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**Friday 29 January 2016**

**ASX Announcement – GENERA BIOSYSTEMS LIMITED (ASX: GBI)  
QUARTERLY CASH FLOW & BUSINESS UPDATE**

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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 2015.

The company held cash at end of quarter of \$160k representing a net decrease of \$517k during the period. Subsequent to 31 December Genera has received its annual R&D tax incentive rebate amounting to approximately \$456k and as of 29 January holds cash at bank of \$548k.

Cash receipts from customers for the period amounted to \$306k, double the immediate preceding quarter and up 257.1% versus the December 2014 quarter. Cash receipts from customers for H1 FY16 were \$459k up 135.5% versus H1 FY15.

Compared to the September quarter Genera incurred materially higher investing cash outflows related to intellectual property as it continued to successfully prosecute its substantial global IP portfolio through numerous national phases as well as investing in additional acquisition of instrumentation systems for both existing and new customers currently running or preparing to launch AmpaSand® tests.

**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, “While we continue to deliver strong growth quarter on quarter in test sales this is from a relatively small base. Our focus for 2016 is to significantly re-base sales taking them to the next level while continuing to deliver significant quarterly growth over the following four to six quarters and beyond. If our team delivers on this goal we will be well positioned to deliver our shareholders the outstanding outcome they deserve.”

Aside from continuing with previously announced deliverables such as manufacturing scale-up, new front-end consumable development and new enzyme integration to materially improve cost, workflow and volume throughput, the Genera team’s focus for the current quarter centers around four key deliverables:

1. Offer exemplary service and support to our existing customers as we seamlessly introduce our new preferred higher throughput instrumentation systems;
2. Support GeneCell in the launch of RTI-plex into India for the remainder of the flu season;

3. In concert with voice of customer feedback from both GeneCell and a prospective global IVD partner finalise two additional AmpaSand based tests to move forward into the development pipeline; and finally
4. Choose our preferred IVD partner and mutually agree a clear and expedited path toward completion and subsequent commercial launch.

### **Introduction of new instrumentation**

Genera is currently introducing new instrumentation systems from a number of global IVD companies replacing previous instrumentation platforms used in running Genera's AmpaSand tests. Both systems have been extensively tested by Genera in-house as well as in significant clinical studies and both have proved to be materially superior to the previously utilised platform in terms of reliability, workflow and throughput. Genera is excited to introduce these new instrumentation systems to its pathology customers and looks forward to seeing its customers enjoy the benefits of these leading platforms running its high value MDx tests.

### **India market launch**

After completion of all required documentation for registering RTI-plex in India, Genera's Indian distributor GeneCell lodged the required 'No Objection Certificate' for import and marketing of RTI-plex during the first half of December. GeneCell aims to have an import license application approved within the next few weeks and is currently undertaking upgrades to their laboratories to facilitate the operation of PCR based MDx assays.

Genera currently anticipates having all instrumentation installed with laboratory technicians trained, alongside necessary regulatory and import approvals being in place by end of February so as to facilitate RTI-plex supply for the remaining few months of the peak Indian flu season.

Richard Hannebery commented, "Experience gained through working with GeneCell taking RTI-plex through the new Indian regulations has been valuable. Whilst this process has taken a few months longer than originally anticipated we are now confident in the roadmap for additional test introductions into the Indian market. Successful launch of Genera's tests with GeneCell greatly enhances the longer term prospects that obviously also exist with SRL Diagnostics, with SRL remaining the largest pathology company in India's organised pathology sector.

Genera believes that new demand from India may smooth out the seasonality of Southern Hemisphere flu season sales. Aside from RTI-plex the company remains focused on developing the business plan with GeneCell for the launch of STI-plex™, a 5-plex sexually transmitted infection assay that is in advanced development by Genera.

### **New AmpaSand assays for development**

Genera is currently refining priorities for its future test development pipeline to best leverage its existing and new customers in both Australia and India as well as those jurisdictions that best appeal to its prospective IVD partners.

The company believes that a broad menu of 6 or more high value MDx tests with robust performance on a single instrumentation platform will maximise sales opportunities in the short to medium term. In the longer term, with adequate resourcing from a global IVD company Genera continues to aim to broaden its menu to greater than 10 tests.

