Advanced Molecular Diagnostic Systems

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Tuesday 31 January 2017

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 31 December 2016. The company held cash at end of quarter of $518k representing a net increase of $387k during the period.

Genera received a $752k rebate from the ATO related to its eligible R&D activities for FY2016 up 49% on the previous corresponding period.

Cash receipts from customers for the quarter amounted to $185k which were down 34% on the September quarter and down 40% versus the previous corresponding period. The decline in cash receipts was largely due to both comparative timing differences in invoice settlement and a trade discount offered to an existing customer to support the introduction of Genera’s new research use only respiratory panel test. As a result of these factors cash receipts from customers for the 6 months to December 2016 were flat.

The company anticipates that cash receipts in the 2nd half should be materially stronger as respiratory testing volumes continue to grow year on year and firmer product pricing is restored.

Indian market

Genera has been disappointed in the performance of its Indian distributor to date. Genera’s distributor appears to have failed to establish adequate pathology supply arrangements in time for the commencement of the Indian flu season which traditionally peaks in the current quarter.

Genera is now exploring various options to address the Indian market opportunity, which the company believes presents significant opportunities in the longer term.

Current Capital Raising

The Company has previously announced to ASX in its Annual Report that it anticipates undertaking a material capital raising to redeem all existing Series B Convertible Notes alongside the $1.0 million mezzanine loan facility. Proceeds of the capital raising will also be applied to accelerating test menu development. It is currently proposed that the capital raising will be conducted via an issuance of Series C Convertible Notes with a maturity date of December 2018 and convertible at $0.30 per Ordinary Share.

Immediately prior to the end of the December half and after discussion with most major Series B noteholders an amendment to the conversion terms of the Series B notes was made. The amended

terms provided for an extension to the Series B Notes Redemption Date by 3 months and a provision to convert all accrued interest as well as principal at a conversion price of $0.30 per Genera Ordinary Share.

Given the amended terms Genera currently anticipates that approximately 40% of the outstanding Series B Notes will either elect for conversion into Ordinary Shares or roll into the proposed Series C issuance. The company intends to offer the Series C financing to existing Genera Shareholders alongside a prominent Australian venture fund.

Genera is also targeting the completion of a further capital raising in Q2 CY2017 to a strategic trade-related investor that can add material strategic value to the global monetisation of Genera's valuable intellectual property.

Pathology Supply Agreement(s) for 2017

After successful clinical validation of its PapType® HPV test the Company had hoped to be able to announce a material new supply agreement with an Australian pathology customer. Due to a number of factors this agreement looks to be deferred for up to 5 to 6 months. Genera does not believe that the delay will have a material impact on the commencement of potential sales with this Australian pathology customer. The new cervical screening regime commences on 1 May 2017 and Genera believes it is well positioned to offer its PapType® HPV test at this time and is confident of receiving the applicable Medicare Benefits Schedule code that will be assigned to complying HPV tests under the new regime.

Genera remains confident of a substantial sales ramp of PapType® in the 2nd half of CY2017 and should it be successful in gaining market traction, the Company will be well-positioned to deliver its maiden operational cash flow positive result over the first full 12 month operating period.

The Company believes that the 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.

Delivery of new PapType® clinical data in US Screening population

Genera's PapType® HPV test has now been involved in a number of independent clinical studies in Australia, the UK and 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.

Genera is currently undertaking an additional significant clinical study in ~6,650 patient samples at the Wolfson Institute (UK) using the Beckman Coulter CytoFLEX™ instrument. This study is now in its final stages of completion. Genera anticipates receiving this key additional clinical data in the later part of February. Subject to clinical performance thresholds being met, the Company plans to use this additional data as part of its compliance package to demonstrate that PapType® is fit for purpose for laboratories undertaking testing in the National Cervical Screening Program.

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, outside of PapType®, the AmpaSand® platform has the flexibility and capability to offer pathology customers a broad menu of high value molecular diagnostic assays used by physicians to diagnose disease, make treatment decisions and monitor patients.

IVD partnering

Genera has progressed a collaboration with Beckman Coulter's Automation group in Indianapolis (USA) to explore how best to provide a more automated workflow for Genera's PapType® HPV test working with the CytoFLEX™ and other Beckman instruments. A new system that would best position PapType® for use in high volume throughput pathology laboratories may be released in the near future. With the release of new instrumentation offerings, further improved workflow and increasing the level of automation is expected to significantly enhance the prospects of pathology laboratories taking up of all other Genera MDx tests in addition to PapType®.

Subsequent to this automation collaboration Genera envisages other commercial collaborative opportunities with Beckman Coulter going forward including the optimisation of reagent transportation logistics.

Genera is cognisant of the need for a full global distribution footprint in order to maximise the value of the AmpaSand® testing platform. To this end Genera has commenced discussions with another significant global IVD company with the view to potentially provide this potential IVD partner non-exclusive access to its expanded test menu. Genera expects the IVD partner's US operations to complete an independent validation, initially of its PapType® HPV test, in the current quarter.

The board believes that the new prospective IVD partner may provide synergies outside of instrumentation and broad distribution capabilities in traditional pathology markets – namely in point-of-care testing engineering development that may be applicable to the development of Genera's next generation QSand™ technology.

