

**Monday 2 October 2017**

**ASX Announcement – GENERA BIOSYSTEMS LIMITED (ASX: GBI)  
2017 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 2017.

Genera continued to grow AmpaSand® product sales with revenue increasing to \$800,800 **up 31.1%** on the previous corresponding period ('pcp'). Other income of \$500,939 relates to the accrued benefit of Genera's 2017 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 \$435,000 of AmpaSand® product sales have been made by the Company, **~55% higher** than the pcp.

The company reported a net loss of \$3,087,778, compared to a net loss of \$3,084,077 in the previous year, largely reflecting increased notional 'non-cash' financing costs from the \$3.0m Series B convertible notes on issue and higher gross margin contribution from Respiratory panel sales and lower operating costs. 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 declined to (\$765,591) **down 44.0%** compared to (\$1,368,218) in the previous year. The Company ended the year with cash of \$219,967 and generated positive normalised operating cash in the September quarter, largely due to record respiratory panel sales volumes stemming from high seasonal 'flu' infection rates. It is currently anticipated that these strong operating cash inflows will continue through to the end of November by which time we also anticipate receipt of our annual R&D tax incentive rebate that is currently expected to be approximately \$500,000.

Genera's AmpaSand® multiplexing molecular diagnostic platform continues to prove itself to be world class and is a genuine multiplexing platform for plate based assays which are the most common format for high throughput MDx assays used by pathology laboratories. With AmpaSand®, 1 well of a plate can deliver 1 multiplexed assay testing for between 5 and ~125 targets from a single sample, performance characteristics which no Real-Time PCR approach can match. Genera's high degree of multiplexing **in a single-well** also delivers materially lower cost of goods when compared to other competing multiplexing approaches.

Operating highlights for the 2017 financial year through to today's date that are discussed in greater detail in the Annual Report include:

- Record and continuing strong RTIplex™ assay sales growth.
- Scale-up program to deliver 5-fold increase in Scoresby manufacturing capacity on track for calendar 2018 implementation.
- Comprehensive audit of Genera's manufacturing facilities undertaken by TGA with audit successfully closed and TGA records being updated to show a final compliance facility rating of A1;

- next re-audit of Genera's manufacturing facility is expected to be performed by the TGA by June 2019.
- The grant of 6 additional patents – Genera now holds a portfolio of 83 granted patents with a further 27 patents pending and new intellectual property continuing to be developed.
  - Final QSand™ portfolio patents granted in India and Brazil adding to successful prosecution of patent grants in the US, Australia, NZ, Canada, China, Mexico and the European Community;
  - Cathedral Biosensors to seek independent funding to commercialise next generation QSand™ technology;
  - RTIplex™ patents commencing grant in major jurisdictions.
- New AmpaSand® enzymes on track to reduce existing PCR run times by ~50% with Genera to enter into attractive Value Added Reseller agreement with global IVD enzyme provider.
- STIplex™ (8 plex) development further advanced, due for RUO release late Q1 calendar 2018 to coincide with new automated instrumentation release.
- Identification of two commercially attractive options providing highly automated instrumentation system that provide unprecedented operator workflow benefits and testing volume throughput capacity for Genera customers:
  - Includes random access for additional plate loading mid-run allowing significant operator workflow benefits and the automated run of additional plates;
  - New instrumentation systems can be well supported in the aftermarket globally without Genera having to add material in-market support resources.
- Throughput on the new automated instrumentation systems able to yield testing volumes in excess of greater than 600 tests per day on a single system:
  - Depending on whether PapType® was run as a 'reflex' or a screening test, operation by prospective pathology customers at such capacity volumes may yield between \$2.0 and \$3.2 million per annum in revenues to Genera per system placement.
- December 1<sup>st</sup> 2017 HPV testing replaces the traditional Pap smear as the front line screening diagnostic test:
  - Australian HPV screening testing volumes to increase from ~55,000 tests per annum to 1,300,000 plus additional ~200,000 test per annum HPV reflex genotyping addressable market;
  - Genera confident of entering into major new commercial supply agreement(s) with domestic pathology customers to leverage Genera's unique market offering.
- BBVplex™ (5 plex) development further advanced.
- Aneuploidy screening assay (~25 plex) for IVF development reinvigorated
  - Estimated cost similar to other AmpaSand® tests with revenue opportunity per test 10 to 20X that of PapType®.
- PapType® now has independent clinical performance data from Australia, the UK and the US involving seven different studies utilising approximately ~17,500 clinical patient samples run on multiple models of flow cytometer analysers.
- Genera currently in the advanced stages of determining its optimal IVD partner route and is on track to announce the outcome of its well-considered process around the time of its 2017 AGM.
- Specialist US Investment bank engaged to raise US\$8.0m in expansion capital via Series C Preferred Share Issuance with completion subsequent to global IVD partnership announcement.

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**About Genera Biosystems:** Genera Biosystems Limited (“GBI”) is an Australian Stock 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 RTI-Plex™, 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.