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)
QUARTERLY CASH FLOW & BUSINESS UPDATE

Genera Biosystems Limited (‘**Genera’**) is pleased to provide an update to accompany the attached Appendix 4C Quarterly Cash Flow report for the period ended 30 September 2016.

The company held cash at end of quarter of $129k representing a net increase of $65k during the period.

Cash receipts from customers for the quarter amounted to $282k which were up 122.9% on the June quarter and 84.1% versus the previous corresponding period.

The company has enjoyed record order levels from its major customer for its research use only RTIplex respiratory panel test and continues to experience solid volume even as the peak southern hemisphere flu season tapers. Genera currently anticipates that with the imminent commencement of the Indian flu season our respiratory franchise is well placed to become less seasonal with cash receipts from India anticipated to peak in the March quarter.

Genera expects to receive approximately $740k from its FY2016 ATO R&D tax incentive rebate during the current December quarter.

Current Capital Raising

The Company has previously announced to ASX in its Annual Report that it anticipates redeeming all existing Convertible Notes alongside the $1.0 million mezzanine loan facility during November to be financed largely by an issue of Series C Convertible Notes redeemable December 2018 and partially by way of an issue of Ordinary Shares.

With respect to the outstanding Series B Convertible Notes holders may elect within 10 business days to convert all or part thereof of their Series B Convertible Notes upon the Notes being called by the Company for redemption. The conversion price of the Series B Convertible Notes is $0.23 per Ordinary Share. The ultimate level of voluntary conversion of Series B Convertible Notes by holders will affect the size of the proposed issue of Ordinary Shares.

Genera currently anticipates closing the Series C financing round contemporaneous to new commercial pathology supply agreement(s) in the coming few weeks and in any event prior to Genera’s scheduled AGM to be held on Thursday 24 November.

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Pathology Supply Agreement(s) for 2017

The Company currently anticipates that ultimate timing of the proposed financing round will be determined by material supply agreement(s) that it is seeking to enter into with Australian pathology customer(s) primarily in relation to the Company's PapType® HPV genotyping HPV test and its proposed sexually transmitted infections multiplex test (STIplex).

The Company remains cautiously optimistic that as a result of a broader portfolio supply of its diagnostic tests that may be made under these commercial agreement(s) Genera is well positioned to deliver its maiden operational cash flow positive result over the first full 12 month operating period.

PapType® uniquely positioned in 2017

One of Genera's proposed pathology partners recently completed an internal clinical validation demonstrating the performance of PapType® against the gold standard Qiagen HC2 HPV test during the quarter.

The Company believes that its PapType® HPV test is very well placed in the market with the introduction of the new cervical screening regime commencing in May 2017. The new cervical screening algorithm requires simultaneous genotyping of HPV types 16 & 18 that cause 70% of cervical cancer incidence. Genera's proprietary PapType® HPV test goes beyond this and simultaneously genotypes 14 HPV types responsible for 99.7% of cervical cancer incidence.

A short video outlining the benefits of Genera's PapType® HPV test can be viewed at http://generabiosystems.com/videos/

A key element of PapType®'s positioning in the Australian market will be as a multi-functional HPV test applicable providing compliance with the newly adopted Australian cervical screening algorithm and as a full reflex genotyping test.[1] Genera aims to achieve a successful listing of PapType® on the Medicare Benefits Schedule as a compliant screening test by April 2017.

Delivery of new PapType® clinical data in US Screening population

In early October Genera advised the ASX that it has received the results from over 2,000 cervical screening specimens collected in a United States-based screening population. The evaluation was undertaken by the University of New Mexico, Health Sciences Center – School of Medicine, Department of Pathology, ('UNMHSC'). This was the first independent clinical study Genera has undertaken with PapType® running on the Beckman Coulter CytoFLEX™ instrument.

Genera received under confidentiality data from UNMHSC as well as an analysis on the data set performed by Prof. Jack Cuzick's group at the Wolfson Institute of Preventive Medicine (London, UK).

[1] PapType's applicability as a screening assay will be determined by submission and acceptance of by MSAC of Meijer compliant clinical data in screening populations. Genera plans to lodge pre-application submission documentation with MSAC by 10 November 2016 with goal of full submission being made to MSAC in early 2017. PapType is currently listed on the ARTG and may be used as a 'reflex' genotyping HPV test with no additional regulatory submissions or clinical data.

The data were broadly consistent with prior data generated by PapType® in other numerous clinical studies in both referral and screening populations in the detection of CIN2+[2] and showed highly sensitive detection of CIN2+ and CIN3+ representing strong performance of PapType® in an independent clinical study.

