



**LBT INNOVATIONS**  
ACN 107 670 673

The Manager  
Company Announcements Office  
ASX Limited

## **LBT INNOVATIONS COMPLETES U.S. REGULATORY SUBMISSION FOR PIONEERING CULTURE PLATE ANALYSIS TECHNOLOGY**

**Adelaide, 22 December 2015:** Australian medical technology company LBT Innovations Limited (ASX: LBT) has completed a *de novo* submission to the US Food and Drug Administration (FDA) seeking classification of APAS as Class II medical device and 510(k) clearance for marketing for the Company's pioneering culture plate analysis technology, the Automated Plate Assessment System (APAS®).

The *de novo* submission covers the initial manual version of APAS, the APAS® Compact, which has been successfully tested in a total of 10,000 patients in three clinical trials conducted in Australia and the US over the past 12 months. In each trial, APAS achieved its target primary endpoints and demonstrated 98% sensitivity in the detection of pathogenic bacteria associated with common urinary tract infections. These results matched or exceeded the findings of a panel of experienced microbiologists.

APAS offers a significant breakthrough in detecting and quantifying bacterial growth on culture plates and removing plates without significant growth from laboratory workflows, thereby enabling microbiologists to focus on plates that are presumed to be positive for infection. The APAS technology is being integrated with high-speed robotic plate-handling equipment to create an automated culture plate reader and sorter that will be marketed as the APAS® Independence by the JV Company, Clever Culture Systems AG.

The FDA submission also represents the completion of the development milestones per the joint venture agreement between the LBT Innovations and Hettich AG Switzerland, with final milestone payment expected in January 2016.

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### **About LBT Innovations**

LBT Innovations is an Australian developer of clinical and diagnostic technology. Based in Adelaide, South Australia, the Company has two breakthrough products in microbiology automation: MicroStreak®, which provides automation of culture plate streaking, and APAS®, a breakthrough in automated culture plate reading, interpretation and reporting.

Based on LBT's innovative intelligent image interpretative platform, APAS specifically addresses the automated imaging, analysis and interpretation of culture plates following incubation. LBT has entered into a joint venture with Hettich AG Switzerland to drive the commercialisation of APAS products. LBT also has a third product in development, Woundvue™, a proposed automation solution to assist in the management of chronic wounds. For more information, see [www.lbtinnovations.com](http://www.lbtinnovations.com)

### **CONTACTS**

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