Advanced Molecular Diagnostic Systems

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Tuesday 31 July 2018

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 June 2018. The company held cash at end of quarter of $78k versus a $387k balance at 31 March 2018. Cash receipts from customers for the quarter and the full year amounted to $174K and $997K respectively which while down 25.0% on a quarterly basis were up 21.4% for the full year versus the corresponding June 2017 periods.

Operating cash outflow was $365k and was approximately $210K higher than the prior corresponding period. Causes of the greater operating cash outflow was largely due to the above mentioned decline in cash operating receipts as a result of a late on-set and less severe domestic flu season. In addition to lower sales receipts there was an increase in R&D expenditure associated with the internal validation of a new enzyme for PapType®. The incorporation of this new enzyme will deliver substantial improvements in run times for customers adopting the PapType® test. Staff costs were also slightly higher during the period, up $50K.

The company anticipates that operating cash receipts in the September quarter will be weak due to the withdrawal of Genera’s respiratory panel with its major customer. Reasons underlying the cessation of RUO Respiratory panel sales to Genera’s major customer were, ironically, focused on workflow issues and the lack of instrument automation running the panel on Genera’s now redundant instrument offering. The company anticipates that operating cash outflows for the current quarter will be largely negated by the anticipated receipt of the FY2018 R&D tax rebate.

Looking forward to the December quarter Genera currently anticipates that Respiratory panel revenues may be largely replaced by the successful launch and introduction of PapType®, initially as a reflexive test, with a number of domestic pathology customers. The re-launch of PapType® into the domestic market will coincide with the market launch of a new high throughput, highly automated workflow to run Genera’s testing menu operating on a fully integrated system supplied and supported by Beckman Coulter.

Global IVD Partnership

As announced to the ASX on 8 May Genera was delighted to complete a distribution partnership with Beckman Coulter Life Sciences during the quarter.

Richard Hannebery, Chief Executive Officer of Genera said, "We were delighted to enter into the distribution agreement with Beckman Coulter Life Sciences. We see enormous commercial opportunity for a broad, affordable test menu that will be able to be run with a highly automated workflow incorporating CytoFLEX™ technology. The integrated system will benefit prospective customers looking for faster throughput and improved workflows for their laboratory processing."

Mr Hannebery added, "The agreement will provide Genera customers a best of breed high throughput automated instrumentation solution capable of walkaway sample-to-results post PCR.[1] A lower throughput solution will also be offered to customers, incorporating an on-deck PCR allowing walkaway sample-to-results post DNA/RNA extraction. Until now a key barrier to wider adoption of AmpaSand® assays has been the lack of availability of an integrated and fully automated instrumentation solution for prospective pathology customers. This agreement unequivocally addresses a prior weakness in the Genera business model."

Genera intends to provide AmpaSand® based assays to customers under reagent rental agreements. The structure of the distribution agreement will allow instrumentation placements to be scaled in a capital light manner helping Genera to optimize its return on invested capital and free cash flow generation.

Each high throughput system will have a capacity of approximately 140,000 tests per annum. The minimum target customer volume will be between 15 and 20% of this capacity. Further planned menu expansion will increase the likely addressable customer base and should aid test sales velocity in driving maximum capacity utilization for pathology customers.

Clinical Validation of PapType on new high throughput instrumentation

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 ~ 17,500 patient samples in both referral and screening populations on multiple models of flow cytometer analysers, 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 in the process of internally validating the new Beckman Coulter system. This process is anticipated to continue until early October. Upon completion of internal validation work Genera plans to validate the performance of PapType® with archived clinical samples utilised in prior studies conducted by the Wolfson Institute. Clinical validation of PapType® on the new automated Beckman Coulter system is anticipated to take approximately 2 to 3 weeks post commencement. Successful validation will demonstrate equivalence with previously generated clinical data and allow Genera to commercially supply PapType® in the domestic market, initially as a reflex test.

Genera is currently planning additional major studies both in the UK, the US and Australia utilizing the new automated high throughput instrumentation system. Data from these studies will form a dossier to demonstrate 'Meijer compliant' clinical performance and indicate that PapType® is fit for purpose for laboratories undertaking front line screening as well reflexive testing in the Australian

[1] *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.*

market and other applicable jurisdictions. These studies will be planned to complete in Q1 of CY2019.

Genera believes that the flexibility of its PapType® HPV test, utilizing its proprietary QPlots™ analytical reporting software places it in a strong position to be commercially attractive to pathology customers adopting the test. Aside robust clinical performance and significantly improved workflow and high volume throughput when run on the new automated instrumentation system, PapType® may offer prospective pathology customers materially improved profitability when incorporating it into their cervical cancer test offering. This is a result of PapType® potentially being able to report multiple patient report results - both screening and subsequently if appropriate, expanded HPV genotyping reflex - in a single test, that does not require pathology customers to undertake an additional run of the assay.[2] Depending on pricing models adopted this increase in profitability for pathology customers adopting PapType® could be as much as 75.0% to 90.0%.

