



Letter from the CEO

In the ten years since the foundation of LBT, I cannot remember a busier time. The last few months have seen the rapid progress of our automated plate assessment system, APAS®, with clinical trials of the core technology about to start in the United States, and equipment development progressing well in Europe.

The grant awarded late last year by BioSA has enabled us to commence independent international market research into our third product, Woundvue®, which will be the second product utilising our intelligent image analysis technology. Early research appears to confirm the commercial viability of our approach, providing further validation of our decision to diversify our portfolio and develop products that answer very specific healthcare needs.

Importantly, the signalling by bioMérieux of a future change in our relationship has brought about an immediate readjustment of our priorities.

As you will read on these pages, 2015 is shaping up to be a landmark year for LBT. With our clinical trial program getting underway in New Mexico, we have entered into a period of intensive activity, focused on completing all of the requirements for the commercial use of APAS in the key U.S. market. Clearance by the U.S. Food and Drug Administration (FDA) will indeed be a landmark achievement.

The anticipated launch of laboratory instruments incorporating APAS early next year will herald a new chapter for our Company. The joint venture with Hettich AG Switzerland is now well established and working towards completing instrument development and securing global distribution partnering.

We will keep the market informed about the outcomes of our ongoing discussions with bioMérieux over the future of PREVI® Isola and we look forward to bringing you more news about APAS in the busy months ahead.

Lusia Guthrie
Chief Executive Officer
LBT Innovations



LBT INNOVATIONS



The LBT Team L-R: Dan Hill, Company Secretary and CFO; Peter Bradley, Vice President Global Business Development; Julie Winson, Quality Assurance Manager; John Glasson, Scientific Director; Lusia Guthrie, CEO; Michael Summerford, Apps Lab Manager and Senior Microbiologist; Mandy Liebelt, Microbiologist; Tomasz Grzegurko, Computer Scientist.

APAS – LBT's novel digital image interpretation technology

LBT is gearing up for a major clinical trial to support our application for clearance of APAS® to be used in laboratory equipment sold in the United States. This requires the submission of a 510(k) *de novo* application to America's regulatory authority, the Food and Drug Administration (FDA).

LBT's Automated Plate Assessment System (APAS) is a novel technology, for which there is no predicate device – meaning there is nothing like it currently in the marketplace. As such, the application is *de novo* ("starting anew") and the FDA registration will be for a Class 2 Medical Device.

Clinical trials were undertaken in Australia late last year at Healthscope Pathology laboratories in Melbourne and Adelaide. LBT is about to commence a large clinical trial at TriCore Reference Laboratories in Albuquerque, New Mexico. The trial will test the efficacy of APAS in reporting the presence of disease-causing pathogens in urine samples from approximately 5,700 patients.

Following the completion of the clinical trial program, there will be substantive analyses and documentation of results followed by preparation of the final submission to FDA. Data from these trials will also be used for the CE Mark process to register APAS in Europe and for other regulatory compliance agencies around the world.

APAS instruments

Design and construction of the first APAS instruments – a standalone plate-reader and an auto-incubator – continues to progress smoothly in Europe under the supervision of LBT's joint venture partner, Hettich AG Switzerland.

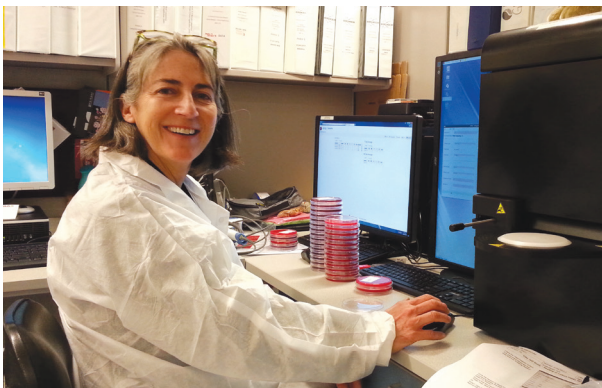
Our JV Company, Clever Culture Systems AG (CCS), will have its own booth at the trade show at the 25th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) in Copenhagen in late April, where it will be publicly demonstrating the APAS technology. APAS will also be on display at trade shows during the American Society of Microbiology (ASM) meeting in New Orleans in May, and the American Association of Clinical Chemists (AACC) in Atlanta in July.

