

CEO AGM Presentation

26 November 2015

Mr. Richard Hannebery
Chief Executive Officer



Forward Looking Statements

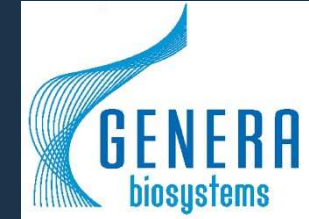


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Actual results could differ materially depending on factors such as the availability of resources, the results of clinical studies, the timing and effects of regulatory actions, the strength of competition and our ability to obtain or maintain patent or other proprietary intellectual property protection; government, industry, and general public pricing pressures; and additional factors that involve significant risks and uncertainties about our products, product candidates, financial results and business prospects. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected.

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Corporate Summary



| Capital Structure | |
|------------------------------|----------|
| ASX code: | GBI |
| TSOI (diluted for B Notes): | 110.4m |
| Share price (at 25/11 2015): | \$0.27 |
| Market capitalisation | \$29.8m |
| Cash at June 30: | \$1.5m |
| Annual cash burn rate: | (\$1.4m) |

| Board of Directors | |
|--|--|
| Mr Lou Panaccio (Non-Exec Chairman) | |
| Mr Richard Hannebery (CEO) | |
| Dr Karl Poetter (CSO & Founder) | |
| Mr David Symons (Non-Exec Director) | |
| Mr Jim Kalokerinos (Non-Exec Director) | |



| Substantial Shareholders | |
|--------------------------|-------|
| Mr Graham Durbin: | 10.1% |
| Dr John Raff: | 7.6% |

What is Genera?



- ❑ Genera Biosystems develops and commercialises ‘multiplexed’ Molecular Diagnostics (MDx)
 - AmpaSand® multiplexing platform offers ability to simultaneously test for 5-150 analytes via a single patient sample (an analyte binds to a specific disease target)
- ❑ ~\$25m invested to date in platform and test development
- ❑ MDx tests detect specific sequences in DNA or RNA - **molecular** biology in medical testing
 - MDx tests are ordered by clinicians for diagnosis of disease and are run by pathology labs
 - MDx is a ~US\$6 Billion market growing at ~13%+ CAGR with the HPV testing market anticipated to be largest double-digit growth sub-segment of overall MDx market with replacement of the ‘pap smear’ as front line in cervical cancer screening
 - Closest multiplexed MDx technology comparables to AmpaSand® are Luminex Corp (NASDAQ:LMNX) and SeeGene Inc (KOSDAQ:096530)

What is Genera?



- ❑ GBI go-to-market hybrid strategy of direct sales and partnership with global IVD
- ❑ 2 CE-IVD MDx tests to date – PapType® a 17-plex simultaneous HPV genotyping/screening assay and RTI-plex™ a 17-plex respiratory panel
- ❑ 2 additional MDx on track for RUO release 2016 - STI-plex™ a 5-plex sexually transmitted infections assay and BBV-plex™ a 5-plex assay for blood borne viruses
 - Business plan is to expand MDx menu to 10 assays by 2018 in concert with global IVD company
 - Grow business to ~US\$15m to US\$20m revenues by 2018 and consider merits of exit to IVD partner
- ❑ Intellectual property well protected with a portfolio of **70 granted** patents across numerous patent families in all major global jurisdictions with more than 35 patents pending
 - Core original patent portfolio has average expiry date of 2025 with pending patents out to 2032

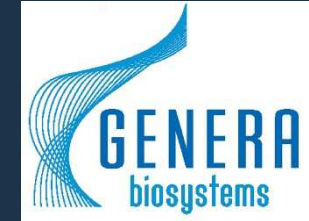
Why invest in MDx?



