Capital Raising and Company Outlook

Open Briefing interview with CEO John Melki

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In this Open Briefing, CEO John Melki discusses:

- **$15 Million Capital Raising**
- **New STI Detection Validation**
- **UCLA Results and US Market**
- **ASRs Opens US Labs**
- **Quarterly Results and Outlook: Product Range Extension, Financial and Market Growth**

Record of interview:

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Genetic Signatures Ltd (ASX: GSS, the Company) has announced a capital raising totalling $14m composing two tranches of 29,787,245 new shares via Institutional Placement at $0.47 per share and a $1m Share Purchase Plan (2,127,660 shares), managed by Bell Potter Securities. Following the completion of the raising, the Company will have a total of 104,589,302 shares on issue and will be well funded to advance the company strategy of growth into the US and Europe. What will the cash position of the Company be at the conclusion of the placement and what was the Board's reasoning behind the decision to raise funds at this point in time? Where will these funds be employed?

CEO John Melki
The response to our recent capital raising was very strong both from domestic and international institutions who truly recognised the unique advantage of our 3Base™ platform (Figure 1) in simultaneously screening for a large number of pathogens per patient specimen. Genetic Signatures' technology represents a new and more effective method for pathogen and disease detection within a very large global market for Molecular Diagnostics (MDx). Our range of products is developing and already receiving strong interest from the markets we are targeting, hence we recognised that it was time to accelerate our marketing and sales strategy both locally and overseas. I am pleased to say that Genetic Signatures is now fully funded to achieve a number of our key aims. The extra funds mean we can implement our strategy more effectively in both the US and Europe with the opening of offices and warehousing facilities in both regions, as well as putting on experienced sales teams to help us achieve these goals.

Collectively this will help build our presence within key US and European hospital and pathology labs as well as advance regulatory approvals. We are also now in a position to ramp-up the research and development of new assays and kits, five of which are already underway, and with our product range poised to grow, Genetic Signatures is in a good position to take advantage of a vast market opportunity. I am confident that by reinforcing this growth strategy with the development and supply of multiple products and jurisdictions we will ensure a de-risking of the commercialisation process.

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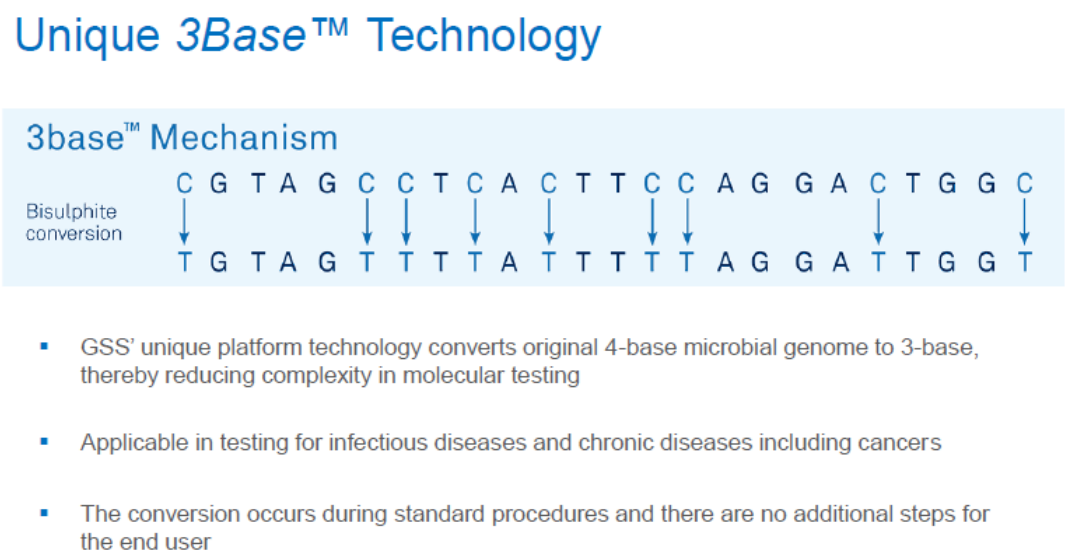
Clinical validation of the new EasyScreen™ sexual health screening kit has commenced. What is the significance of this new test, both for the market and for Genetic Signatures, and what is the development and approval path from this point?

