Lodge Partners Research
ABN: 25 053 432 769
AFSL: 246271

BUY	Price	19 cents
	Target Price	70 cents
	Implied Return	268%

Genera Biosystems Limited (GBI)

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Trial results will add value

Company Details

ASX Code:	GBI
Price:	19 cents
Shares on Issue (fully diluted):	107m
Market Capitalisation:	$20m
12-Month Price Range:	16.5 – 30 cents
Monthly Volume (shares, Sept 2016)	683k

Financials

Year ending Jun	2016A	2017F	2018F	2019F
Lodge adj profit	(3.1)	(2.4)	4.2	8.5
Reported profit (pre abn)	(3.1)	(2.4)	4.2	8.5
EPS pre goodwill (¢)	(3.1)	(1.6)	2.8	5.7
EPS growth	**-5.0%**	**48.4%**	**n/a**	**102.4%**
P/E ratio	**-6.1 x**	**-11.9 x**	**6.8 x**	**3.4 x**
DPS (¢)	0.0	0.0	0.0	0.0
NTA per share	$0.01	$0.01	$0.01	$0.13
Pr / NTA	19.0 x	19.0 x	19.0 x	1.4 x

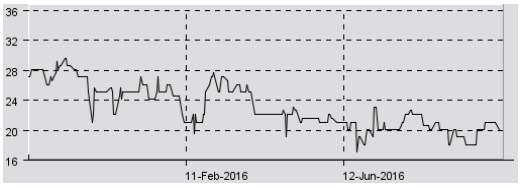
Directors & Chief Executive

Lou Panaccio	Chairman
Richard Hannebery	Chief Executive Officer
Dr Karl Poetter	Executive Director (CSO)
Jim Kalokerinos	Non-Executive Director
David Symons	Non-Executive Director

Major Shareholders

Durbin Superannuation Fund	11.5%
JPS Distribution Pty Ltd (Raff SF A/C)	7.5%
Richard Hannebery (Holdings Consolidated)	6.3%

Share Price Chart



Source: Iress

Event: Genera Biosystems announced on the 3rd October, 2016, that it had received the results of a study undertaken with its cervical cancer screening test, PapType®, in a US-based screening population of 2,025 patients by the University of New Mexico, Health Sciences Center – School of Medicine, Department of Pathology (UNMHSC). Renowned cervical cancer screening expert Dr Cosette Wheeler of UNMHSC was the study's Principal Investigator, with similarly renowned Prof Jack Cuzick's group at the Wolfson Institute of Preventative Medicine (London, UK) performing the data analysis. Although Genera has both the raw data sets and the analysis by Prof Cuzick's group, the results will remain confidential until they are presented at a scientific conference and/or published in a peer-reviewed scientific journal, as per standard industry practice. *Genera, however, has reported that the data was consistent with prior data generated by PapType®.*

Discussion: Many countries are replacing their first-line testing method in cervical cancer screening programs from Pap smear testing to molecular diagnostic (MDx)-based human papilloma virus (HPV) testing. While there are several reasons for this, the main ones are that:

- Persistent HPV infection is believed to be the cause of cervical cancer in almost every case
- MDx are much more sensitive in diagnosing persistent HPV infection than Pap smears
- MDx provide additional clinically relevant information over and above that provided by Pap smear

As a result of this switch to MDx testing, Genera believes the global market opportunity for such testing will grow to exceed USD2 billion per year.

The Relevance
The current study brings the combined number of patient samples Genera has studied PapType® in to over 11,000 and a further study in approximately 6,650 patients is underway at the Wolfson Institute. While data is not the only thing that determines the type of MDx that a pathology laboratory or screening program will use, it is a key parameter. A test that lacks sensitivity will miss more pre-cancerous and cancerous lesions, while a test that lacks specificity will lead to excessive follow-up costs (e.g. colposcopies, a visual inspection of the cervix using a device that provides a magnified view of the cervical cells) and unnecessary patient duress, the latter being an often overlooked/underappreciated aspect of cancer screening programs, including cervical cancer screening programs.

