

The Manager  
Company Announcements Office  
ASX Limited

## COMPANY UPDATE

**Adelaide, October 27, 2016:** LBT Innovations Limited (ASX: LBT) is pleased to release a company update presentation which accompanies this announcement. An abbreviated version will be presented by CEO and Managing Director of LBT Innovations, Brent Barnes at the annual AusBiotech Invest forum in Melbourne today.

### INVESTMENT HIGHLIGHTS

- Long-established company developing automated products using intelligent imaging and interpretive software to improve healthcare delivery;
- US FDA granted approval of proprietary APAS® software – October 2016;
- APAS® is a validated technology that represents a new level of intelligence in microbiology automation; no competitive product which “reads and interprets” plates;
- Significant interest in LBT due to FDA Announcement; growth stock being realised;
- Focus of attention is on completion of laboratory instruments to be integrated with APAS®;
- Joint Venture vehicle Clever Culture Systems in discussions with global diagnostics companies for the distribution and/or alliance partnership of APAS® product portfolio;
- APAS Independence first sale to occur in late 2017 with various milestones to be achieved and announced leading up to first sale;
- New CEO with global commercial experience.

CEO and Managing Director of LBT Innovations, Brent Barnes, said, “The approval this month by the US FDA of LBT’s proprietary APAS® software is the culmination of many years of hard work and innovation. It has repaid the faith of shareholders and laid a solid platform from which LBT can expand into the world’s biggest medical market.”

– ENDS –

### About LBT Innovations

About LBT Innovations LBT Innovations (LBT) is an Australian developer of clinical and diagnostic technology. Based in Adelaide, South Australia, the Company has two class-leading products in microbiology automation: MicroStreak®, which provides automated culture plate streaking and APAS®. 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 Clever Culture Systems AG (CCS) with Hettich AG Switzerland to drive the commercialisation of APAS® products. LBT also has a third product in early development, WoundVue®, a proposed automated 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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**LBT INNOVATIONS**