CEO John Melki
Sexually Transmitted Infections (STIs) are a massive concern for global health in terms of reproduction with the World Health Organisation (WHO) currently reporting that there are more than one million STIs contracted daily. STIs can be highly infectious and difficult to detect as often there are no immediately obvious symptoms. Due to the asymptomatic nature of STIs, there is a clear requirement for more effective screening so that options can be applied to allow faster patient care and targeted treatment. Genetic Signatures' new *EasyScreen*™ STI Detection Kit simultaneously identifies 12 of the most significant and commonly encountered STIs. By being able to bring this detection into our suite of products, it demonstrates that the MDx 3Base™ technology is effective across different types of disease states and represents a significant expansion milestone in our *EasyScreen*™ product strategy.

For Genetic Signatures this opens up a whole new product range built on our existing platforms, and consequently offers a significant new potential revenue stream which aligns with our strategy of developing new products into the customer pipelines we have already identified. It is also another example of multiple products delivered into multiple jurisdictions, thus reducing risk of reliance on any single product.

The clinical validation of the new kit will provide an efficient progress pathway toward regulatory approval for this product and full market release.

Figure 1. 3Base™ Technology



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UCLA recently announced that the product evaluation trials completed on Genetic Signatures' rapid pathogen screening assays were very successful and showed 'improved pathogen detection compared to traditional methods'. UCLA Senior Vice Chair, Scott W. Binder MD also declared that UCLA looked forward to working with Genetic Signatures and commented that the products had many globally impactful applications.

What are the next steps for the Company in relation to gaining sales in the UCLA pathology network and what would be the leader products? How large is the broader US market for GSS products?

CEO John Melki
Both UCLA and Genetic Signatures were extremely happy with the trial success and the comments from Dr. Scott W. Binder are a strong industry validation for the Company. UCLA's Section Chief, Clinical Microbiology Dr. Romney Humphries Ph.D also commented that her department would soon be sharing the results in upcoming clinical publications, so we also look forward to that. As the US West Coast hub for other hospitals and pathology labs, UCLA's endorsement will help open the market further for us and we anticipate full FDA approval for supply of our first EasyScreen™ kits soon.

Furthermore, the launch of our range of Analyte Specific Reagents (ASRs) at the American Society of Microbiology conference in Boston in June was another important milestone for Genetic Signatures as these are essentially the basic blocks for in-house testing and clinical labs are already freely able to purchase these products. As such, US laboratories regulated by the Clinical Laboratory Improvement Act (CLIA) may purchase and use ASRs to develop proprietary tests thereby enabling our 3Base™ products to be sold into potentially 11,000 CLIA certified laboratories.

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With product trial success and new product launches in the US now commencing and a promising European distributorship now settled, what is the planned suite of GSS products that are targeted for distribution in these two markets?