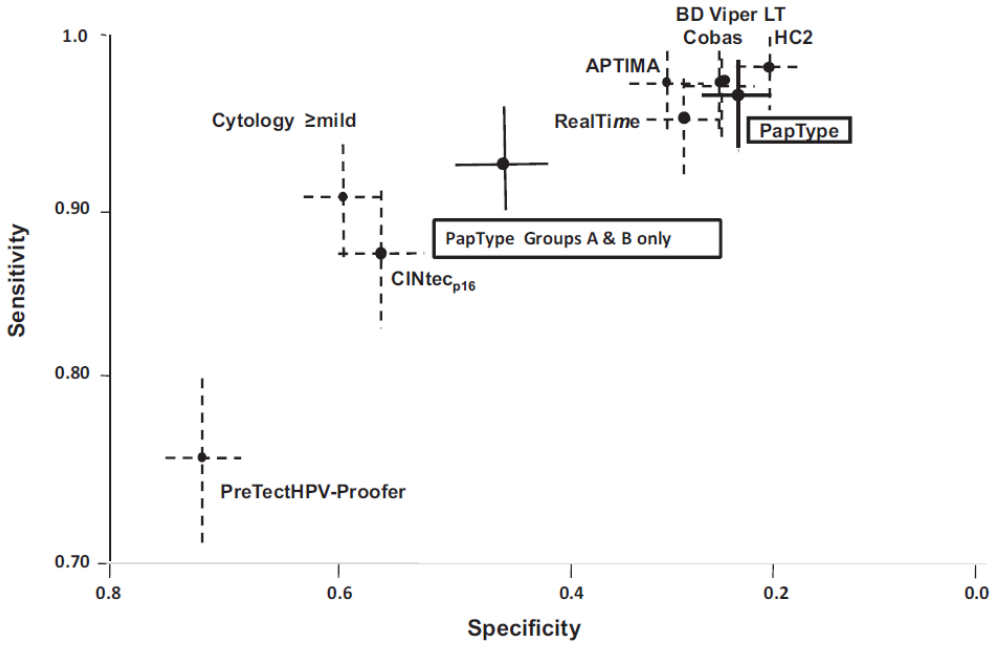
Results – The Signal
While the announcement did not specify the results of the study, CEO, Richard Hannebery, did state, *"it (the UNMHSC study) represents the strongest performance of PapType® in an independent clinical trial we have delivered to date"*. The most recent paper to truly focus on PapType® (J Clin Virol. 2014 May;60(1):44-9.; here) found a sensitivity for cervical intraepithelial neoplasia graded 2+ (CIN2+) of 94.6%, with a specificity of 22.4%. The study compared the performance PapType® with that of several other commercially available HPV tests.

The body of data supporting Genera's PapType® continues to grow

Figure 1 provides a good summary of the results from that study in terms of sensitivity and specificity. A good test from a sensitivity and specificity point of view will sit in the upper left hand corner of the figure and, as such, it is clear that PapType®'s performance in the study was right in the zone of the other commercially available tests. **Essentially, Hannebery is suggesting in the announcement that PapType®'s results will be stronger than these.** In terms of the figure, this means performance further toward that upper left hand corner of the graph. Obviously, the results from the UNMHSC study should then improve PapType®'s competitive positioning in the eyes of clinicians, pathology laboratories and potential *in-vitro* diagnostics (IVD) partners.

Figure 1. The sensitivity and specificity of each of the HPV tests studied by Cuzick in J Clin Microbiol. 2012 Jun;50(6):1867-73 and J Clin Virol. 2014 May;60(1):44-9. Note, the results for "PapType® Groups A & B only" was a subset analysis done to illustrate the significant improvement in PapType®'s specificity, at little expense to sensitivity, ultimately obtainable due to the ability of PapType® to identify more specific HPV types than the other tests.