**ASX code: LBT**  
**lbtinnovations.com**

# **LBT Innovations Limited (ASX:LBT)**

## **Business Overview**

**Brent Barnes**

**Chief Executive Officer & Managing Director**

*October, 2016*

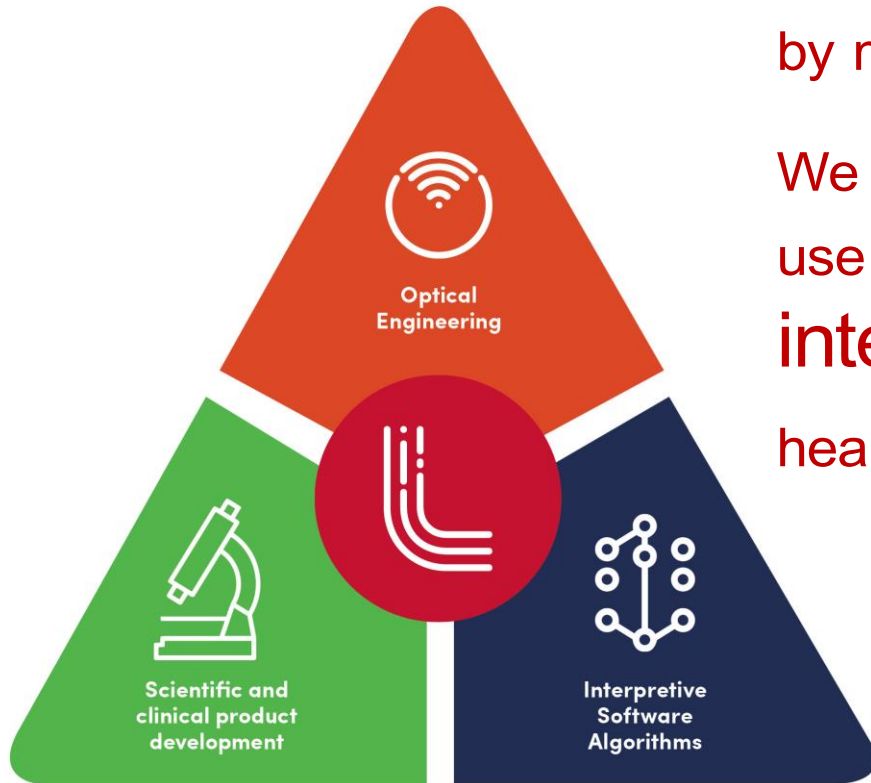
# Disclaimer

*This document contains certain forward-looking statements that involve risks and uncertainties. Although we believe that the expectations reflected in the forward-looking statements are reasonable at this time, we can give no assurance that these expectations will prove to be correct.*

*Given these uncertainties, readers are cautioned not to place undue reliance on any forward-looking statements. Actual results could differ materially from those anticipated in these forward-looking statements due to many important factors, risk and uncertainties including, without limitation, risks associated with medical device development and manufacture, risks inherent in the extensive regulatory approval processes mandated by regulatory authorities, delays in clinical trials, future capital needs, general economic uncertainty and other risks detailed from time to time in the Company's announcements to the ASX.*

*Moreover, there can be no assurance that others will not independently develop similar products or processes or design around patents owned or licensed by the Company, or that patents owned or licensed by the Company will provide meaningful protection or competitive advantages.*

# Our Purpose



LBT improve patient outcomes by making healthcare more efficient.

We develop automated products that use **intelligent imaging** and **interpretive software** to improve healthcare delivery.



# Our Business

LBT Innovations is a medical technology company that develops the latest **intelligent imaging** technology and **interpretive software** to improve the efficiency and quality of clinical diagnosis across a wide spectrum of healthcare applications. This benefits patients who can receive quicker and more reliable treatment so they can get back to full health faster.

Portfolio of products by LBT:

**Automated Plate Assessment System (APAS)** - a platform technology for the automation of culture plate **screening** and **interpretation**, currently being developed under a JV with Hettich AG Switzerland called Clever Culture Systems.

**Microstreak** - an automated microbiology system for streaking biological samples onto agar plates. MicroStreak was licensed to the French diagnostics company "BioMérieux", who sold it internationally as PREVI Isola.

**Woundvue** - a small, portable, hand-held imaging device with software embedded providing a proposed automation solution to assist in the management of chronic wounds. It is focussed on fast-growing chronic wound market.





# Key milestone 10<sup>th</sup> Oct, 2016: US FDA Grants Approval for LBT's APAS®



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ACN 107 670 673

## ASX/MEDIA RELEASE

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### US FDA GRANTS APPROVAL FOR LBT'S APAS®

- FDA clears APAS® imaging and software technology as a Class II medical device

**ADELAIDE, Australia, 10th October, 2016:** Clever Culture Systems AG (CCS), the Swiss based joint venture between Australian medical technology company LBT Innovations Limited (ASX: LBT) and Hettich AG (Switzerland) has received clearance of its 510(k) *de novo* submission to the US Food and Drug Administration (FDA) for APAS® as a Class II medical device.

APAS® (Automated Plate Assessment System) is a breakthrough artificial intelligence technology for the automated imaging, image analysis, interpretation and reporting of growth on microbiology culture plates after incubation. APAS® enables the faster diagnosis and reporting of infectious diseases.

Developed by LBT Innovations, APAS® has been licensed on a global, exclusive basis to CCS, which is integrating APAS with laboratory robotic instrumentation. CCS is targeting to bring APAS to market in 2017 as an automated stand-alone plate reader (APAS® Independence) followed by the integrated incubator (APAS® Incubot).

The 510(k) *de novo* submission used a manual version of APAS to test 10,000 patients in a series of clinical trials conducted in Australia and the US over a 12-month period. In each trial, APAS achieved its target primary endpoints and the results matched or exceeded the findings of a panel of experienced microbiologists.