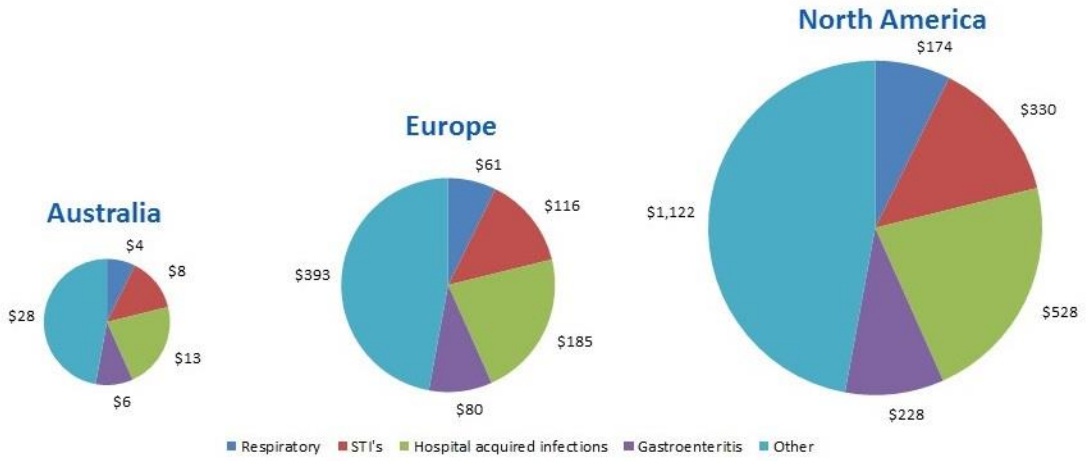
CEO John Melki
I'll begin this answer with a reference to our growth here in Australia where our first EasyScreen™ product was launched approximately three years ago. Our FY16 sales revenue of A$1.83M currently accounts for 3% of the total Australian MDx market (estimated to be worth A$59M[1], see Figure 2) and we have been growing that over the last three years at 92% CAGR (compound annual growth rate). Given the positive take-up of our 3Base™ products domestically, I am confident that acceptance and sales in our target markets will be comparable. And once again, the strategy of multiple products and multiple jurisdictions de-risks the commercialisation process and gives Genetic Signatures every opportunity for success.

In Europe we estimate the addressable market to be worth around US$435M[1] and are targeting our first significant sales in FY17 with four EasyScreen™ kits with CE-IVD approval for *C. difficile* detection and Enteric Protozoan and Bacteria infections. We also have two more kits undertaking CE-IVD approval processes for respiratory and enteric viral infections. With a Netherlands based European sales director now appointed, and strong client engagement progressing well, we also look forward to developing this market further in the foreseeable future.

The US addressable market is in the order of US$1.26B[1] and our market approach there is based on a direct sales and support model driven by an established and experienced US sales team. We anticipate initial sales penetration from our newly launched ASR product range as well as a number of products being prepared for full FDA approval. Ultimately unrestricted sales in the US will open up a much broader range of clinical laboratory customers for the Company. Our first product for approval will be the Enteric Protozoan kit.

In addition, Genetic Signatures has been certified by Health Canada, clearing the way for us to register in vitro (IVD) sales into the Canadian market.

Figure 2. MDx infectious disease market (US$million) for Australia, Europe and North America



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Incumbent suppliers of pathogen detecting products in the US and Europe would surely be distributed by very large global companies. Do you perceive impediments to Genetic Signatures taking market share away from such large companies? How confident are you that your products will gain market share from current providers?

CEO John Melki
The global MDx market is large and growing, with an estimated addressable market estimated at US$2.1B[1] by 2017. Our 3Base™ technology offers many advantages over incumbent methods, not least of which is the speed with which our assays can detect the presence of microorganisms over traditional based methods. This means patients can be treated within hours versus several days thanks to the wide array of targets we can detect in a high-throughput capacity compared with other molecular methods. To give you a practical example, one laboratory with a single technician can assay for over 20 causes of gastroenteritis in hundreds of patients during a standard working day. The difference this can make in a large populated hospital ward threatened with a virulent pathogen cannot be understated.

On top of the benefits of the diagnostic speed and wide array of detectible targets, our technology is compatible with both DNA and RNA microorganisms. Furthermore, our highly cost effective tests work with traditional equipment currently used in laboratories today, meaning that the laboratory does not need the expensive outlay of new equipment to start using our tests. Instead, using their existing equipment, small pathology labs can apply a high-throughput workflow from sample to result, performing 200+ specimen assays per day. Testing for multiple 'nasties' in one assay rather than singular testing per target pathogen is a significant and cost effective step change to the way this type of detection of pathogens has been carried out to date.

