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

Friday 30 October 2015

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 2015.

The company held cash at end of quarter of $669k representing a net decrease of $817k during the period. During the quarter Genera incurred substantial one-off annual payments relating to insurances, intellectual property and annual listing fees. In addition to these expenses, Genera paid for a substantially extended key license agreement with a global in vitro diagnostics business. The license agreement relates to certain fluorescent dyes used in Genera’s current AmpaSand® assays. Genera has elected to extend this license out to 31 December 2022, thereby providing additional comfort and certainty for Genera’s prospective commercial partners in assessing freedom to operate risks to Genera’s AmpaSand based tests.

Cash receipts from customers for the period amounted to $153k. Cash receipts were up 106.8% versus the June 2015 quarter and invoiced kit sales rose by 66.5% with a trade receivable balance of $227k at 30 September which is anticipated to be received during the December quarter. In addition to its current trade receivables balance Genera currently anticipates receipt of its annual R&D tax incentive rebate during the December quarter amounting to approximately $450k. The company anticipates delivering positive operating cash flows in the December quarter.

BUSINESS UPDATE

Cash receipts for the quarter were wholly derived from sales of RTI-plex™ Genera’s upper respiratory tract multiplex MDx test. Genera Chief Executive Officer Richard Hannebery commented, “As with last quarter, while these figures are coming off a small base the growth curve continues to slope positively and remains encouraging. Our focus for the rest of the year is to launch RTI-plex in India with CureHealth and SRL Diagnostics, with new demand from India hopefully smoothing out the seasonality of kit sales.”

Having finalized all required documentation for registering RTI-plex in India Genera is now focused on developing the business plan for the launch of STI-plex™, a 5-plex sexually transmitted infection assay that is in advanced development with an anticipated launch in the 2nd half of CY2016.

IVD PARTNERING DISCUSSIONS

Genera continues to work diligently toward the completion of a significant global partnering deal with a leading global IVD company. While the Board of Genera is cognisant of the significant time

that this important process has taken, this has been unavoidable due to the Board's desire to derisk the partnership from a technical perspective prior to announcement.

Richard Hannebery commented, "We look forward to providing shareholders with a detailed update regarding our proposed IVD partnership at our annual general meeting scheduled for Thursday 26 November."

SCALE UP OF MANUFACTURING CAPACITY

In preparation for a significant ramp-up of test volumes sold in concert with a global IVD partner Genera has made significant progress during the quarter with the manufacturing team working toward the successful scale-up of our ISO 13485 accredited manufacturing process at the Scoresby facility. The production explosion is planned to be implemented during 2016. The current scale-up is anticipated to provide a 5-fold increase in Genera's Scoresby manufacturing capacity to ~5m tests per annum.

OTHER DEVELOPMENT INITIATIVES

Genera made considerable progress during the quarter on a number of exciting initiatives to further improve the competitiveness of our AmpaSand MDx testing platform.

Genera intends to introduce a new 384-well plate format that will deliver a 3.8x increase in volume throughput capacity over a single working shift for a pathology customer compared to the current 96-well plate format. Genera anticipates that the new 384-well format can be made available to customers in early 2017 prior to the implementation of the new Australian cervical screening regime.

Alongside increased throughput from new well formats to be implemented Genera is advancing the development of a new proprietary 'front-end' AmpaSand system. This AmpaSand 3.0 system may reduce sample preparation time by more than 70% removing the need for what is currently a critical workflow step and along with this the requirement for an expensive reagent currently offered for sale by a significant global IVD company whom Genera has no current intention to partner with. The current development schedule for AmpaSand 3.0 projects a market launch in late calendar 2016/early 2017.

Prior to Xmas 2015 Genera plans to launch its AmpaSand 2.1 system which will reduce the run time for a single 96-well plate below 5 hours offering customers daily throughput capacity of > 500 tests when running 2 cytometers contemporaneously.

AmpaSand 3.0 throughput volumes running the 384-well plate format may deliver > 1,000 tests per working shift for pathology laboratories when running 2 cytometers contemporaneously. Such throughput would compare favourably to the current leading market offering, Roche Diagnostics' Cobas® 6800 and 8800 systems which according to specification may deliver 384 and 960 test results respectively over an 8 hour shift.

PREDICTORS 3 – PIVOTAL CLINICAL DATA

In Australia the company anticipates significant traction for Genera's PapType® HPV assay during the latter part of calendar year 2016 and beyond. Whilst currently negligible, volumes of HPV testing in

the Australian market are expected to immediately grow to 1.3m tests per annum with the introduction of the new cervical cancer screening regime from May 1st 2017.

