

**Monday 3 October 2016**

**ASX Announcement – GENERA BIOSYSTEMS LIMITED (ASX: GBI)  
2016 ANNUAL REPORT HIGHLIGHTS**

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Genera Biosystems Limited (**'Genera'**) is pleased to present its Final Report for the financial year ended 30 June 2016.

Genera continued to grow AmpaSand<sup>®</sup> product sales with revenue increasing to \$615,750 up 66.2% on the previous corresponding period. Other income of \$734,170 relates to the accrued benefit of Genera's 2016 R&D tax incentive rebate. This receivable is currently anticipated to be received by Genera late in H1 of the current financial year. Subsequent to 30 June, and to the date of this report a further \$255,200 of RTIplex<sup>™</sup> product sales have been made by the company. Subject to product demand from the commencement of the Indian flu season (November) the Company may surpass full year 2016 sales during the December quarter.

The company reported a net loss of \$3,084,077, compared to a net loss of \$2,789,474 in the previous year, largely reflecting an increase of \$552,954 in laboratory expenses due to an increase in R&D and clinical trials activity while depreciation expenses increased by \$99,557 to \$700,229 due to an increase in instrumentation systems acquired. Also contributing to the increased loss was a slight increase in notional 'non-cash' financing costs from the \$2.5m Series B convertible notes issued during 2015 which were on issue for the full 12 month period. No cash interest is payable on the Series B notes in the event that they are converted into ordinary shares.

Cash used in operating activities increased to (\$1,368,218) up 43.1% compared to (\$956,932) in the previous year. The company ended the year with cash of \$66,635 and currently has a cash balance of \$129,360, with the Company expecting positive operational cashflow in the current quarter<sup>1</sup>.

Genera's AmpaSand<sup>®</sup> multiplexing molecular diagnostic platform continues to prove itself to be world class and it is a genuine multiplexing platform for plate based assays, the most common format for high throughput molecular diagnostics (MDx) assays used by pathology laboratories. With AmpaSand<sup>®</sup>, 1 well of a plate can deliver 1 multiplexed assay testing for between 5 and 150 targets from a single sample, performance characteristics which no Real-Time PCR approach can match.

Operating highlights for the financial year and to the date of this report include:

- Record and continuing strong RTIplex<sup>™</sup> assay sales growth;
- Successful introduction of new CytoFLEX<sup>™</sup> instrumentation system manufactured and supported by Beckman Coulter;
- New enzymes utilized in Genera's tests allowing for improved commercial use by materially cutting run times of AmpaSand<sup>®</sup> based assays;

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<sup>1</sup> Excluding current trade payables which were \$514,290 at 30 September.

- successful release of AmpaSand® Version 2.1 – reduces single plate run-time below 5 hours and daily throughput > 500 samples;
- Importation and sale license approval of RTIplex™ in India which allows for approved IVD sales of RTIplex™ pan India with license in force for a term of 3 years;
- Scale-up program to deliver 5-fold increase in Scoresby manufacturing capacity well advanced and on track for end of calendar 2016 implementation - ~5m tests per annum;
- The grant of 9 additional patents – Genera now holds a portfolio of approximately 80 granted patents with a further 25 patents pending and new intellectual property continuing to be developed;
  - US *Solid phase* PCR patent recently granted which protects the revised version of PapType®, RTIplex™, STIplex™ and all other AmpaSand® based tests developed and sold by Genera (expiry ~2028);
  - Final cornerstone QSand™ US patent granted;
- AmpaSand® Version 3.0 advanced and scheduled for release Q4 calendar 2017 – may reduce sample preparation time by 70% and decrease customer reagent costs used in DNA/RNA preparation by over 60% compared to currently available methods;
- New 384-well plate format to be introduced delivering 3.8x increase in volume throughput and scheduled for release Q3 calendar 2017;
- STIplex™ development further advanced, release due Q2 calendar 2017 to coincide with significant market launch of PapType®
- May 1<sup>st</sup> 2017 HPV testing replaces the traditional Pap smear as the front line screening diagnostic test in Australia;
  - Genera confident of entering into major new commercial supply agreement(s) with domestic pathology customers to leverage Genera’s unique market offering;
- BBVplex™ development further advanced and Aneuploidy screening assay for IVF development recommenced;
- Data from 2,025 US screening population evaluation for PapType HPV test received
  - First independent study of PapType® utilizing the Beckman Coulter CytoFLEX™ instrumentation;
  - Performance consistent with prior studies in both ASCUS referral and screening populations in detecting CIN2+;
  - Data showed sensitive detection of CIN2+ and CIN3+ representing the *strongest performance* of PapType in an independent clinical study to date;
- PapType® now has independent clinical performance data from Australia, the UK and the US involving six different studies utilising approximately 11,000 clinical patient samples;
- Additional PapType® ~6,650 patient study at Wolfson Institute (UK) also utilising the CytoFLEX™ instrumentation – study well underway with data due November 2016;
- Scientific Advisory Board re-established constituting leading *global* key opinion leaders in HPV screening from Australia, the UK and potentially the US; and
- Identification of a preferred instrumentation partner for a proposed global partnering deal. Genera believes it has selected a partner that offers a platform with clear advantages over competitors in terms of price, performance and versatility with which to marry our high value AmpaSand® molecular diagnostic tests.

Genera Chief Executive Officer, Richard Hannebery said, “There is no doubt that the past 12 months has been the most productive year in Genera’s history with a lot of things which have been planned for a long period of time slotting nicely into place. This is the result of the hard work of our small but highly capable team executing our clear plan. The foundation is now laid and with some further well-considered execution, and some more hard work, the Genera team looks forward to delivering the outstanding outcome that our shareholders deserve.”

***Please note, an amended and corrected version of Genera’s 2016 Financial Report has been lodged with the ASX Monday 3 October 2016.***

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For further information please contact:

Mr Richard Hannebery  
Chief Executive Officer  
Genera Biosystems Limited  
Telephone: +61 (0)3 9763 1287  
[www.generabiosystems.com.au](http://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. GBI has successfully developed two products to date, PapType® and RTIPlex™, both of which are CE-IVD approved with several additional products in the company’s development pipeline. Genera manufactures these products in its Therapeutics Goods Administration (TGA) certified manufacturing facility in Scoresby, Victoria, Australia.