Genetic Signatures 3Base™ technology is a working example of modern and innovative science that is effective, efficient and allows for broader results. This is very appealing to our customers as it saves time, money and lives.

"I find that the fast turnaround time and the number of targets tested in the *EasyScreen*™ assays allow me to more rapidly identify highly infectious agents, potentially stopping the spread to other healthy individuals and thereby saving the health system money."
- Dr Damien Stark,
KOL and Senior Microbiologist, St. Vincent's Hospital Sydney

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The FY16 revenue, at $1.83m, represented an increase of 75% on the previous year of $1.04m and an increase of 167% on the 2014 revenue figure of $684,277. Obviously the products are now gaining traction in the domestic market. What is the opportunity to continue to increase product rollout and continued sales improvement in Australia? Do you expect US and European sales to contribute significantly to the next quarter revenues? How quickly can the new products such as ASR's, be taken up, given the UCLA trial success?

CEO John Melki
The Company's Board and management are satisfied by our three year CAGR of 92% in the Australian market and note that FY16 sales revenues of A$1.83m represents only 3% of the domestic MDx market, so we think we have much more of the 'local pie' to take, especially with several more products currently in advanced development. With our technology validated and our initial products proving popular, the Company's future new product pipeline with new and existing customers is promising.

Given historical acceptance and take-up of comparable health technology and applications in hospitals and clinical laboratories to date we are therefore confident that the year ahead will see significant increases in our revenues as we execute on our growth strategy both locally and offshore.

New products currently in R&D will continue to utilise our unique 3Base™ platform for detection of other diseases such as atypical pneumonia, meningitis, antibiotic resistance markers and Flavivirus infections (including Zika, West Nile, Dengue and Yellow Fever) as well as developing other assays that are unique to our 3Base™ technology, which is not limited to infectious diseases but has applications across a range of diseases.

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What do you see as the most significant impacts for Genetic Signatures in 2017 and what can shareholders expect to see from Genetic Signatures in the coming months?

CEO John Melki
Genetic Signatures has been exceptionally busy over the past year and have stepped up by moving out from our Australian marketplace into the US with the launch of our ASR products and through alliances with leading health laboratories such as UCLA. FDA approvals for full diagnostic kits are underway. Subsequently we anticipate our first US sales to commence soon. We have also ramped-up our R&D process that is feeding through new product and helping the Company become recognised for our unique technology.

Products and development activity that we expect to roll-out in FY17 include:

- Expansion of the EasyScreen™ product range with the release of new products to target significant market opportunities;
- The release of two new products into the Australian market in FY2017, which will form the basis for subsequent approvals and release in the EU and US;
- Advancing development of atypical pneumonia, meningitis, antibiotic resistance markers and Flavivirus (including Zika, West Nile, Dengue and Yellow Fever); and,
- Continued IP protection and maintenance of the Company's existing patent portfolio.

Following the completion of this fund raising we will be able to advance the Company's growth and strategy on a number of fronts as I've outlined, the result of which will put us well ahead of our original stated plan following IPO. We can now focus on driving shareholder value by accelerating revenues via growing distribution and direct sales activities; by R&D providing more next generation products; by accelerating jurisdiction approvals; and, by continuing to build our already established brand as a unique and successful global MDx company that is helping solve a global problem.

We are targeting breakeven cash flow in FY18 and in the coming months I look forward to delivering continuing positive news and company reports to our shareholders.

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Thank you John

For more information about Genetic Signatures Limited, visit www.geneticsignatures.com or call John Melki on +61 2 9870 7580

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[1] Source: World Market for Molecular Diagnostics, 5th. Edition (Infectious Disease, Oncology, Blood Screening, Pre-Natal and Other Areas) Kalorama Information, Published: 1/9/2013, page 168 and www.transparencymarketresearch.com/pressrelease/global-enteric-disease-testing-market.htm