- ❑ MDx is the growth segment of the global IVD market (~13% CAGR versus ~4%)
 - MDx market anticipated to grow to > US\$8 billion by 2018
- ❑ Large global IVD's driving consolidation via very active M&A activities
- ❑ Attractive M&A candidates may possess the following characteristics:
 - ✓ ~US\$20m + revenues that can be leveraged into global sales & distribution networks
 - ✓ Selling product on sharp pricing but have strong clinical data – scope for price increases
 - ✓ Strong intellectual property > 7+ years life (granted patents are important)
 - ✓ Platform technology applicable to many markets - ex-US is new focus growth area for most IVDs – does economics work on 'price & volume' in lower paying regions ? – normally requires plate based MDx assays versus cartridges
 - ✓ Is there scope for new products to be developed/introduced within a 2 year timeframe from acquisition ?

Market based MDx comparable values range between 6 to 8x LTM sales with some 'outliers' > 10x due to great timing/luck - US\$150m+ deals par for course

Key criteria for success in MDx market



- ❑ By \$ value and volume MDx tests are largely used by commercial diagnostic pathology laboratories and to a lesser extent hospitals

What factors will a laboratory consider when assessing a new or replacement test(s)?

| | |
|--------------------------|---------------------------------|
| Clinical validation | Test performance |
| Information provided | Clinician demand |
| Cost per test (reagents) | Ease of use/workflow |
| Labour cost per test | Turn around time (single shift) |
| Reliable instrumentation | Lab technician skills required |

Given the above the broader the test menu offered the easier the sale

- ❑ Success requires a clear path to market to sell globally – ability to address most jurisdictions is better than sole focus on crowded US market

What is different about our tests?



- ❑ AmpaSand® is a true low cost high multiplexing MDx platform
 - Plate based assay format positions Genera far down cost curve versus cartridges

Key product/platform discriminators

1 well of 96 well plate = 1 panel*

AmpaSand can yield best in class volume throughput

Single wells can be reacquired < 2 mins versus > 2 hours for re-run of marginal calls

No Real-Time PCR royalty payable to Roche = better economics

Pricing flexibility well suited to ex-US

PapType® is unique/best in class and has now been extensively validated - KOLs

- Recent 6k screening study confirms competitive market position
- Roche and others doing heavy lifting
- 384-well format = world leading volume throughput in single shift
- Version 3.0 lowers costs even further and reduces run time < 3.5 hours

* **All** Real-Time PCR MDx can multiplex but only a small handful of plate format MDx assays possess ability to > 5-plex without sacrificing volume throughput

Genera runs 8 different controls in a 96-well plate with 16 controls anticipated in 384-well plate format



Genera's path to commercial success



- ❑ Validate product demand with customers and economics of margin chain
- ❑ Maximise product sales whilst generating positive operating cash flow
 - Requires a global footprint in sales, marketing & distribution and instrumentation support
 - Realism regarding capital availability/quantum whilst also cognisant of unnecessary dilution to shareholders regardless
- ❑ Bundle products with instrumentation to facilitate margin switching in tenders
 - Some IVD's actually make good margin on instruments as 'stand alone' sales
- ❑ Offer the broadest possible test menu alongside unique HPV position
- ❑ Being in the bottom quartile with costs – affords more flexibility in sales and adds to partnering appeal

We have a high degree of confidence in closing a global deal capable of delivery of US\$15m+ revenues by 2018 excluding direct revenues ~US\$10m

Direct sales, global partner or both?



- ❑ Market is dominated by large multinational IVD companies with well established sales, marketing, distribution and relationships – and is fiercely competitive!
- ❑ Roche Molecular (US\$222.7Bn), Hologic/GenProbe (US\$10.7Bn), Becton Dickinson (US\$29.3Bn), Qiagen (US\$6.1Bn), Abbott (US\$62.9Bn), Beckman Coulter (US\$9.0Bn/US\$60.1Bn), Thermo Fisher Scientific (US\$50.4Bn)
- ❑ Genera best leverage to sell its products globally is via global IVD
- ❑ For Genera a strong IVD company fit centers around their 'strategic gap to fill'
 - Genera fills the gap very nicely with two of the global IVD's listed above
 - Substantial sunk HPV costs may work against others being competitive
- ❑ Hybrid strategy of some direct sales with majority via IVD partner highly attractive
 - Retains some independence/flexibility whilst leveraging existing global infrastructure and laying ground work for ultimate exit

Do MDx markets differ by region?