Richard Hannebery added, "During the past quarter we welcomed the receipt of robust pivotal data for our PapType HPV assay from the Wolfson Institute's 6,000 patient HPV screening study."

Genera received summary clinical data from the Wolfson Institute in early August to enable it to share this data under confidentiality with its prospective global IVD partners. As the study was independently undertaken by the Wolfson Institute of Preventive Medicine and supported by Cancer Research UK Programme grants, full public disclosure of the data will be made upon the group publishing its paper in a respected peer reviewed medical journal later in the year.

Respecting confidentiality restrictions, the company was pleased to advise during the quarter that whilst the data delivered to it was in summary form only, it was consistent with prior data generated by PapType in the Predictors 2 study. The performance of PapType in the 1,099 patient Predictors 2 study was comparable to other high sensitivity tests for detecting CIN2+ - approximately 95% sensitivity - whilst being capable of delivering additional information and substantially higher specificity when applying a diagnostic classification of oncogenic HPV genotypes by sequentially maximising Positive Predictive Values (PPVs).

The main strength of the Predictors 3 study was a head-to-head comparison of seven commercially available HPV tests in a screening population, conducted by an independent global key opinion leader in cervical cancer screening, in which all women were evaluated by all tests on a like for like basis. No other such comparison exists in any other clinical study done to date. Tests from major global IVD companies included in the study were: Roche - Cobas®, Abbott - Real-time®, Genprobe - Aptima®, Becton Dickinson - Onclarity® and Qiagen - Hybrid Capture® 2.

It is notable that, of the HPV tests evaluated in the Predictors 3 study only four deliver some form of simultaneous genotyping and PapType is the only test able to simultaneously genotype all 14 high risk HPV sub-types that compared the performance of PapType against all other commercially available assays.

Richard Hannebery added, "Clinical performance in a screening population, throughput and workflow will be key differentiators of HPV tests in the coming years. On all of these fronts we remain confident of our unique PapType HPV test. We have developed an extremely robust assay that was substantially ahead of its time until recently. The combination of full simultaneous genotyping - of all high risk cancer causing types - alongside strong clinical data from large respected studies bodes well for PapType's position in the market."

Since receipt of the Predictors 3 clinical data Genera is pleased to advise that it is currently finalising participation of PapType in a prestigious ~2,000 patient prospective clinical study from a screening setting in the United States. The US study is being led by Prof Cosette Wheeler- a global KOL in HPV vaccination and screening and recent addition to Genera's advisory board. The company believes that this clinical data will further add to the attractiveness of the adoption of the PapType HPV test in a screening setting, particularly with the introduction of new screening algorithms.

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. A high

performing HPV test partnered with a leading global IVD company could be expected to capture a significant portion of this market opportunity.

WORLD CLASS CLINICAL AND SCIENTIFIC ADVISORY BOARD ESTABLISHED

Genera was pleased to announce on 23 October that it had that it has established a world class clinical and scientific advisory board with a particularly strong focus on human papilloma virus (HPV) screening. Members of the advisory board include Prof Jack Cuzick, Prof Cosette Wheeler, Prof Susan Garland and Associate Prof Sepehr Tabrizi.

Richard Hannebery commented, "We are humbled by the calibre of individuals we have been able to attract to this very important board. To be able to not only pique the interest of the likes of Jack Cuzick and Cosette Wheeler in what we are doing with our PapType HPV assay, but to secure their services in joining this advisory board in a formal capacity, gives us tremendous comfort that we are doing something right in our approach to the HPV screening market.

"We are of the view that coupled with strong clinical data, Jack and Cosette's participation and interest with PapType may provide significant cut-through with many clinicians around the world who understand the merits of HPV testing in cervical cancer screening."

Other members of the new advisory board Prof Susan Garland and Associate Prof Sepehr Tabrizi, besides having strong pedigree in HPV testing, share a more general interest in sexually transmitted infections that is highly relevant to Genera's next assay targeting regulatory approval - STIplex.

