Tuesday, 17 October, 2017

RESEARCH REPORT

Genera Biosystems

Annual Report & Business Update

BUY

12 Month Target	$0.70
Price	$0.21
Implied Return	233%

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Company Data

ASX code	GBI
ASX price	21 cents
Shares on issue	101m
Market capitalisation	$22.1m
12 month price range	11.5 – 31.0 cents
ASX turnover (shares, Sept, 2017)	483k

Financials

@21 cents	2017A	2018F	2019F	2020F	2021F
Lodge Profit	-$3.1m	$0.3m	$5.1m	$9.1m	$10.2m
Rep. Profit	-$3.1m	$0.3m	$5.1m	$9.1m	$10.2m
EPS(¢)	-3.1	0.2	3.6	6.4	7.2
EPS growth	6.3%	106.9%	1600%	78.4%	12.1%
P/E ratio	n/a	99.4x	5.8x	3.3x	2.9x
NTA/share	-$0.06	$0.02	$0.05	$0.12	$0.27
Price/NTA	-$3.6x	9.6x	4.6x	1.8x	0.8x

Board of Directors

Lou Panaccio[1]	Chairman[1]
Richard Hannebery	CEO
Karl Poetter	Director & CSO
David Symons[1]	Director
Jim Kalokerinos[1]	Director

[1]Non-Executive

Substantial Shareholders

Durbin Superannuation Pty Ltd	11.7%
JPS Distribution Pty Ltd	7.7%
Richard Nicholas Hannebery	7.0%

The Year Gone By

Outwardly, last year appeared to be a fairly quiet year for Genera. The implementation of new national cervical screening guidelines in Australia were delayed, which would have given the company's human papilloma virus (HPV) test, PapType®, an opening to start generating significant revenues. In addition, there was a lack of partnering news, with Genera's most likely suitor, Beckman Coulter, being sidelined, while its owner Danaher Corp (NYSE: DHR) looked at and, subsequently, acquired the molecular diagnostics (MDx) company, Cepheid. With the acquisition completed, though, Beckman is likely to be back in the game, hopefully, creating the competitive tension for a deal to be done.

Over FY17, Genera generated $801k in revenue, primarily from RTIplex®, the company's respiratory tract infection test, which was 31% up on FY16. Net loss was flat at -$3.1m and cash used in operations down 44% to -$0.76m.

The Year to Come

More important than the year gone by is the year to come.

Major events

Based on Genera's statements, we expect two major events this year:

1) The implementation of HPV testing as the primary cervical cancer screening tool in Australia on December 1st of this year and the likelihood that, via a recommendation from the US Preventive Services Task Force (USPTF), many US healthcare providers will take a similar stance next year (CY18). Genera expects to take a significant slice of the Australian HPV testing market once the new guidelines are in place.

2) The company will find the partner it has been seeking, which can take Genera's test menu global. Likely partners seem to be Beckman or Siemens, using instrumentation that provides a significantly improved work flow that Genera has identified. We expect a partner to be announced before this year's AGM, which is likely to occur in late November.

Capital Management

We expect, again, based on Genera's statements that the company will engage in a financing at the same time or shortly after the partnering announcement. The company has appointed a US based boutique investment bank to arrange up to an USD8m financing via a Series C preferred share issue. The money raised will be used to redeem Genera's existing Series B convertible note and to provide working capital for the company.

Further Assay Development and Upgrades

The following can be expected in terms assay development and upgrades:

- A new enzyme will be incorporated in Genera's tests that the company believes will halve polymerase chain reaction runtimes, benefiting customers
- Further development of the company's sexually transmitted diseases panel (STIplex™), with release of a research use only version early next year (CY18)
- Further development of BBVplex™, which tests for hepatitis C, B and HIV, and leverages US Centre of Diseases Control recommendations
- Restart development of an Aneuploidy test. Used in *in vitro* fertilisation procedures, the current test attracts a fee of $5k per cycle

Recommendation

Given the conviction of Genera's recent statements regarding partnering and capital management activities, we are holding firm on our **BUY** recommendation and **12-month price target of 70 cents.**

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The Year Gone

A major bug bear for Genera has continued to be that lack of mandated guidelines that incorporate human papilloma virus (HPV) testing as the prescribed first-line method for cervical cancer screening. What many would have thought would become the standard of care seven or eight years ago, should finally be implemented on the first of December of this this year (2017) in Australia. The US is also likely to go that way soon, too, as discussed below. In the meantime, Genera has continued to build a data package to support PapType® that is compliant with the guidelines of Meijer et. al. (here). These guidelines spell out high-risk HPV test requirements for primary cervical screening and validation guidelines for candidate HPV assays.

