

## **US MARKET UPDATE**

Accelerated commercial activities following FDA regulatory clearance on 17 May 2019

Adelaide, Australia, 19<sup>th</sup> June 2019: Australian medical technology company LBT Innovations Limited (ASX: LBT) (LBT or the Company), a leader in medical technology automation using artificial intelligence, is pleased to provide an update of its recent commercial activities in the United States.

The Company is pleased to report that there has been an increased level of activity on a number of fronts commercially, following the 510(k) clearance on 17 May 2019 from the United States Food and Drug Administration (FDA) for the APAS<sup>®</sup> Independence instrument with urine module.

As previously advised, the Company's joint venture company Clever Culture Systems (**CCS**), reached out to over 800 laboratory stakeholders in the United States to generate sales leads in the months preceding the recent FDA clearance. The intention was to generate qualified leads and follow a sales process developed from the Australian sales experience.

The Company can now report that Brent Barnes and a number of his senior management team will have spent the best part of the month of June in the US supporting commercialisation activities. This included visits to three tier one hospital facilities in the United States to present the APAS<sup>®</sup> Independence technology and the detailed value proposition. These visits were attended by key decision makers from the hospitals and included discussions on potential placement of an instrument for evaluation prior to a decision to purchase. While the sales process is hard to predict and can take a long time, these early interactions are positive and demonstrate the start of an encouraging sales process.

As part of the ramp up in sales activities, CCS is now in the process of establishing a direct sales presence in the United States, to lead these ongoing sales and commercial efforts. The intention to appoint a distributor remains unchanged, and in parallel, CCS has also been engaging with potential distributors for key geographies in the United States. Generating customer interest and conversion of early sales is a precursor to distributor appointment which is expected sometime in 2020.

Later this week, CCS and LBT management will also attending the American Society of Microbiology (**ASM**) Microbe meeting in San Francisco. This meeting will provide another opportunity to showcase the APAS<sup>®</sup> Independence to a number of U.S. based clinicians and industry participants, for the first time following FDA clearance.

After ASM Microbe, CCS will be also attending regional ASM meetings across the country to increase customer awareness of the APAS<sup>®</sup> Independence and drive the growth of the sales pipeline. CCS's reference site at Hennepin Medical Centre will also host a number of customer demonstrations showcasing the APAS<sup>®</sup> Independence in use in a clinical setting.

Brent Barnes CEO and Managing Director said:

"The FDA clearance for the APAS<sup>®</sup> Independence last month has positively changed the narrative for us with a number of U.S. stakeholders. To capitalise on this, the team and I have spent much of the last month in the United States meeting with three potential customers as well as clinicians and other stakeholders to ramp up our U.S. commercial activities. We see the U.S. as a tremendous market opportunity and while it will take time, we are highly focused on executing our commercial plans to achieve success.

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## About LBT Innovations

LBT Innovations (LBT) improves patient outcomes by making healthcare more efficient. Based in Adelaide, South Australia, the Company has a history of developing world leading products in microbiology automation. Its first product, MicroStreak®, was a global first in the automation of the culture plate streaking process. The Company's second product, the Automated Plate Assessment System (APAS®) is being commercialised through LBT's 50% owned joint venture company Clever Culture Systems AG (CCS) with Hettich Holding Beteiligungs- und Verwaltungs-GmbH. The APAS® instrument is based upon LBT's intelligent imaging and machine learning software and remains the only US FDA-cleared artificial intelligence technology for automated imaging, analysis and interpretation of culture plates following incubation.



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