The company continues to move forward development of both STI-plex and BBV-plex™, in concert with market based voice of customer feedback from both GeneCell and its prospective IVD partners, Genera aims to add a further 2 tests to its assay development program in the later part of the current quarter. Final decisions around the exact composition of these additional tests will be made closer to the final choice of the prospective IVD partner.

### **IVD partnering**

Genera continues to work diligently toward the completion of a significant global partnering deal with a leading global IVD company.

Richard Hannebery commented, “Since our AGM in late November we have had a number of meetings via teleconference and in person with the leadership teams of our prospective partners. While the Board of Genera is cognisant of the significant time that this important process has taken we welcome the progress that we have made in the past few months in clearly understanding the forward schedule of our respective partners to conclude a significant global partnering deal. By the end of the March quarter Genera believes that it will be in a clear position to commit to move forward on an exclusive basis to close a mutually beneficially deal with our prospective IVD partner.”

### **PapType US Clinical trial**

As previously flagged in Genera’s prior quarterly market update, PapType has been accepted to be included in a prestigious ~2,000 patient prospective clinical study from a screening setting in the United States. The choice of the preferred instrumentation platform has now been agreed with set-up anticipated to take place during February and clinical samples acquired during the months to the end of April. The US study is being led by Prof Cosette Wheeler- a global KOL in HPV vaccination and screening.

The company believes that this US clinical data will further add to the attractiveness of the adoption of Genera’s PapType HPV test in a screening setting, particularly with the introduction of new screening algorithms.

Results from the US screening study are anticipated during Q3 of CY2016 and Genera believes that this study will further complement the robust market positioning of PapType, particularly when taken in tandem with the data already generated from the 6,000 patient clinical study led by Prof Jack Cuzick’s group at the Wolfson Institute (London).

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.

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-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.

# 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

69 098 663 837

Quarter ended ("current quarter")

31 December 2015

### Consolidated statement of cash flows

Cash flows related to operating activities	Current quarter \$A'000	Year to date (6 months) \$A'000
1.1 Receipts from customers	306	459
1.2 Payments for:		
(a) staff costs	(221)	(534)
(b) advertising and marketing	-	-
(c) research and development	(68)	(306)
(d) leased assets	-	-
(e) other working capital	(183)	(465)
1.3 Dividends received	-	-
1.4 Interest and other items of a similar nature received	1	4
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	(91)	(143)
(b) R & D tax rebate received	-	-
(c) Government grant received	-	-
(d) R&D contract contributions received	-	-
<b>Net operating cash flows</b>	<b>(256)</b>	<b>(985)</b>

+ 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 (6 months) \$A'000
1.8 Net operating cash flows (carried forward)	(256)	(985)
<b>Cash flows related to investing activities</b>		
1.9 Payment for acquisition of:	-	-
(a) businesses (item 5)	-	-
(b) equity investments	-	-
(c) intellectual property	(80)	(123)
(d) physical non-current assets	(181)	(226)
(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)	-	-
<b>Net investing cash flows</b>	<b>(261)</b>	<b>(349)</b>
<b>1.14 Total operating and investing cash flows</b>	<b>(517)</b>	<b>(1,334)</b>
<b>Cash flows related to financing activities</b>		
1.15 Proceeds from issues of shares, options, etc.	8	8
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	-	-
<b>Net financing cash flows</b>	<b>8</b>	<b>8</b>
<b>Net increase (decrease) in cash held</b>	<b>(509)</b>	<b>(1,326)</b>
1.21 Cash at beginning of quarter/year to date	669	1,486
Exchange rate adjustments to item 1.20	-	-
1.23 <b>Cash at end of quarter</b>	<b>160</b>	<b>160</b>

+ 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	84
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 December 2015 quarter.
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**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

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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

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**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.

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

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**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	160	669
4.2 Deposits at call	-	-
4.3 Bank overdraft	-	-
4.4 Other (provide details)	-	-
<b>Total: cash at end of quarter</b> (item 1.23)	160	669

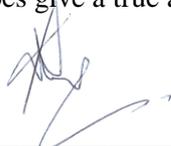
**Acquisitions and disposals of business entities**

	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:

  
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 (Chairman)

Date: 29 January 2016

Print name: L J Panaccio

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+ See chapter 19 for defined terms.

## 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.

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