While PapType® already fits within these guidelines, the company has continued to collect data on PapType® performance. The more data supporting PapType® the more competitive the test will be in the market.

Still Genera showed solid positive growth in revenue from ordinary activities, growth in cash receipts was up 31% on the previous corresponding period (PCP), from $616 to $801k. The increased revenue is from RTIplex®, the company's respiratory tract infection test. The flu season in Australia this year has been particularly bad and is reflected in the **84% increase** in 4QFY17 sales revenues.

Net loss remained flat, at -$3.1m, with a significant proportion of this loss being non-cash notional financing expenses associated with its Series B Convertible Notes (~$3.0m) and mezzanine loan facility (~$1.5m).

The Year to Come

Genera has always been open an honest about its desire to partner with a larger *in-vitro* diagnostic (IVD) company. While they didn't manage to cut that deal last year, there is a strong hint that a deal is likely to be struck prior to this year's AGM, as part of what the company has referred to as a "material capital raising".

Balance Sheet Management

Genera has appointed a boutique investment bank in the US. The principal of which has an approximate five-year history with Genera from a prior role with another company. Apparently, this prior exposure drove them to approach Genera to judge the company's appetite for a capital raising. Obviously, this is a positive signal.

Genera intends to redeem the outstanding Series B convertible notes, which have been voluntarily extended by holders each quarter since becoming redeemable in December 2016, with proceeds of the proposed US financing..

Genera has said that the the Series C Preferred Shares will have a conversion price of $0.25 per Genera Ordinary Share. The interest rate on the Series C shares is also likely to be materially lower than that on the Series B convertible notes.

Strategic Partner

As to who the strategic partner is likely to be it is difficult to tell. It has long been speculated that the company would do a deal with Danaher (NYSE: DHR) subsidiary, Beckman-Coulter. Danaher chose to shut down Beckman's MDx platform, the DxN Veris, after it acquired Cepheid. Cepheid had developed the GeneXpert and GeneXpert Infinity, which Danaher thought provided a more expansive test menu, better workflow and better throughput than the Veris. It should be known, though, Cepheid's cartridge based GeneXpert platform has been designed for the US market and its high rates of reimbursement and that they are unlikely to take a large market share outside the US.

A significant strength of the technology on which Genera's tests are based, the AmpaSand® bead technology, is its low cost of goods sold (COGS). Whoever the partner (or instrument supplier) may be, it would not be surprising if Genera and that partner were to embark on a strategy focused on the BRICS nations (Brazil, Russia, India, China and South Africa). Genera has previous experience in Brazil and India and these markets play to Genera's strengths, in terms of COGS, expanding test menu, etc. making it an ideal partner for a instrumentation manufacturer with a sales force interested in this type of strategy.

Genera, in its Monday, 2nd October 2017, annual report highlight announcement, said that it had identified "two commercially attractive options for providing highly automated instrumentation systems" on which Genera's tests could run. The announcement also states that both "systems can be well supported in the aftermarket globally, without Genera having to add material in-market support resources". It is relatively clear from these statements that Beckman could still be that partner for Genera, given they already have the instrumentation and that Genera's AmpaSand® technology has been exhaustively validated on it. Obviously, Danaher would not want a lower cost AmpaSand®/Beckman offering competing with the Cepheid platform, so a BRICS strategy may suit Danaher/Beckman quite well.

Reading between the lines in the annual report, it appears Siemens could be the other potential partner, using Hamilton instrumentation (Roche already has the Cobas® 4800 system and a HPV test of its own). Siemens uses a lot of Hamilton instrumentation and, consequently, a lot of Siemens products are optimised for it. The tie up is probably not as tight as with Beckman, given the extensive validation work that has been done with Beckman over the past 2 years. Still, the more Hamilton

instrumentation that is out there, the better it is for Siemens for compatibility reasons. A Genera/Siemens deal also wouldn't suffer the possible cannibalisation issues of a Genera/Beckman deal and, so, could go straight to the US market. This is important given the United States Preventive Services Task Force (USPTF) draft guidance discussed below.

Assay Upgrades

Genera has also stated that it has accessed a new, as yet unnamed, enzyme which it is looking to incorporate into its assays. Once it is successfully integrated, Genera believes that the polymerase chain reaction run times will be approximately halved. This, in turn, will, of course, increase test throughput, making Genera's tests even more attractive to pathologysupport resources

laboratories.