Back in Australia, LBT is establishing a formal production facility in Adelaide to create the suite of 'plug-ins', or software modules, that will be sold to APAS customers to enable the automated reading of different specimen types and culture mediums in their laboratories.

APAS patent

During March, LBT was notified of the successful receipt of a U.S. patent for our method of "colour calibrating" images captured by APAS – a critical feature for the classification of bacterial colonies and other microbial growth. This represents the first in a family of five patent applications to the U.S. Patent & Trademark Office, which will safeguard the APAS core technology over the long term.

At present, development of the integrated software and equipment is targeted to be completed by the end of 2015, with a potential global launch date in the first half of 2016.



Patti Doherty, Clinical Trial Coordinator (Albuquerque).



TriCore team, Albuquerque.

APAS distribution

Now that we have made significant progress in the FDA process, Clever Culture Systems is fast-tracking negotiations with potential global partners for the APAS technology. During March, senior managers held positive meetings in Europe with several potential distribution partners. Several key players have indicated that FDA approval represents a key milestone, and two companies have already completed feasibility studies or undertaken due diligence on the APAS technology.

While several competitors in the global market have plate-imaging technologies, the key point of difference with APAS – and its competitive advantage – is its ability to automatically discriminate between clinically significant and non-significant organisms. This allows for faster plate-reading, eliminates plates with no significant growth, and allows microbiologists to focus on the specimens that matter – all contributing to significant savings in time and laboratory efficiency.

Global culture plate volumes are estimated to be in the order of 2.1 billion annually, with APAS potentially addressing more than 50% of this market opportunity. With initial studies suggesting that LBT's technology could save microbiology labs up to 40% of their per-plate processing costs, the implications for lab owners are enormous. Important qualitative savings would also be generated from a reduction in time between plate incubation and the delivery of results to physicians – with clear implications for earlier diagnosis and treatment.

MicroStreak – PREVI® Isola / bioMérieux update

LBT announced on 12 January that it had received a Letter of Intent from bioMérieux regarding termination of our licence agreement for MicroStreak®, which is well established in the global marketplace as PREVI® Isola.

The termination of the agreement, which stems from bioMérieux's recently announced alliance with Italian microbiology company Copan, has raised a range of potential opportunities for LBT in respect of MicroStreak, which has already gained a worldwide reputation during its affiliation with the French company.

Negotiations are now well advanced with bioMérieux over termination of the licence agreement for MicroStreak, and the potential

continuation of support to customers of the PREVI Isola streaking instrument under a new licence. Details of a new agreement should be announced to the market in a matter of weeks.

LBT is guaranteed a royalty income from bioMérieux of at least US\$600,000 during 2015 and we are expecting this to be higher, with confirmation that the minimum royalty target was surpassed in 2014, with more than 400 instruments installed globally.

MicroStreak is well established in the global microbiology marketplace and we believe that the technology has a strong future in the growing laboratory automation sector. We will keep shareholders advised of all progress as it occurs.

Woundvue – Towards a new imaging revolution?

LBT's second prospective imaging technology, Woundvue®, continues to advance steadily towards development, with the enthusiastic support of medical professionals in the United States market. In recent months, the Company has enlisted the help of American nurses and clinical staff, as well as our computer imaging partners at the University of Adelaide, to 'prove up' the clinical needs and required features of Woundvue.

The conceptual model of Woundvue is a handheld device that offers simple, operator-friendly imaging, analysing and reporting on the status of chronic wounds, to assist nurses and clinicians in the delivery and monitoring of consistent treatment regimes.

Medical professionals in the U.S. as well as Australia have been enlisted in market surveys to evaluate practical clinical needs in a variety of wound care settings, as well as the physical and analytical capabilities that will be required to make Woundvue an important diagnostic tool.

The surveys are being funded with the first stage of a \$250,000 grant received late last year from the South Australian Government's bioscience agency, BioSA.

LBT is currently exploring several other avenues for funding the development of Woundvue, including a grant application to the Australian Government's Accelerating Commercialisation program, which offers grants of up to \$1 million to take high-potential products to market.

The Company is also advancing negotiations with a number of Australian technology companies that have expressed an interest in partnering with LBT on the next stage of this exciting journey.

IMPORTANT ANNOUNCEMENT

LBT shareholders will henceforth receive all newsletters and product news directly by email. If you have a preference for the email address we should use, please send it to us at info@lbtinnovations.com. All shareholder communications will also be available on the LBT website and via our social media channels.



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