Biotech Daily

Thursday March 20, 2025

Daily news on ASX-listed biotechnology companies

FDA Approves Nanosonics' Coris For Endoscopes

Nanosonics says it the US Food and Drug Administration has approved its Coris device for cleaning biofilm in flexible endoscopes.

In its 2022 full year report, Nanosonics said its Coris endoscope cleaner had US Food and Drug Administration Safer Technologies Program acceptance and de-novo status, with non-US approval expected by the end of 2023 (BD: Sep 23, 2022).

At that time, the company said Coris was roughly the same size as its existing Trophon product, previously described as about the size of a microwave oven on its side, but the technology did not use nebulized hydrogen peroxide, like the Trophon.

In its 2023 annual general meeting presentations, Nanosonics said Coris was significantly more effective than manual cleaning for removing biofilms from simulated endoscope air and water channel lumens (BD: Nov 3, 2023).

Last year, the company said it had filed a de novo application to the FDA for Coris; and later, said a study showed Coris outperformed manual cleaning air, water and suction endoscope channels (BD: May 1, 2024).

Today, Nanosonics said the first phase of commercialization was expected by October and included raising market awareness and conducting a targeted and controlled market release with a number of hospitals to gain initial experience before a broader roll-out.

Nanosonics managing-director Michael Kavanagh said Coris was “a significant opportunity for the organization; and the FDA de novo clearance marks a key milestone for the company and an important step in bringing this much needed innovation to market”.

“The Coris system has been designed to automate and provide superior cleaning outcomes for the channels of all categories of flexible endoscopes,” Mr Kavanagh said.

“The initial submission to the FDA was associated with colonoscopes and the intent is to expand these indications to cover all major categories of flexible endoscopes over time,” Mr Kavanagh said.

“The company continues its preparations for commercial launch including obtaining the necessary approvals in the UK, Europe and Australia,” Mr Kavanagh said.

Mr Kavanagh said the additional approvals in further jurisdictions were expected by October 2025.

“In parallel, the first 510(k) submission for expanded scope indications is being prepared for FDA submission,” Mr Kavanagh said.

Nanosonics was up 61 cents or 14.0 percent to $4.98 with five million shares traded.