Advanced Molecular Diagnostic Systems

1 Dalmore Drive,
Scoresby,
Victoria 3179
AUSTRALIA
T: +61 (0)3 9763-1287
F: +61 (0)3 9763-2817
www.generabiosystems.com

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ASX Announcement – GENERA BIOSYSTEMS LIMITED (ASX: GBI)
BECKMAN COULTER DISTRIBUTION AGREEMENT

Genera Biosystems Limited (‘**Genera’**) is pleased to provide the following Joint Press Release announcing a Distribution Agreement with Beckman Coulter.

For further information please contact:

Mr Richard Hannebery
Chief Executive Officer
Genera Biosystems Limited
Telephone: +61 (0)3 9763 1287
www.generabiosystems.com.au

About Genera Biosystems : Genera Biosystems Limited (“GBI”) is an Australian Securities Exchange listed molecular diagnostics company, which develops, manufactures and distributes advanced PCR molecular diagnostics tests.

Genera’s single-well high multiplex AmpaSand® testing platform can detect up to 125 target analytes in a single-well of a reaction plate. Unlike traditional real-time PCR approaches, AmpaSand® single-well multiplex tests when run on a seamlessly integrated flow cytometry and liquid handling system can provide unparalleled throughput capability and cost efficiency for high volume pathology laboratories qualitative molecular testing needs.[1]

Genera manufactures products in its Australian Therapeutics Goods Administration certified manufacturing facility in Scoresby, Victoria, Australia.

[1] All ‘plate based’ Real Time PCR platforms can ‘multiplex’ up to 4 targets per well assuming 4 available channels of a Real Time PCR instrument. To multiplex greater than 4 target analytes in a test most platforms require use of additional wells of a plate to test for the additional target analytes. As such commercially, their multiplexing capability is restricted due to a direct trade-off with volume throughput per plate (96 or 384 well). Genera’s AmpaSand® technology facilitates the multiplexing of up to ~125 target analytes **in a single-well** of a plate. On a like for like basis depending on the number of target analytes detected in a multiplex assay Genera’s AmpaSand® technology facilities > 4X relative volume throughput. High volume throughput is a key commercial consideration for all large pathology labs undertaking HPV and STI testing.

PapType®, an ARTG listed and CE-marked MDx test, simultaneously detects and identifies 14 high-risk types of HPV and 2 low risk HPV types in a single-well. These high-risk HPV types are responsible for 99.7% of all cases of cervical cancer.

In addition to PapType®, Genera has also commercialized and gained ARTG listing and CE mark for RTIplex™, a single-well multiplex MDx that identifies 15 common upper respiratory tract pathogens, including Influenza A & B, as well as 10 other viral and 3 bacterial disease-causing microbial targets.

Genera's development pipeline includes a new 8-plex sexually transmitted infections panel that is expected to be available in the 2nd half of 2018, with plans to broaden the AmpaSand® test menu further to 6 highly competitive single-well multiplex MDx assays by 2019.

PapType®, RTIplex™, and the tests in development, employ the AmpaSand® biochemistry as well as Genera's proprietary ARTG listed and CE-IVD marked QPlots™ automated analytical and reporting software that is compatible with most Laboratory Information Management Systems ('LIMS') .

All the components of the Genera MDx system, including AmpaSand® and QPlots™, have been optimized to run on Beckman Coulter's innovative CytoFLEX™ flow cytometry system.

INDIANAPOLIS, USA and MELBOURNE, AUSTRALIA – (May 8th, 2018) – Beckman Coulter Life Sciences, a leader in the fields of automation and flow cytometry, and Genera Biosystems Limited ("Genera"; ASX: "GBI"), an Australian molecular diagnostics ("MDx") company, announced today that they have entered into a distribution agreement.

This replaces the December 2017 announcement, made concerning a proposed co-marketing partnership between the parties.

Richard Hannebery, Chief Executive Officer of Genera said, "We are pleased to enter into this distribution agreement with Beckman Coulter Life Sciences. We see enormous commercial opportunity for a broad, affordable test menu that will be able to be run with a highly automated workflow incorporating CytoFLEX™ technology. The integrated system will benefit prospective customers looking for faster throughput and improved workflows for their laboratory processing."

Mr Hannebery added, "The agreement will provide Genera customers a best of breed high throughput automated instrumentation solution capable of walkaway sample-to-results post PCR.[1] A lower throughput solution will also be offered to customers, incorporating an on-deck PCR allowing walkaway sample-to-results post DNA/RNA extraction."

Matthew Grigg, Commercial Director of Beckman Coulter, Australia, New Zealand and Rest of Asia said, "A key objective of pathology laboratories is to improve workflow and lab throughput capacity and we are excited to enter into this agreement with Genera and equally, we see great commercial opportunity."

Under the terms of the agreement the initial launch will be in Australia and New Zealand with an intention to expand into additional territories subject to relevant local regulatory requirements. In providing low cost, high multiplex target analysis in a single-well, Genera believes that its AmpaSand® assays are uniquely placed within the medical diagnostics market in terms of competiveness in a number of significant emerging markets. Due to prevailing pricing parameters in MDx these markets are currently under-penetrated because of socio-economic factors and limited healthcare budgets that result in a lack of wide-spread reimbursement from both public and private payors.

Dr Mario Koksch, Vice President and General Manager of Beckman Coulter's Cytometry Business Unit said, "Flow cytometry is a powerful tool for the detailed and fast analysis of complex populations. We are delighted that Genera has chosen CytoFLEX™ technology and are excited by the opportunity this distribution agreement will provide Genera customers when coupled with our leading instrumentation solutions."

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[1] *Not available for sale in the US, except in circumstances for Research Use Only ("RUO") under which assays and instrumentation are validated and performed under relevant CLIA guidelines.*

The fully enclosed high throughput system will seamlessly integrate the CytoFLEX™ technology with Beckman Coulter's next generation automation system, the Biomek™ i-Series platform.[2]

Beckman Coulter has a solid market position as an equipment supplier of choice for many of the customers that Genera is targeting. As part of the distribution agreement Genera will support focused strategic sales to facilitate an expanding global presence. The initial Australasian launch will be supported by Genera's current management with 2 regional sales application specialists to be hired in the second half of CY2018.

Genera intends to provide AmpaSand® based assays to customers under reagent rental agreements. The structure of the distribution agreement will allow instrumentation placements to be scaled in a capital light manner helping Genera to optimize its return on invested capital and free cash flow generation.

Each high throughput system will have a capacity of approximately 140,000 tests per annum. The minimum target customer volume will be between 15 and 20% of this capacity. Further planned menu expansion will increase the likely addressable customer base and should aid test sales velocity in driving maximum capacity utilization for pathology customers.

********** **ENDS** **********

[2] *CytoFLEX is Research Use Only, Not Intended for Diagnostic Purposes. Class I laser product.* Based upon *CytoFLEX* technology Beckman Coulter also offers in selected jurisdictions, the *DxFLEX,* an IVD approved clinical cytometer. The Biomek i-Series automated workstation *is Research Use Only, Not Intended for Diagnostic Purposes.*

Beckman Coulter instrumentation systems will be supplied on a *Research Use Only* basis until integrated systems receive required IVD approval according to market regulations in relevant jurisdictions. There is no guarantee when the integrated systems shall receive relevant IVD approval, if at all.

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