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Slide No. 4

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# Current Focus – Commercialisation of APAS

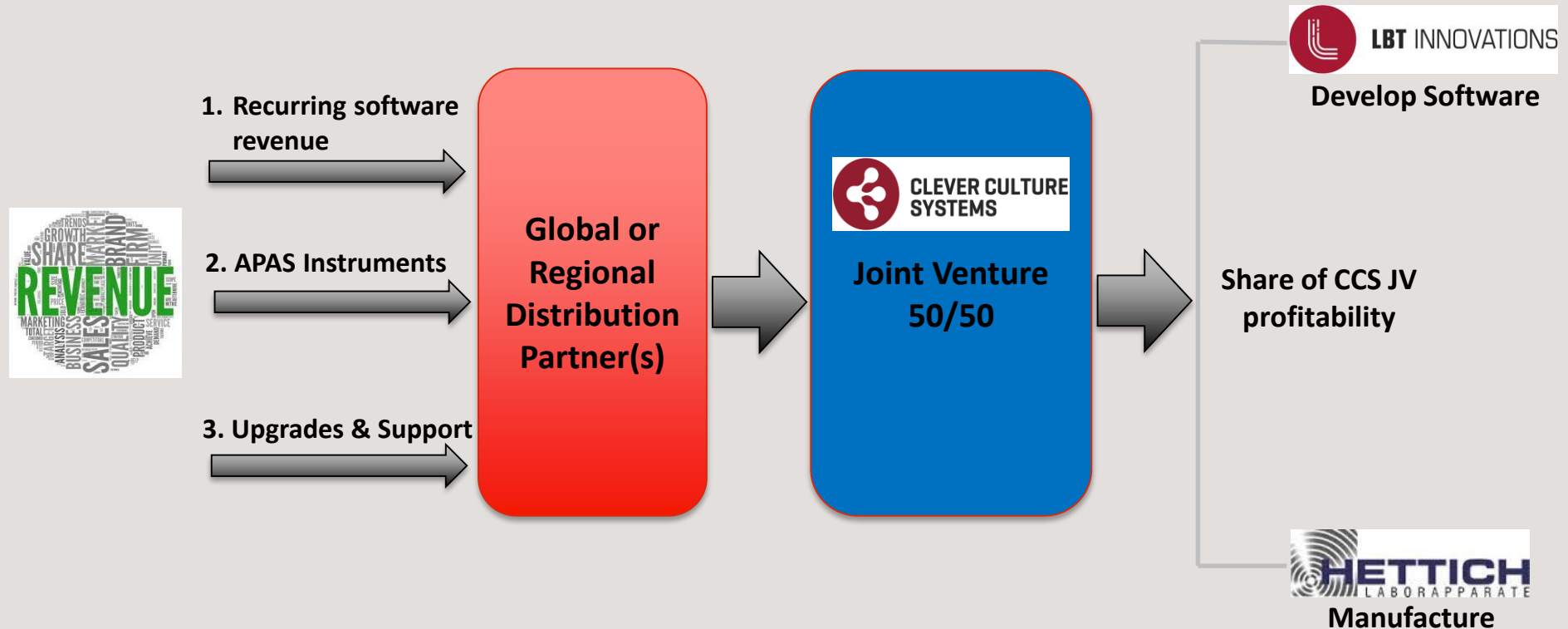
## Current Status

- The focus of attention is on completion of laboratory instruments to be integrated with APAS
  - Commercial version of **APAS Independence** will be available within the next 12 months, and expected ready for sale late 2017 following in-lab trials;
  - Design processes under way for second product- **APAS Incubot** an automated incubator and plate reader;
  - LBT Innovations intends to produce the APAS software plug-ins for both instruments.
- In discussions with a international diagnostic companies to form a marketing and distribution alliance;
- Early stage development now underway for further line extensions up and down the microbiology culture plate work flow process.

**APAS Independence first sale, late 2017.  
Incubator stock transitioning into becoming a growth stock.**



# Revenue Model: APAS<sup>®</sup> Joint Venture Structure



LBT future revenue streams from share of supply of annual software income plus share of profitability of CCS including any license fees.