Genera is indicating that the performance of PapType® in the UNMHSC study betters its performance illustrated in the figure opposite



Source: J Clin Virol. 2014 May;60(1):44-9

As a reminder, CIN are clusters of abnormal cells that while not cancerous at that stage, are pre-cancerous and may develop into cervical cancer. Most CIN1+ lesion regress, such that their detection is undesirable, leading to excessive unnecessary follow-up procedures and patient duress, as for a test that lacks specificity. Experts have determined that CIN2+ (CIN2, CIN3 and cervical cancer) lesions are the earliest and most desirable lesion to detect, because they have significant malignant potential and are easily and effectively treated using a range of out-patient methods.

First major study using the Beckman Coulter CytoFLEX™

This is the first study using Beckman Coulter's CytoFLEX™

Beckman Coulter is a subsidiary of Danaher Corp (NYSE: DHR; Mkt Cap: USD54b)

The US-based screening population data was the first set of data generated by PapType® using the Beckman Coulter CytoFLEX™ instrument. The results of the study will be of interest to Beckman as they look to expand the approved applications of the instrument in various markets. In its latest quarterly results announcement it appears that the CytoFLEX™ is becoming a strategic growth engine for Beckman. *"Beckman Life Sciences continued to outperform, with high single-digit core growth that was driven by strong demand in flow cytometry, in particular in North America and China, stated Danaher President and CEO Thomas Jocye said. The flow cytometry growth was largely driven by demand for the new CytoFLEX™, he said."*

We believe that adding an IVD assay consumable business to CytoFLEX™ instrumentation sales may be of increasing interest to Beckman.

Australia's New Cervical Cancer Screening Program

PapType® provides more clinically relevant information than Australia's cervical cancer screening guidelines require allowing pathology laboratories to better serve doctors' and their patients

As of the first of May next year (2017), Australia, PapType®'s largest prospective market in the near term, will switch to MDx-based first-line cervical cancer screening, replacing the traditional Pap smear. While the guidelines call for the screening MDx to detect types 16 and 18 (and, optionally, 45), they also require a pooled (single) result for the other 11 to 12 HPV types that are deemed high risk. While PapType® provides the results required under the new screening guidelines, it also specifically types the remaining high risk types (plus two low risk types, 6 & 11, which are responsible for 90% of genital warts according to the CDC) at equivalent or lower pricing than other available tests. These other high risk types, while ~270% to 320% more prevalent than 16 & 18, account for ~30% of all incident cases of cervical cancer, according to a study lead authored by Dr Cossette Wheeler (Int J Cancer. 2013 Jan 1;132(1):198-207; here). Obviously, 30% is not a clinically trivial number. Given their malignant potential (ability to cause cervical cancer), clinicians can use this additional full genotyping information to better serve the requesting doctor and their patients, which in turn, should drive improved revenue via various mechanisms for pathology laboratories.

New Domestic Pathology Supply Agreement(s)

With new supply agreements, Genera believes sales will materially increase in 2Q CY17

Genera has announced it is currently pursuing significant new supply agreement(s) with major domestic pathology companies. Should Genera enter into the proposed supply agreement(s) which relate to both its PapType® HPV and its new STIplex™ tests, test volumes sold by Genera may increase materially commencing in the second quarter of CY17. Should this new data prove to be robust, it may materially enhance Genera's prospects of delivering on this goal.

Cervical Cancer Screening in a HPV Vaccine Environment

Despite the presence of the HPV vaccine Gardasil (human papillomavirus quadrivalent vaccine, recombinant; Merck & Co), which guards against HPV types 6, 11, 16 and 18, since 2006 and the recent US approval of Gardasil-9 (human papillomavirus 9-valent vaccine, recombinant), which guards against HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58 in 2014, cervical cancer screening is still widely recommended by, for example by Australia's Medical Services Advisory Committee.