Genera's PapType® HPV test has now been involved in a number of independent clinical studies in Australia, the UK and now the US involving in excess of 11,000 patient samples in both referral and screening populations overseen by world opinion leaders in cervical cancer screening. The performance of PapType® has been largely consistent across all studies providing confidence in PapType's robust clinical performance, reliability and reproducibility.

Full public disclosure of the data will be made by Drs. Wheeler and Cuzick through peer reviewed publication.

Commenting on Genera's US Screening Population data Dr. Mario Koksch, Vice President and General Manager of Beckman Coulter's Cytometry Business Unit said, "We congratulate Genera on the great data set delivered by PapType® running on the CytoFLEX™ and we look forward to continuing to collaborate and partner with the Genera team to build on the strong relationship we have formed over the past few years. Beckman Coulter has a strong pedigree in providing robust world class instrumentation systems incorporating user friendly workflow for both researchers and clinical laboratories and we look forward to exploring what else we can do together to further improve the customer experience in running Genera's AmpaSand® based tests."

Genera is currently undertaking an additional significant clinical study in ~6,650 patient samples at the Wolfson Institute (UK) also using the Beckman Coulter CytoFLEX™ instrument. This study is well underway and Genera currently anticipates receiving this key additional clinical data during the month of November. This data will be used alongside existing clinical data as part of the required documentation to be lodged with MSAC in Genera's submission for approval of PapType® as a screening test under Australia's new cervical screening regime.

The global market opportunity for HPV testing is expected to exceed ~US$1.5 to US$2 billion per annum as numerous countries follow Australia's lead in replacing the traditional Pap smear with HPV testing as the front line screening tool in the fight against cervical cancer in women. The Netherlands and Italy have also implemented national screening programs similar to what Australia is formally adopting on May 1st 2017 with Germany expected to follow. A high performing HPV test partnered with a leading global IVD company could be expected to capture a significant portion of this market opportunity.

As a true, high throughput, plate based multiplex technology[3], outside of PapType®, the AmpaSand® platform has the flexibility and capability to offer pathology customers a broad menu of high value

[2] Should squamous cervix cells be abnormal they are called cervical intraepithelial neoplasia (CIN). They are graded according to how deep the abnormal cells are within the surface of the cervix. This is detected by taking a sample of tissue biopsy from the surface of the cervix. Early changes are graded as CIN 1, and they will usually disappear without treatment. Further abnormal changes are graded as CIN 2 or CIN 3 and will require treatment. Treatment for CIN 2/3 may include cryotherapy, laser therapy, loop electrosurgical procedure (LEEP), or cone biopsy to remove or destroy the abnormal tissue.

[3] All 'plate based' Real Time PCR platforms can 'multiplex' utilising additional wells of a plate to test for additional target analytes. As such commercially, their multiplexing capability is restricted due to

molecular diagnostic assays used by physicians to diagnose disease, make treatment decisions and monitor patients.

IVD partnering

Genera currently anticipates in late 2016 to commence a close collaboration with Beckman Coulter's Automation group in Indianapolis (USA). The aim of this collaboration will be to provide a more highly automated workflow for Genera's PapType® HPV test working with the CytoFLEX™ and other Beckman instruments so as to best place PapType® for use in high volume throughput pathology laboratories for cervical cancer screening. This improved workflow and level of automation will as a result be also made available to all other Genera MDx tests aside PapType®.

Subsequent to this automation collaboration Genera envisages numerous other commercial opportunities with Beckman Coulter going forward.

Other Development initiatives

Genera remains on track in its Scoresby manufacturing capacity expansion as part of its plans to ramp up ahead of launching material supply of its PapType® and STIplex™ tests into the market during 2017. Existing capacity stands at approximately 1 million AmpaSand® tests per annum with the goal to achieve a 5-fold increase.

Development of the new STIplex™ 7.0 assay made significant progress during the quarter. The assay incorporates CT/NG which account for the bulk of existing testing volumes in sexually transmitted infections pathology testing in most markets as well as 5 other targets. The Company currently anticipates a Research Use Only version of the STIplex™ assay being offered to customers in Q1 CY2017 with a submission for ARTG listing following.

In addition to its CE marked PapType® HPV and RTIplex™ respiratory tests Genera, is currently focused on broadening its testing menu with the development of a number of new assays in the areas of sexually transmitted infections (STI's), HIV, Aneuploidy Screening for IVF and Circulating Tumor DNA.

For further information please contact:

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

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a direct trade-off with volume throughput per plate (96 or 384 well). Genera's AmpaSand® technology facilitates the multiplexing of up to ~150 target analytes **in a single well** of a plate.

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 RTI-Plex™, both of which are CE marked 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.