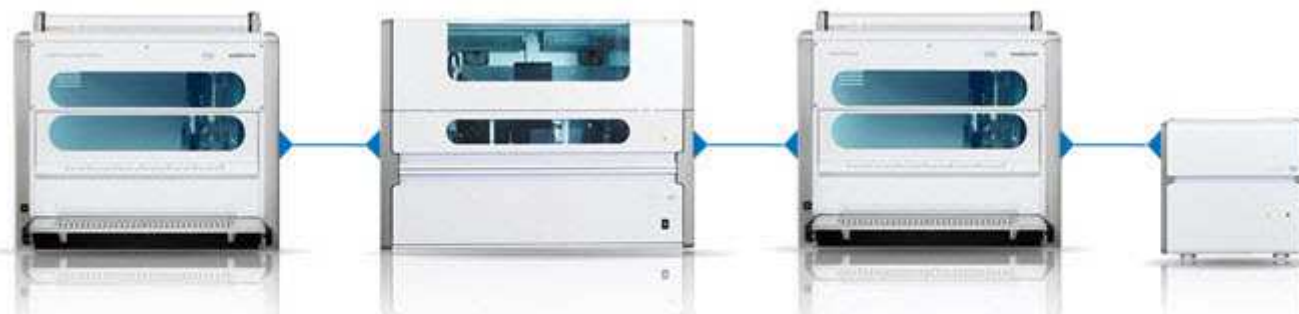
- ❑ Yes greatly – clinician demand driven by cost as largely funded ‘out-of-pocket’ – these markets offer however same opportunity in terms of revenue \$ than US market
- ❑ ‘All-in’ labour and reagent costs on a per-test critical outside of the US market which has bloated reimbursement structures

| | Operator costs | Labour as % of variable cost |
|--------------------------|----------------|------------------------------|
| Sydney (Australia) | US\$33.75/hr | 12.0% |
| New Jersey (USA) | US\$33.15/hr | 11.9% |
| Delhi/Mumbai (India) | US\$2.75/hr | 1.1% |
| Sao Paolo (Brazil) | US\$4.45/hr | 1.8% |
| Beijing/Shanghai (China) | US\$5.25/hr | 2.1% |

Full MDx workflow automation in Delhi, Sao Paolo or Shanghai is not as important as cost of reagents

US style/USD reagent costs do not appeal to the customer in a large part of the global market