Cervical cancer screening programs are still required in a vaccine environment

The reasons for this are multi-fold and include:

- The lead times for vaccines to have an impact on cervical cancer incidence
- Variable vaccination rates
- Incomplete coverage of all high risk HPV types by current vaccines
- The unknown consequences of vaccination on the virulence, prevalence and cancer causing potential of other HPV types for which vaccines are not available (e.g. a low prevalence, seemingly low risk type, may become a highly prevalent, high risk type due to the lack of competition from the current dominant types).

What this all means is that while the need for cervical cancer screening is unlikely to change, what is likely to change is the screening algorithms used to screen for cervical cancer. This is because, as the landscape of the different types of HPV changes due to the impact of the vaccines, the most effective algorithms used to screen for cervical cancer will also change.

PapType® is well suited to the changing vaccine-driven HPV landscape

The wealth of information provided by PapType® makes it well suited to the study of the HPV landscape as it changes. More importantly, the adaptability of the test to different screening algorithms means that once ensconced in cervical cancer screening programs, it will likely remain in them, in turn creating long term defendable revenues for the company and, ultimately, investors.

Other Studies – Deepening Pool of Data to Draw Upon

Genera and PapType® are set to have a significant presence in India

Contemporaneous to this announcement Genera provided a full year review of its operations and noted that it had submitted a commercial supply tender for a significant state government funded project to screen half a million women in a rural and semi-urban district of Thane near Mumbai, over a period of 5 years. The project aims to screen 100,000 women annually and will use a combination of visual inspection as a primary screen, followed by reflex to HPV DNA testing (PapType®) and thereafter, reflex, again, to HPV RNA testing. The HPV RNA testing will be undertaken if the infection is active with a high risk HPV type or is a persistent infection of a lesser type. Supply of PapType® will be made on a USD free on board basis ex-Scoresby, Australia.

This program is the largest state government sponsored cervical screening program incorporating both HPV DNA and RNA testing ever undertaken within India and we believe that such a significant study would be of interest to the likes of a Beckman Coulter type company, who have a strong presence in the Indian market.

Further data to come from an additional 6,650 patient UK study also using the CytoFLEX™

As previously stated, Genera is also currently undertaking an additional significant PapType® clinical study in ~6,650 patient samples at the Wolfson Institute (UK) also using the Beckman Coulter's CytoFLEX™ instrument. This study is well underway and Genera currently anticipates receiving this additional clinical data during the month of November.

Genera has stated that it plans to utilise this additional UK data as part of a submission to MSAC for a screening approval indication for PapType in early 2017.

PapType® is currently listed in the Australian Register of Therapeutics Goods, but, not yet, as a tool for cervical cancer screening. The additional data collected and being collected, should make its inclusion as a compliant screening tool a fait accompli with subsequent listing on the Medicare Benefits Schedule, allowing pathology laboratories to charge Medicare for it.

US Market Opportunities

Genera believes that PapType® is one of only a few commercially available CE marked HPV tests that simultaneously detects and specifically identifies all 14 carcinogenic types of HPV. These HPV types have different abilities to infect, persist and cause cervical disease. It is persistent infection with the **same** carcinogenic HPV type that is the cause of 99.7% of all cervical cancer.

Experts indicate that cervical cancer screening is heading in the direction of the detection of more HPV types than currently recommended

For the interested reader, Drs Cuzick and Wheeler recently authored an article expounding the virtues of specifically identifying a much broader range of HPV types than currently recommended (Papillomavirus Res. 2016 Dec;2:112-15; here). In doing so, they reference the pivotal trial which gained a cervical cancer screening approval from the US FDA for Roche's Cobas® HPV test. The Cobas® test is one of only three tests approved by the FDA for screening and it is the only one which provides for the specific identification of any HPV types, but only types 16 and 18. The article by Drs Cuzick and Wheeler is not only interesting from an academic perspective, but appears to clearly identify the technological direction first-line screening for HPV is headed in, which, as alluded to earlier, is the **specific identification** of a much wider array of cancer causing HPV types, with follow-up screening tailored to the specific type.