Genera's QSand™ technology has exciting potential in the point-of-care market as well as traditional pathology markets. Based upon the concept of 'Whispering Gallery Modes' ('WGMs') - a new photonic principle involving discrete measurement of spectral shifts in light/wavelengths, QSand™ provides a unique method for analyte detection which leverages Genera's core intellectual property and knowhow in chemically modifying silica microspheres to produce custom Quantum dots.

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Other Development initiatives

Development of the new sexually transmitted infections assay continued to move forward during the quarter and Genera currently anticipates offering a Research Use Only version of the assay in late Q1 CY2017 with a submission to the TGA and ARTG listing following. The targets included in the assay have been further refined after receiving additional 'voice of customer' feedback including input from some of Australia's leading sexual health experts. Genera now believes that it has the construct of an optimal assay for comprehensive STI testing.

For further information please 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. 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.

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.

+Rule 4.7B

Appendix 4C

Quarterly report for entities subject to Listing Rule 4.7B

Introduced 31/03/00 Amended 30/09/01, 24/10/05, 17/12/10, 01/09/16

Name of entity

Genera Biosystems Limited

ABN	**Quarter ended ("current quarter")**
69 098 663 837	31 December 2016

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (6 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	185	466
1.2	Payments for		
	(a) research and development	(319)	(565)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(311)	(558)
	(f) administration and corporate costs	(210)	(280)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	-	-
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives (R&D)	753	753
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**98**	**(184)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) property, plant and equipment	-	(75)
	(b) businesses (see item 10)	-	-
	(c) investments	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
	(d) intellectual property	(86)	(94)
	(e) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) property, plant and equipment	-	-
	(b) businesses (see item 10)	-	-
	(c) investments	-	-
	(d) intellectual property	-	-
	(e) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	**Net cash from / (used in) investing activities**	**(86)**	**(169)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of shares	-	-
3.2	Proceeds from issue of convertible notes	375	375
3.3	Proceeds from exercise of share options	-	-
3.4	Transaction costs related to issues of shares, convertible notes or options	-	-
3.5	Proceeds from borrowings	-	457
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	(27)
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	**Net cash from / (used in) financing activities**	**375**	**805**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of quarter/year to date	131	66
4.2	Net cash from / (used in) operating activities (item 1.9 above)	98	(184)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(86)	(169)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	375	805

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (6 months) $A'000**
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of quarter**	**518**	**518**

5.	**Reconciliation of cash and cash equivalents** at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	**Current quarter $A'000**	**Previous quarter $A'000**
5.1	Bank balances	518	131
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**518**	**131**

6.	**Payments to directors of the entity and their associates**	**Current quarter $A'000**
6.1	Aggregate amount of payments to these parties included in item 1.2	127
6.2	Aggregate amount of cash flow from loans to these parties included in item 2.3	-

6.3 Include below any explanation necessary to understand the transactions included in items 6.1 and 6.2

Salary, superannuation and directors fees related to directors.

7.	**Payments to related entities of the entity and their associates**	**Current quarter $A'000**
7.1	Aggregate amount of payments to these parties included in item 1.2	-
7.2	Aggregate amount of cash flow from loans to these parties included in item 2.3	-

7.3 Include below any explanation necessary to understand the transactions included in items 7.1 and 7.2

8.	**Financing facilities available** *Add notes as necessary for an understanding of the position*	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $A'000**
8.1	Loan facilities	1,000	1,000
8.2	Credit standby arrangements	-	-
8.3	Other (Convertible Note)	3,000	2,850

8.4 Include below a description of each facility above, including the lender, interest rate and whether it is secured or unsecured. If any additional facilities have been entered into or are proposed to be entered into after quarter end, include details of those facilities as well.

Immediately prior to the end of the December half, the Company entered into variation deeds providing extension of the repayment date of the Series B Convertible Notes to the to 31 March 2017 and an extension to the maturity date of the Mezzanine Loan Facility from 31 December 2016 to 31 May 2017.

The Company issued an additional 3,750 Series B Convertible Notes during the quarter.

9.	**Estimated cash outflows for next quarter**	**$A'000**
9.1	Research and development	350
9.2	Product manufacturing and operating costs	50
9.3	Advertising and marketing	75
9.4	Leased assets	-
9.5	Staff costs	300
9.6	Administration and corporate costs	150
9.7	Other (Redemption of Series B Notes)	2,900
9.8	**Total estimated cash outflows**	**3,825**

10.	**Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)**	**Acquisitions**	**Disposals**
10.1	Name of entity	-	-
10.2	Place of incorporation or registration	-	-
10.3	Consideration for acquisition or disposal	-	-
10.4	Total net assets	-	-
10.5	Nature of business	-	-

Compliance statement

1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.

2 This statement gives a true and fair view of the matters disclosed.

Sign here: ..... Date: 31 January 2017
(Non-Executive Chairman)

Print name: Lou Panaccio

Notes

1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity that wishes to disclose additional information is encouraged to do so, in a note or notes included in or attached to this report.

2. If this quarterly report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.

3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.