# APAS Product Overview -

## Primary competitive advantage through **Intelligent** Imaging



### **APAS Independence prototype – demonstrated at conferences:**

European Congress of Clinical Microbiology and Infectious Diseases, April 2016

American Society of Microbiology, June 2016

### Features

- At least **3 times** more efficient than manual plate reading;
- Expect to be **first to market** with Intelligent Imaging;
- Modular design easily integrated into culture plate work flow;
- More affordable stepwise entry into Lab automation.

### Opportunity

- APAS targets small, medium and large laboratories, offering modular approach;
- **~27,000+** laboratories globally in this target segment.

# APAS Automation: Manual Microbiology Culture Plate Process Flow

## Process Steps for Culture Plate Flow

Culture Plate  
Streaking

Incubate

Plate  
Reading

Identification &  
antibiotic  
sensitivity testing

Products that  
automate  
manual steps

APAS  
Independence  
H2 2017

1

APAS Incubot  
2018

2

Potential APAS Line Extensions  
Timing dependent on product prioritisation

3



# Microbiology Competitive Overview



Laboratory Size	Plates Processed Per Day	Number Laboratories Globally	APAS Product Portfolio	Current Microbiology Automation
Small	< 400	15,000	✓	
Medium	400 - 1000	12,000	✓	Inoqula, WASP
Large	> 1,000	400	✓	Kiestra, WASPLab, WASP

**No competitive product which “reads and interprets” plates.**

**APAS brings to bear a new level of **Intelligence** into microbiology automation via culture plate **reading** and **Interpretation****



# Engineering & Manufacturing Partners

## Hettich



- 100 year old family business based in Tuttlingen, Germany;
- Established leader in centrifuge design and manufacturing
  - ~40,000 centrifuge devices made per year.
- Developed an automated incubator, to be integrated as part of the APAS Incubator.



## Planet Innovation



- Formed in 2009, Melbourne based, excellent track record
- Product Development and commercialisation focusing on biomedical and hi-tech industries
- CCS partner for APAS Development.

# LBT IP Position and APAS Licensing to CCS JV

- Core IP owned by LBT with 4 patent families approved or in process in Australia, Japan, USA, China, Europe, India, South Korea.
- APAS core technology (imaging application and interpretive software) exclusively licensed to the CCS JV covering the specific use in microbiology culture plates.
- LBT retains full IP rights into all other Healthcare opportunities such as Woundvue for the Intelligent Imaging Platform

# APAS Regulatory Strategy

- 510(k) de novo approval for ASPAS Compact – Manual version.
- TGA & CE Marking will utilise existing trial data plus instrumentation validation data- self certifying.
- APAS Independence and Incubot will require a 510(k) Supplement filings linked to the original 510(k) de novo approval.
- Further 510(k) approvals also required as indications for use are expanded.
- Global launch strategy: dependent on discussions with Global Diagnostic Partner. With FDA Approval, all options are available.





# Other Key Areas of Focus

## Intelligent Imaging Platform – New product Stream

- Woundvue product progressing through research development following market survey:
  - Positive results from important US market survey;
  - Reimbursement process being carefully assessed;
  - Prototype development to be completed in Q2, 2017.
- Several other Healthcare product opportunities being evaluated.

## Organisational capability

- Recruitment of new CEO complete;
- Continuing to leverage Lusia Guthrie through role as Chairman for CCS JV.



# Financials – Year Ended June 2016

<u>Profit &amp; Loss</u>	Year Ending June 15	Year Ending June 16
<b>Revenue</b>	\$ 2,367	\$ 7,726
Including License Fees, Upfronts & Milestones	\$ 1,000	\$ -
MicroStreak license fee renegotiation	\$ 846	\$ 7.52
Net Profit/(Loss) before tax	-\$ 336	\$ 4,120
Net Profit/(Loss) after tax	\$ 549	\$ 3,541
Basic EPS (cents)	0.28	3.08
<b><u>Balance Sheet</u></b>		
Cash Position	\$ 1,818	\$ 4,684
Accounts Receivable	\$ 838	\$ 525
R&D tax concession receivable	\$ 1,825	\$ 1,331
Intangible assets MicroStreak & APAS		
Development Costs	\$ 16,868	\$ 20,583
Shares on issue (millions)	114.723	114.988
Options on issue (missions)	2.60	3.20

## **Key Driver in 2015/16**

Renegotiation of MicroStreak license with bioMerieux A\$7.5 million

## **Future Direction**

- Building recurring product revenue stream via APAS and its line extensions;
- Relicense or sale of MicroStreak;
- New product direction building off Intelligent Imaging Platform.