Current Financing Activities

As announced in the Capital Structure Update to ASX on 9 July, Genera has made a request to the ASX that its shares remain in suspension while it prepares and lodges a long form prospectus for a non-renounceable entitlements issue of Ordinary Shares to raise up to $11.2m ('Entitlements Issue').

Contemporaneous with the proposed Entitlements Issue Genera continues to engage with selected institutional investors exploring support for an investment that will strengthen the Company's financial position and support the planned rollout of Genera's test menu operating on the new automated Beckman Coulter system ('Institutional Investment').

In addition to the Entitlements Issue and Institutional Investment, Genera continues to engage with a well-credentialed trade-related party in relation to a jurisdictional licensing of PapType® for China and potentially other selected markets excluding the Australian, New Zealand, US and Canadian markets ('Strategic Financing'). Any completed licensing transaction would involve an upfront license fee payment that may further strengthen Genera's financial position and support the commercial roll-out of Genera's valuable AmpaSand® test menu running on the new Beckman Coulter system.

Genera will make a further announcement to the ASX providing an update to all shareholders once it has lodged and received clearance from ASIC for the Entitlements Issue Prospectus. This is currently anticipated to occur in the second half of August and trading in Genera Shares will be suspended until this time.

[2] As an example Medicare reimbursement for HPV screening tests has been set at **$35.00 per test.** The applicable 'reflex' test market opportunity is approximately 10% of anticipated screening volumes. While reflex testing is not currently reimbursed by the MBS, there are clear precedents for consumers being willing to pay 'out-of-pocket' for valuable clinical information in relation to cancer risk. Genera's market research indicates that many women would be willing to pay an amount of at least **$75.00** to glean additional clinical information on HPV type specific infection **once diagnosed with an 'oncogenic' HPV infection** aside HPV types 16 and 18.

Persistent infection with the same high-risk viral type is the primary cause of cervical cancer and Genera believes that the additional genotype information provided by PapType® can aide clinicians in monitoring 'at risk' women, particularly those who present with **HPV type 31 and 33 infections**.

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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'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.[3]

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

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 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.

[3] All 'plate based' Real Time PCR platforms can 'multiplex' up to 4 targets per well assuming 4 available channels of a Real Time PCR instrument. To multiplex greater than 4 target analytes in a test most platforms require use of additional wells of a plate to test for the additional target analytes. As such commercially, their multiplexing capability is restricted due to a direct trade-off with volume throughput per plate (96 or 384 well). Genera's AmpaSand® technology facilitates the multiplexing of up to ~125 target analytes **in a single-well** of a plate. On a like for like basis depending on the number of target analytes detected in a multiplex assay Genera's AmpaSand® technology facilities > 4X relative volume throughput. High volume throughput is a key commercial consideration for all large pathology labs undertaking HPV and STI testing.

+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	30 June 2018

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (12 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	174	997
1.2	Payments for		
	(a) research and development	(181)	(768)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(281)	(1,094)
	(f) administration and corporate costs	(77)	(664)
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)		422
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(365)**	**(1,107)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) property, plant and equipment		(21)
	(b) businesses (see item 10)	-	-
	(c) investments	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
	(d) intellectual property	(27)	(241)
	(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**	**(27)**	**(262)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of shares	-	-
3.2	Proceeds from issue of convertible notes	-	-
3.3	Proceeds from exercise of share options	-	1,027
3.4	Transaction costs related to issues of shares, convertible notes or options	-	-
3.5	Proceeds from borrowings	83	279
3.6	Repayment of borrowings	-	(79)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	**Net cash from / (used in) financing activities**	**83**	**1,227**

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	387	220
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(365)	(1,107)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(27)	(262)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	83	1,227

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (12 months) $A'000**
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of quarter**	**78**	**78**

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	78	387
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)**	**78**	**387**

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	82
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	1,548	1,548
8.2	Credit standby arrangements	-	-
8.3	Other (Convertible Note)	2,875	2,875

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.

Loan facilities include Convertible Notes and Mezzanine Loan.

9.	**Estimated cash outflows for next quarter**	**$A'000**
9.1	Research and development	100
9.2	Product manufacturing and operating costs	25
9.3	Advertising and marketing	25
9.4	Leased assets	25
9.5	Staff costs	300
9.6	Administration and corporate costs	150
9.7	Other (Debt repayment)	4,100
9.8	**Total estimated cash outflows**	**4,725**

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 July 2018
(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.