A major aim of Genera's is to have PapType® approved by the FDA for cervical cancer screening

Obviously, the direction Drs Cuzick and Wheeler describe is one that would give PapType® a, literally, huge advantage over the three FDA approved cervical cancer screening tests. With the increasing body of clinical data that Genera has and continues to generate with PapType®, alongside potential advances in instrumentation, Genera has stated that it is confident that, with the right partners, a successful US FDA regulatory submission could be delivered by late 2018.

Approval of PapType® by the FDA as a tool for cervical cancer screening, which would require a substantial investment by Genera, would be a major catalyst for a re-rating of the company. The continually increasing body of clinical data particularly that from screening populations, may provide the comfort to justify and support such a study.

Recommendation: The announcement regarding the study results is a positive. Taking a wait and see approach, however, we prefer to see the actual data before revisiting our price target. **Buy recommendation** and **70 cent 12-month price target** maintained.

Genera Bisosytems Limited (GBI: $0.190)

Mkt Cap: $20m

Valuation data

Year ending Jun	2016A	2017F	2018F	2019F	2020F
Lodge adj profit	**(3.1)**	**(2.4)**	**4.2**	**8.5**	**11.4**
Reported profit (pre sig)	(3.1)	(2.4)	4.2	8.5	11.4
EPS_{adj} (¢)	**(3.1)**	**(1.6)**	**2.8**	**5.7**	**7.6**
EPS_{adj} growth	(5.0%)	48.4%	n/a	102.4%	34.1%
P/E ratio	-6.1 x	-11.9 x	6.8 x	3.4 x	2.5 x
DPS (¢)	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
NTA per share	$0.01	$0.01	$0.01	$0.13	$0.22
Pr / NTA	19.0 x	19.0 x	19.0 x	1.4 x	0.9 x

Balance sheet ($M)

Year ending Jun	2016A	2017F	2018F	2019F	2020F
Cash	0.1	3.4	7.6	9.0	17.5
Receivables	0.9	1.0	2.5	2.5	2.5
Inventories	0.0	0.3	0.5	0.8	0.9
Other	0.0	0.0	0.0	0.0	0.0
Current assets	**1.0**	**4.7**	**10.6**	**12.3**	**20.9**
Net PPE	0.5	0.8	1.3	1.5	2.0
Capitalised development costs	1.3	1.9	3.1	3.6	4.2
Intangibles	1.9	1.8	1.9	1.8	1.8
FITB	0.0	0.0	0.0	0.0	0.0
Other	0.0	0.0	0.0	0.0	0.0
Non-current assets	**3.7**	**4.5**	**6.3**	**6.9**	**8.0**
Total assets	**4.7**	**9.2**	**16.9**	**19.2**	**28.9**
Debt (inc Payables)	4.7	0.9	1.5	1.8	1.9
Provisions	0.2	0.3	0.5	0.6	0.7
Other	0.0	0.0	0.0	0.0	0.0
Total liabilities	**4.9**	**1.2**	**2.0**	**2.4**	**2.6**
Equity / reserves	27.2	33.2	33.2	33.2	33.2
Retained profits	(27.4)	(30.3)	(23.2)	(11.5)	1.1
Total s/h funds	**(0.2)**	**2.9**	**10.0**	**21.7**	**34.3**
Minorities	0.0	0.0	0.0	0.0	0.0
Total funds emp.	**4.4**	**0.4**	**3.9**	**14.5**	**18.7**

Ratio analysis

Year ending Jun	2016A	2017F	2018F	2019F	2020F
EBITDA / sales	-468%	-209%	51%	55%	56%
EBITAg / sales	-581%	-282%	38%	47%	50%
EBIT / sales	**-581%**	**-282%**	**38%**	**47%**	**50%**
Return on assets	-78%	-53%	34%	71%	94%
Return on equity	**1550%**	**-83%**	**42%**	**39%**	**33%**

Profit and loss ($M)