## **September Quarterly 2016 Appendix 4C**

- Cash at end of September 2016 \$2.34 million;
- R&D tax claim submitted with a refund estimated at \$1.1m;
- Options exercised in October has raised an additional \$0.45m cash.

# Anticipated news flow 2016 - 2017

Date	Category	News details
2016	Joint Venture CCS	Observations on Variations in Manual Reading of Cultures, published in Journal of Clinical Microbiology
	Joint Venture CCS	Letter of Intent with global diagnostics company for APAS®
	Imaging Platform	Evaluation of further clinical applications for product pipeline
2017	Joint Venture CCS	Signing of alliance/distribution agreement with global partner(s) for APAS®
	Joint Venture CCS	Market acceptance testing of APAS® lab instruments
	Joint Venture CCS	APAS Product on display at European Congress of Clinical Microbiology and Infectious Diseases in Vienna, Austria (22-25 Apr, 2017)
	MicroStreak®	Signing of license or sale agreement with new partner
	Joint Venture CCS	APAS Independence® first commercial sale by global alliance partner
	Imaging Platform	Woundvue® prototype complete.



# LBT Investor Summary October 2016



## Key Statistics

Code	ASX:LBT
Listed	ASX 2006
Current Price (12 October 2016)	58.0 cents
52 Week High (12 October 2016)	95.0 cents
52 Week Low (12 October 2016)	9.5 cents
Shares Outstanding (12 October 2016)	115.04 million
Market Cap (12 October 2016)	A\$66.72 million
Net Cash (30 June 2016)	A\$4.68 million
Directors and Senior Management (12 October 2016)	9.0%

- Significant interest in LBT due to FDA Announcement;
- High liquidity;
- Growth stock being realised.



# Questions?



**LBT INNOVATIONS**

## **Brent Barnes**

Chief Executive Officer & Managing Director

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# Incoming CEO and Managing Director

- Started 8<sup>th</sup> August, 2016 and Adelaide based;
- Previously Senior Executive with Cochlear Limited (ASX: COH);
  - 11 Years at Cochlear;
  - 4 years based in USA;
  - 4 years Asia Pacific;
  - Global Commercial experience.
- Masters of Project Management (University of Adelaide);
- Graduate of Australian Institute of Company Directors.



**Brent Barnes**  
LBT Innovations Chief Executive Officer



# LBT Directors



**ROBERT FINDER**  
CHAIRMAN

Bob Finder has more than 35 years' experience in the international pharmaceutical and chemical industries. He recently retired as Chief Executive Officer of Novozymes GroPep Limited.



**BRENT BARNES**  
CHIEF EXECUTIVE OFFICE AND  
MANAGING DIRECTOR

After beginning his career with global defence contractor Thales, Brent spent 11 years gaining broad Senior Executive experience in a variety of roles with Australian medical device manufacturer Cochlea...



**CATHERINE COSTELLO**  
NON-EXECUTIVE DIRECTOR

Kate Costello was in management with a commercial law firm before establishing a management consultancy specialising in corporate governance practices and board performance.



**STEPHEN MATHWIN**  
NON-EXECUTIVE DIRECTOR

Stephen Mathwin has more than 30 years' experience as a legal practitioner, including being a partner with the Adelaide law firm, Kelly & Co, from 1988 to 2001, and currently remains a consultant.



**CAROLINE POPPER**  
NON-EXECUTIVE DIRECTOR

Caroline Popper is a US-based pathologist and business consultant, with more than 20 years' operational experience in the international diagnostics.



**DANIEL HILL**  
CFO & COMPANY SECRETARY

Dan has worked as a director, CFO or company secretary for a variety of companies in the construction, technology and financial services sectors.

