchmarking analytics to help clinics manage their business more efficiently.

VHT's technology and services have been used by customers and/or research projects in 36 countries and are supported by numerous patents, trademarks and regulatory clearances, including FDA clearance and CE marking. Since its listing on the ASX in April 2016, VHT has raised A\$40 million, including A\$20 million in April and May 2018. VHT is based in Wellington, New Zealand.

For more information, visit www.volparasolutions.com