The company also plans to:

- Further develop STIplex™, the company's test for sexually transmitted infectious diseases, with a Research Use Only version expected for release in Q1CY18
- Further develop BBVplex™, which detects human immunodeficiency virus (HIV), hepatitis C (HCV) and hepatitis B (HBV) infections. HCV transmission is common in HIV affected individuals and the US Centre for Disease Control and Prevention Guidelines (MMWR / June 5, 2015) recommends all persons with HCV for whom HIV and HBV infection status is unknown should be tested for these infections
- Restart development of an Aneuploidy screening test, which determines if there are an abnormal number of chromosomes within a cell. This is useful in the *in vitro* fertilisation industry. Genera believes the revenue opportunity from an aneuploidy test could be 10 to 20 times that of PapType®, given the growth in pre-implantation screening recently. Current aneuploidy screening prices are $5k per cycle

USPTF Cervical Cancer Screening Recommendations

While Genera may not be looking at entering the US market in the near term from what we can tell, it looks like the USPTF will provide positive guidance in terms of the use of HPV testing for cervical cancer screening in the majority of women in its next set of guidelines. The USPTF is a widely respected independent body of national experts that provides evidence-based guidelines in terms of practices patients can undertake to reduce the risk that they will develop a particular major illness, in this case cervical cancer. The USPTF guidelines carry a very significant amount of weight in the US healthcare industry.

Currently, the USPTF recommends that women between the ages of 30-65 years old have cytology (Pap smear) screening every three (3) years **or** a combination of Pap smear and HPV testing every five years. A draft version of the new guidelines dispense with the need for co-screening, recommending either Pap smear alone every three years **or** HPV screening every five (5) years in women over 30. All in all, if the draft guidelines are accepted, this is a clear win for HPV screening, because:

- The screening interval is longer for HPV testing at five (5) years
- The method of sample collection (a scraping of cervical epithelial cells) remains the same
- There is little to no differential in terms of cost, at least, as far as the patient is concerned

Given, the overall trend is for HPV testing to replace Pap smear for cervical cancer screening, we see no reason why the draft USPTF guidelines will not be adopted in one of the most progressive countries in the world when it comes to healthcare.

Conclusion

Genera continues to maintain a low risk approach to commercialisation of its AmpaSand® bead-based tests, by seeking a partner who can bring instrumentation and a sales force, including after-market support, to the offering. Genera has been particularly strong in its statements that it is in the advanced stages of partnering and expects to make an announcement around the time of the 2017 AGM, which has tended to be around the 25th to 28th of November, in past years.

Locally, the business is growing its revenues, through RTIplex™. Next year will be all about PapType®, with the switch from Pap smear to HPV testing as the primary method of cervical cancer screening. If Genera can take a significant slice of this market locally, they will experience significant growth in revenues that will materially affect the bottom line and, given the cost base, drive the company toward profitability.

Recommendation

The coming year could be transformational for Genera. Taking a cautious approach, though, we are maintaining both our **BUY recommendation** and **price target** of **70 cents**. Should Genera hit some of the milestones, particularly the partnering deal, our price target is likely to increase.

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Genera Biosystems (GBI): 21 cents

Market Capitallisation: $21.1m

Valuation data

Year ending Jun	2017A	2018F	2019F	2020F	2021F
Lodge adj profit	**(3.1)**	**0.3**	**5.1**	**9.1**	**10.2**
Reported profit (pre sig)	(3.1)	0.3	5.1	9.1	10.2
EPS_{adj} (¢)	**(3.1)**	**0.2**	**3.6**	**6.4**	**7.2**
EPS_{adj} growth	6.3%	106.9%	1600.0%	78.4%	12.1%
P/E ratio	n/a	99.4 x	5.8 x	3.3 x	2.9 x
DPS (¢)	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
NTA per share	-$0.06	$0.07	$0.07	$0.14	$0.29
Pr / NTA	-3.6 x	3.2 x	3.1 x	1.5 x	0.7 x

Balance sheet ($M)