For further information please contact:

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

Rule 4.7B

Appendix 4C

Quarterly report for entities admitted on the basis of commitments

Introduced 31/3/2000. Amended 30/9/2001, 24/10/2005, 17/12/2010

Name of entity

Genera Biosystems Limited

ABN	Quarter ended ("current quarter")
69 098 663 837	30 September 2015

Consolidated statement of cash flows

	Cash flows related to operating activities	Current quarter $A'000	Year to date (3 months) $A'000
1.1	Receipts from customers	153	153
1.2	Payments for:		
	(a) staff costs	(313)	(313)
	(b) advertising and marketing	-	-
	(c) research and development	(238)	(238)
	(d) leased assets	-	-
	(e) other working capital	(283)	(283)
1.3	Dividends received	-	-
1.4	Interest and other items of a similar nature received	3	3
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Other items		
	(a) Net GST (paid to)/recovered from ATO	(51)	(51)
	(b) R & D tax rebate received	-	-
	(c) Government grant received	-	-
	(d) R&D contract contributions received	-	-
	Net operating cash flows	(729)	(729)

+ See chapter 19 for defined terms.

Appendix 4C
Quarterly report for entities
admitted on the basis of commitments

		Current quarter $A'000	Year to date (3 months) $A'000
1.8	Net operating cash flows (carried forward)	(729)	(729)
	Cash flows related to investing activities		
1.9	Payment for acquisition of:	-	-
	(a) businesses (item 5)	-	-
	(b) equity investments	-	-
	(c) intellectual property	(43)	(43)
	(d) physical non-current assets	(45)	(45)
	(e) other non-current assets	-	-
1.10	Proceeds from disposal of:	-	-
	(a) businesses (item 5)	-	-
	(b) equity investments	-	-
	(c) intellectual property	-	-
	(d) physical non-current assets	-	-
	(e) other non-current assets	-	-
1.11	Loans to other entities	-	-
1.12	Loans repaid by other entities	-	-
1.13	Other (provide details if material)	-	-
	Net investing cash flows	(88)	(88)
1.14	**Total operating and investing cash flows**	(817)	(817)
	Cash flows related to financing activities		
1.15	Proceeds from issues of shares, options, etc.	-	-
1.16	Proceeds from sale of forfeited shares	-	-
1.17	Proceeds from borrowings	-	-
1.18	Repayment of borrowings	-	-
1.19	Dividends paid	-	-
1.20	Capital raising costs	-	-
	Net financing cash flows	-	-
	Net increase (decrease) in cash held	(817)	(817)
1.21	Cash at beginning of quarter/year to date	1,486	1,486
	Exchange rate adjustments to item 1.20	-	-
1.23	**Cash at end of quarter**	669	669

+ See chapter 19 for defined terms.

Payments to directors of the entity and associates of the directors

Payments to related entities of the entity and associates of the related entities

		Current quarter $A'000
1.24	Aggregate amount of payments to the parties included in item 1.2	68
1.25	Aggregate amount of loans to the parties included in item 1.11	-

1.26 Explanation necessary for an understanding of the transactions

Directors' fees and wages paid during the September 2015 quarter.

Non-cash financing and investing activities

2.1 Details of financing and investing transactions which have had a material effect on consolidated assets and liabilities but did not involve cash flows

-

2.2 Details of outlays made by other entities to establish or increase their share in businesses in which the reporting entity has an interest

-

Financing facilities available

Add notes as necessary for an understanding of the position.

		Amount available $A'000	Amount used $A'000
3.1	Loan facilities	-	-
3.2	Credit standby arrangements	-	-

+ See chapter 19 for defined terms.

Reconciliation of cash

Reconciliation of cash at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts is as follows.		Current quarter $A'000	Previous quarter $A'000
4.1	Cash on hand and at bank	669	1,486
4.2	Deposits at call	-	-
4.3	Bank overdraft	-	-
4.4	Other (provide details)	-	-
	Total: cash at end of quarter (item 1.23)	669	1,486

Acquisitions and disposals of business entities

		Acquisitions *(Item 1.9(a)*	Disposals *(Item 1.10(a))*
5.1	Name of entity	-	-
5.2	Place of incorporation or registration	-	-
5.3	Consideration for acquisition or disposal	-	-
5.4	Total net assets	-	-
5.5	Nature of business	-	-

Compliance statement

1 This statement has been prepared under accounting policies which comply with accounting standards as defined in the Corporations Act (except to the extent that information is not required because of note 2) or other standards acceptable to ASX.

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

Sign here: _____ Date: 30 October 2015
(Chairman)

Print name: L J 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 wanting to disclose additional information is encouraged to do so, in a note or notes attached to this report.

2. The definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report except for any additional disclosure requirement requested by AASB 107 that are not already itemised in this report.

3. **Accounting Standards.** ASX will accept, for example, the use of International Financial Reporting Standards for foreign entities. If the standards used do not address a topic, the Australian standard on that topic (if any) must be complied with.

+ See chapter 19 for defined terms.