Roche Molecular Systems

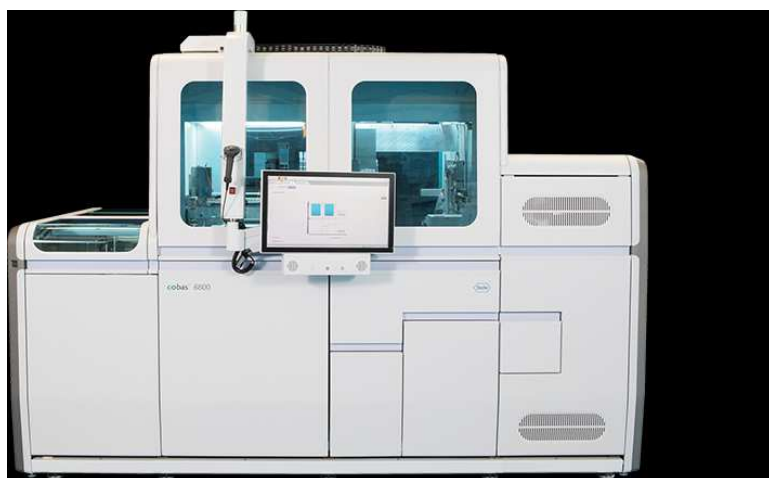


Primary Sample Instrument

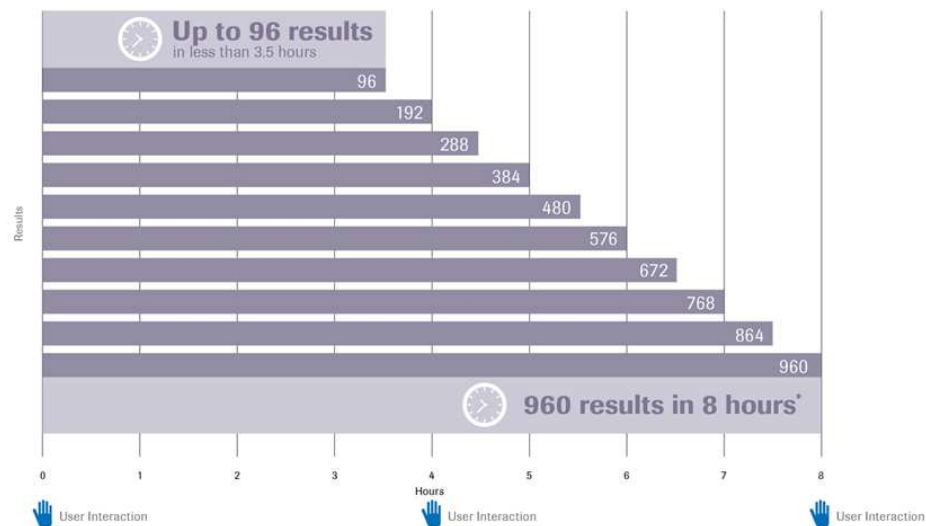
MagNA Pure 96 Instrument

PCR Set Up Instrument

Roche qPCR Instrument



Cobas® 6800 – 384 tests/8 hour shift



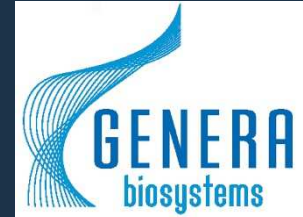
* May vary based on workflow demands of assay

Attraction of Genera to a global IVD?



- ❑ Significant investments made by most IVDs in HPV testing (~US\$50m to US\$1.6Bn)
 - Roche have made requirement for simultaneous HPV genotyping 'front and centre' – thank you Roche Cobas® HPV and we also welcome BD Onclarity® HPV!
- ❑ Genera offers highly competitive HPV market position with appeal of broader high multiplex MDx menu
 - PapType CE-IVD approved with robust ~9k patient data going to ~11k by mid-2016 – world class SAB with global HPV KOLs further validates data – by a relative minnow!
 - RTI-plex clinical data > 3k patients to date
- ❑ Genera has proven that its AmpaSand based assays work well with prospective IVD partner's instrumentation
- ❑ High throughput multiplexing capability on plate based assays has high appeal to IVD's
 - AmpaSand based assays can offer bottom quartile COGS – highly competitive on the cost curve allows gross margin >65% with world's sharpest pricing – faster TAT = \$ cost
 - IVD's offering instrumentation affords bundling and 'margin switching' with pathology customers
 - IVD's can take AmpaSand test prep (ie. dry reagents) and automation to the next level

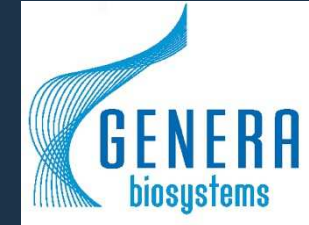
Preferred Instrumentation Systems



A Thermo Fisher Scientific Brand



AmpaSand® CE-IVD MDx test menu



PapType®

- Simultaneously detects and genotypes all 14 high risk HPV strains and 2 low-risk
- A ***future proofed*** HPV test with very solid clinical screening performance
- Projected global market US\$500M+ growing to US\$1,500M+ with widespread screening adoption = ~20-25% CAGR to 2019 (Roche recently reported Q3 HPV sales growth of 24%)
- Genera anticipates PapType revenues to take off mid-2017 (>~\$5m revenues)
- High technical barriers to entry in HPV screening