Year ending Jun	2017A	2018F	2019F	2020F	2021F
Cash	0.2	5.8	5.6	11.9	24.5
Receivables	0.6	1.2	1.2	1.4	1.6
Inventories	0.0	0.3	0.7	1.2	1.4
Other	0.1	0.0	0.0	0.0	0.0
Current assets	**0.9**	**7.3**	**7.5**	**14.5**	**27.5**
Net PPE	0.4	0.7	1.0	1.5	2.0
Capitalised development costs	0.0	0.0	0.0	0.0	0.0
Intangibles	2.9	2.9	2.9	2.9	2.9
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	**3.3**	**3.6**	**3.9**	**4.4**	**4.9**
Total assets	**4.2**	**10.9**	**11.4**	**18.9**	**32.4**
Debt (inc Payables)	(7.0)	(1.2)	(1.4)	(1.2)	(1.3)
Provisions	(0.2)	(0.2)	(0.3)	(0.6)	0.7
Other	0.0	0.0	0.0	0.0	0.0
Total liabilities	**(7.2)**	**(1.4)**	**(1.7)**	**(1.8)**	**(0.6)**
Equity / reserves	27.5	35.5	35.5	35.2	35.2
Retained profits	(30.5)	(27.5)	(24.2)	(13.3)	(0.4)
Total s/h funds	**(3.0)**	**8.0**	**11.3**	**21.9**	**34.8**
Minorities	0.0	0.0	0.0	0.0	0.0
Total funds emp.	**(10.2)**	**1.0**	**4.3**	**8.8**	**9.0**

Ratio analysis

Year ending Jun	2017A	2018F	2019F	2020F	2021F
EBITDA / sales	-213%	56%	57%	61%	63%
EBITAg / sales	-300%	6%	49%	55%	57%
EBIT / sales	**-300%**	**6%**	**49%**	**55%**	**57%**
Return on assets	-60%	2%	84%	126%	125%
Return on equity	**102%**	**4%**	**45%**	**42%**	**29%**

Profit and loss ($M)

Year ending Jun	2017A	2018F	2019F	2020F	2021F
Sales revenue	0.8	1.6	10.0	16.0	17.4
growth over pcp	*-20%*	*100%*	*525%*	*60%*	*9%*
EBITDA	(1.7)	0.9	5.7	9.8	10.9
D&A	(0.7)	(0.8)	(0.8)	(1.0)	(1.0)
EBITAg	**(2.4)**	**0.1**	**4.9**	**8.8**	**9.9**
Goodwill amortisation	0.0	0.0	0.0	0.0	0.0
EBIT	**(2.4)**	**0.1**	**4.9**	**8.8**	**9.9**
growth over pcp	*-50%*	*104%*	*4800%*	*80%*	*13%*
Net interest expense	(1.2)	(0.1)	(0.1)	(0.1)	(0.1)
Pre-tax profit	(3.6)	0.0	4.8	8.7	9.8
Tax	0.5	0.3	0.3	0.4	0.4
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)**	**0.3**	**5.1**	**9.1**	**10.2**
Reported Net Profit pre-adj.	(3.1)	0.3	5.1	9.1	10.2
Adjustment	0.0	0.0	0.0	0.0	0.0
Reported net profit	(3.1)	0.3	5.1	9.1	10.2

Cashflow ($M)

Year ending Jun	2017A	2018F	2019F	2020F	2021F
EBIT	(2.4)	0.1	4.9	8.8	9.9
Net interest paid	(1.1)	(0.1)	(0.1)	(0.1)	(0.8)
D&A	(0.7)	(0.8)	(0.8)	(1.0)	(1.0)
Tax paid	0.5	0.3	0.3	0.4	0.4
Gross cash from op'ns	**(2.3)**	**1.1**	**5.9**	**10.1**	**10.5**
(Inc) / dec in w k'g cap	(0.3)	(0.3)	(0.9)	(0.8)	(0.3)
Inc / (dec) in Other Liab.	0.5	0.0	0.0	0.0	0.0
Other	0.8	0.0	0.0	0.0	0.0
Operating cashflow	**(1.3)**	**0.8**	**5.0**	**9.3**	**10.2**
growth over pcp	*8%*	*162%*	*525%*	*86%*	*10%*
Investing cashflows					
Capital expenditure	(0.1)	(0.3)	(0.3)	(0.5)	(0.5)
Asset sales	0.0	0.0	0.0	0.0	0.0
Development costs	0.0	(0.6)	(1.0)	(1.1)	(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	10.2	0.0	0.0	0.0
Dividends paid	0.0	0.0	0.0	0.0	0.0
Chg in loans	**1.1**	**(5.7)**	**0.0**	**0.0**	**0.0**
Other non-op flows	0.0	0.0	0.0	0.0	0.0
Net chg in cash	**(0.3)**	**4.4**	**3.7**	**7.7**	**8.9**

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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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