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ASX Announcement – GENERA BIOSYSTEMS LIMITED (ASX: GBI) CO-MARKETING PARTNERSHIP WITH BECKMAN COULTER

**MELBOURNE, AUSTRALIA** – **(6 December 2017)** – 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 will enter into a comarketing partnership.

The commercial partnership brings together the power and capabilities of high content flow cytometry, liquid handling automation and high multiplex MDx testing in a single streamlined workflow. As part of the agreement, Beckman Coulter will provide integrated flow cytometry based upon CytoFLEX™ technology to its next generation automation system − the Biomek™ i-Series platform. The system will empower scaled up throughput for multiplex AmpaSand® MDx assays supplied by Genera.

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. This partnership will enable Genera's single-well AmpaSand® MDx assays to meet the needs of pathology laboratories in Australia first and followed by an expansion into other countries. These integrated solutions incorporate Beckman Coulter's technical instrumentation excellence."

Genera's 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 early 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.\*\*

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. When this technique is utilized with Genera's novel AmpaSand® testing technology it also enables unparalleled multiplexing of molecular assays in a single-well. We are delighted that Genera has chosen CytoFLEX™ technology and are excited by the opportunity this partnership will provide AmpaSand® assay customers when coupled with our leading instrumentation solutions."

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.

Demaris Mills, Vice President and General Manager of Beckman Coulter's Automation Business Unit added, "The Biomek i-Series platform is designed to enable continuous innovation to help our customers meet their goals by delivering improved levels of simplicity, efficiency, adaptability, reliability and throughput. Our ability to deliver enhanced throughput is particularly relevant to pathology laboratories utilizing AmpaSand® based assays."

Richard Hannebery, CEO of Genera said, "Over the last three years we have developed a close collaboration with the Beckman Coulter Life Science team and formalization of this commercial partnership now provides the basis for a launch of AmpaSand® MDx assays. Genera's significant voice-of-customer feedback over recent years saw us focus on finding the best integrated instrumentation solution for high volume pathology laboratories. We believe the solution to be provided by Beckman Coulter will deliver on all fronts."

Mr Hannebery added, "Beckman Coulter has a leading market position as the equipment supplier of choice for many of the pathology customers that Genera is targeting. As part of the co-marketing partnership Genera is pleased to be able to support focused strategic sales to facilitate an expanding global presence. For its part, Beckman Coulter will implement and support the instrumentation placements running Genera's multiplexed MDx test menu."

A strategic roadmap has been developed for the staged release of products starting in Australia and then expanding in other geographies.

Through this partnership Genera Biosystems and Beckman Coulter intend to provide a solution to customers that can:

- Reduce manual preparation and analysis time for the validated AmpaSand® MDx tests;
- Increase throughput while retaining reliability of results;
- Enable the flexibility required for expansion of Genera's MDx test menu over time; and
- Empower pathology providers to deliver price competitive, high throughput, multiplexed MDx tests with the support of a major international player with decades of experience in supply of instrumentation and reagents for the pathology market.



## Notes:

Genera Biosystems' PapType® and RTIplex<sup>TM</sup> assays hold ARTG listing and CE-IVD mark as does  $QPlots^{TM}$  clinical reporting software.

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.

- \* ARTG = Australian Register of Therapeutic Goods
- \*\* CytoFLEX is Research Use Only, Not Intended for Diagnostic Purposes. Class I laser product.

## **Beckman Coulter Life Sciences**

For Beckman Coulter's worldwide office locations and phone numbers, please visit www.beckmancoulter.com/contact





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**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 has successfully developed two products to date, PapType® and



RTI-Plex™, both of which are CE-IVD approved with several additional products in the company's development pipeline.

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.

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