RTI-plex™

- Simultaneously detects and types 12 viral and 3 bacterial upper respiratory pathogens
- Projected global market US\$200-500M
- Genera currently anticipates >\$1m 'direct' RTI-plex revenues in forward 12 months

- Post global IVD deal a 510(k) will be pursued with FDA for RTI-plex (2016 RUO and 2017 approval) with PapType PMA study TBD



AmpaSand® MDx test pipeline



□ STI-plex™

- 5-plex detecting Chlamydia trachomatis (CT), Neisseria gonorrhoeae (NG), Trichomonas vaginalis (TV) and Herpes Simplex Viruses 1 & 2 (HSV-1 & HSV-2)
- RUO launch July 2016
- STI-plex assay could generate >\$3m 'direct' revenues in 2017 and >2X this via IVD
- US FDA 510(k) regulatory submission is a priority – global market US\$500M+

□ BBV-plex™

- 5-plex detecting HIV-1 Group M, HIV-1 Group O, HIV-2, Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV) – ex-US market US\$250M+
- RUO launch September 2016
- CE-IVD approval will be sought 2017, US FDA PMA as with PapType TBD

□ One other confidential assay currently in development - next 5 AmpaSand tests TBD post IVD deal with their input



Status of IVD partnering



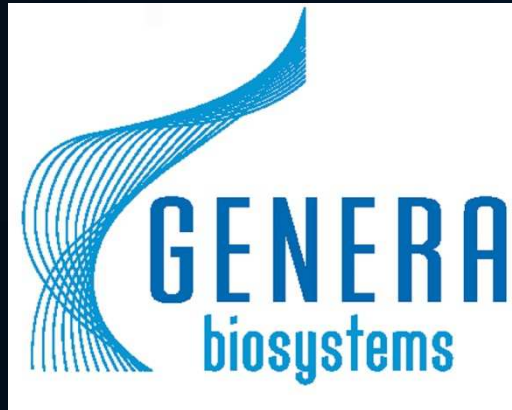
- ❑ Genera has been engaged with a number of highly credible IVD's over past 12 months
 - Process to date has been focused upon delivering a global deal involving the following:
 - material investment into Genera by IVD (~15.0% to 19.9% equity at premium valuation) – funds deployed in assay development, regulatory activities and clinical studies;
 - transfer pricing of assays variable depending upon quantum of investment;
 - carefully planned chronology for various jurisdictional launch of Genera's AmpaSand based assays;
 - close collaboration in further product pipeline expansion to broaden AmpaSand test menu - leverage IVD partner knowledge and "Voice of Customer" wish list
- ❑ Goal has been to consummate deal with clear business plan put in place to drive revenues to > US\$15m over next 2-3 years
- ❑ Board prepared to let current process run but no later than end of Q1 2016
- ❑ Potential pivot to restructure quantum of upfront ask to allow more timely deal closing whilst delivering higher gross margin may take months off process.



Upcoming milestones



- ❑ December/January 2016 - Indian market launch of RTI-plex
 - Significantly reduces seasonality of RTI-plex sales
- ❑ **Option 1** - Pivot strategy end January 2016 Global IVD partnership deal
- ❑ March 2016 - Completion of 2k patient US screening study with HPV KOL
- ❑ **Option 2** - Global IVD partnership with material investment end March 2016
- ❑ June 2016 - Alpha development completed AmpaSand[®] version 3.0
 - 3.0 reduces assay run time < 3.5 hours and reagent prep costs by material \$\$\$
- ❑ July 2016 - RUO Launch of STI-plex
- ❑ September 2016 - RUO launch of BBV-plex
- ❑ Sept 2016 - Assays launched in 2-4 additional countries by global IVD



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