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Company Announcements Office
Australian Securities Exchange

Nanosonics receives US FDA clearance for the latest generation of trophon – trophon®2

Nanosonics (ASX: NAN), a leader in infection control solutions, today announced receipt of the pivotal FDA 510(k) clearance for its 2nd generation trophon platform device – trophon2.

"This is excellent news delivering earlier than anticipated FDA clearance for our next generation trophon device. Further, it delivers the first regulatory approval of our targeted new infection prevention solutions," said Michael Kavanagh, Nanosonics' Chief Executive Officer and President.

"Building on the success of the original trophon® EPR, Nanosonics' next generation ultrasound probe High Level Disinfection system, trophon2, reflects a completely new mechanical and software design that delivers a range of new benefits based on input and feedback from our global community of customers. This included input from infection prevention specialists on future trends and requirements in the area of semi-critical device reprocessing. Some of the new features of trophon2 include a redesigned chamber to facilitate existing and future probe designs as well as new functionality to further optimise point of care usage and clinical workflow including a large high definition colour touch screen that facilitates ease of installation, training and use, whisper quiet operation and programmable options.

"Central to the new design is a totally new software platform which delivers superior capabilities including the all-new AcuTrace™ feature. AcuTrace delivers paperless traceability and documentation of disinfection cycles through the latest state of the art RFID technology embedded in ultrasound probe tags, operator cards, the Sonex disinfectant as well as the chemical indicators. The trophon2 device can store over 100,000 disinfection records and this electronic data capture provides more accurate and complete records for improved compliance with required standards. In addition to AcuTrace, trophon2 also delivers AcuTrace Plus digital connectivity functionality which enables the trophon2 device to be seamlessly integrated with hospital IT systems for a streamlined, paperless and completely integrated reprocessing solution.

"We see strong potential for the AcuTrace system to assist hospitals with their audit compliance, as well as providing them with a seamless and easily integrated system to store and retrieve disinfection cycle data. From a user's perspective it means that at the touch of a button they can verify that any probe, at any moment in time, has been successfully disinfected, resulting in peace of mind for patients and their care providers.

"This new software platform also future readies the device by allowing new functionality to be implemented through firmware upgrades.

"The trophon2 device also includes new functionality designed to meet specific European market requirements including the ability to monitor in real time and report on all the process parameters (dosage, temperature, time) for each disinfection cycle. This provides the customer confidence that the device is operating within all the operating specifications automatically in real time. Together with the full feature set of trophon2, this new functionality helps pave the way to establish trophon2 as the new standard of care in Europe as new country specific guidelines requiring HLD for all

semi-critical ultrasound probes are introduced. The regulatory submission for Europe is currently under review.

"It is anticipated that the commercial release of the new trophon2 in the USA will take place during the first quarter of the 2019 financial year. The product is currently being introduced into manufacturing with a ramp up in production expected to take place over the next 3 months.

"The original trophon EPR device will remain in the market as an entry level product however we anticipate a significant proportion of sales to shift from trophon EPR to the new trophon2 system. As a result of the earlier than anticipated regulatory clearance, expectations are that the market and our distributor partners will now commence the transition to trophon2 which means it is likely there will be a short term impact on both inventory and trading volumes which will have a transitionary impact on revenue recognition in the current quarter. However, it is expected that trophon2 will continue to drive installed base growth as well as introduce the opportunity for an upgrade market, and any impact on short term sales of trophon® EPR due to the imminent release of trophon2 is anticipated to be made up after the full commercial release of trophon2.

"This regulatory clearance from the FDA for trophon2 further underpins our geographical expansion plans and will form the basis for feasibility assessments and potential regulatory submissions for new markets. With the introduction of trophon2, Nanosonics aims to further build on its leadership position delivering to the market the most complete automated point of care solution with full traceability for ultrasound probe reprocessing."

Michael Kavanagh
CEO / President

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About Nanosonics:
Nanosonics Limited is developing a portfolio of decontamination products designed to reduce the spread of infection, improving the safety of patients, clinics their staff and the environment. The Company is an innovator in infection prevention and owns intellectual property relating to a unique disinfection and sterilisation technology which can be suited to a variety of global markets that aim to deliver improved standards of care. Initial market applications are designed for the reprocessing of reusable medical instruments. The Company's first product is designed to disinfect Ultrasound Transducers. For more information about Nanosonics please visit www.nanosonics.com.au