Year ending Jun	2016A	2017F	2018F	2019F	2020F
Sales revenue	0.6	1.1	8.5	15.2	21.5
growth over pcp	*66%*	*77%*	*673%*	*79%*	*41%*
EBITDA	(2.9)	(2.3)	4.3	8.4	12.0
D&A	(0.7)	(0.8)	(1.1)	(1.2)	(1.3)
EBITAg	**(3.6)**	**(3.1)**	**3.2**	**7.2**	**10.7**
Goodwill amortisation	0.0	0.0	0.0	0.0	0.0
EBIT	**(3.6)**	**(3.1)**	**3.2**	**7.2**	**10.7**
growth over pcp	*5%*	*14%*	*n/a*	*125%*	*49%*
Net interest expense	(0.2)	(0.2)	0.2	0.6	0.6
Pre-tax profit	(3.8)	(3.3)	3.4	7.8	11.3
Tax	0.7	0.9	0.8	0.7	0.1
Effective tax rate	*N/A*	*N/A*	*N/A*	*N/A*	*N/A*
Minorities	0.0	0.0	0.0	0.0	0.0
Lodge adjustments	0.0	0.0	0.0	0.0	0.0
Lodge adj profit	**(3.1)**	**(2.4)**	**4.2**	**8.5**	**11.4**
Reported Net Profit pre-adj.	(3.1)	(2.4)	4.2	8.5	11.4
Adjustment	0.0	0.0	0.0	0.0	0.0
Reported net profit	(3.1)	(2.4)	4.2	8.5	11.4

Cashflow ($M)

Year ending Jun	2016A	2017F	2018F	2019F	2020F
EBIT	(3.6)	(3.1)	3.2	7.2	10.7
Net interest paid	(0.2)	(0.2)	0.2	0.6	0.8
D&A	0.7	0.8	0.9	1.2	1.3
Tax paid	0.5	0.7	0.8	0.7	0.1
Gross cash from op'ns	**(2.6)**	**(1.8)**	**5.1**	**9.7**	**12.9**
(Inc) / dec in w k'g cap	0.0	(0.3)	(0.4)	(0.2)	(0.2)
Inc / (dec) in Other Liab.	0.0	0.0	0.0	0.0	0.0
Other	1.2	0.0	0.0	0.0	0.0
Operating cashflow	**(1.4)**	**(2.1)**	**4.7**	**9.5**	**12.7**
growth over pcp	*-43%*	*-50%*	*n/a*	*102%*	*34%*
Investing cashflows					
Capital expenditure	(0.3)	(0.5)	(0.5)	(0.5)	(0.5)
Asset sales	0.0	0.0	0.0	0.0	0.0
Development costs	(0.3)	(0.6)	(0.8)	(0.8)	(0.8)
Divestments	0.0	0.0	0.0	0.0	0.0
Other	0.0	0.0	0.0	0.0	0.0
Financing cashflows					
Net equity raised	0.0	6.0	0.0	0.0	0.0
Dividends paid	0.0	0.0	0.0	0.0	0.0
Chg in loans	**0.6**	**(3.3)**	**0.0**	**0.0**	**0.0**
Other non-op flows	0.0	5.0	0.0	0.0	0.0
Net chg in cash	**(1.4)**	**4.5**	**3.4**	**8.2**	**11.4**

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Recommendations are assessments of each Lodge Partners Analyst's view of potential total returns over a 1 year period.

Expected total Return is measured as (capital gain (or loss) + dividend)/purchase price

We have divided our recommendations into three main categories:

Buy: Expected Total Return in excess of 15% over a 1 year period.

Hold: Expected Total Return between 0% and 15% over a 1 year period.

Sell: Expected Total Return less than 0% over a 1 year period.

Analyst Verification

I verify that I, Marc Sinatra, have prepared this research report accurately and that any financial forecasts and recommendations that are expressed are solely my own personal opinions. In addition, I certify that no part of my compensation is or will be directly or indirectly tied to the specific recommendation or financial forecasts expressed in this report.

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