Advanced Molecular Diagnostic Systems

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Thursday 19th November 2009

Chairman's Address to the Genera Biosystems Limited Annual General Meeting 11 a.m. on 19 November 2009

Genera Biosystems Limited (Genera) has had a productive and successful period in the 12 months since I addressed the company's first AGM as a publicly listed company.

At that time, Genera had only been listed on ASX for a few months, having raised capital in a difficult market.

We were finding our feet as a listed company dealing with the challenges of encouraging long-term supporters for Genera and its business plan at a time when the life sciences sector more broadly was attracting very little interest.

However we were confident that Genera had promising intellectual property and that our platform technologies had great prospects in molecular diagnostics. Our challenge was to deliver on that potential.

With that focus in mind, shortly after listing we tabled a business plan with clearly identified milestones for realising the near-term potential of our company. That was the Australian and European

registration of our lead product, *PapType*, to be followed by commercialisation of this product.
I am pleased to report that, thanks to a lot of effort and hard work, Genera is delivering against that plan and target deliverables.
The significant events of the **2009 review year**, and through to today, have included:

October 2008: The release of results of a 100 sample trial using archival material from women who had had equivocal pap smears. This pilot study was undertaken in conjunction with the Royal Women's Hospital in Melbourne and indicated that *PapType* shows improved pre-cancer detection rate as compared with Qiagen's Hybrid Capture 2 (HC2). At Genera, we were delighted that these results hinted that *PapType* may have superior performance characteristics when compared with the market-leading HPV test.

December 2008: Genera relocated to a custom-designed laboratory and manufacturing facility in the Small Technologies Cluster at Scoresby. This provides Genera with a world class facility and the ability to supply 80-100,000 tests per month. The move was a necessary step in positioning Genera for TGA approval for *PapType* and subsequent products.

April 2009: Mining a 1000 sample data set provided by Gribbles Pathology, Genera establishes that *PapType* was equally effective with both leading Liquid Based Cytology processes - Hologic's *ThinPrep* and Becton Dickinson's *SurePath.* (It should be noted that Gribbles Pathology has been successfully using a laboratory validated version of *PapType* for three years on over 8000 specimens)

September 2009: Genera announced the results of a clinical study in conjunction with the Royal Women's Hospital, Melbourne, on cervical smear specimens of almost 900 women with abnormal Pap smears. This was a pivotal study for Genera. Testing with *PapType* resulted in significantly fewer false negative results (8.9%) than testing with Hybrid Capture 2 (20.9%). This result provided statistically significant confirmation of *PapType's* superiority over the market leading HPV diagnostic product at detecting cervical pre-cancer.

October 2009: The Australian Therapeutic Goods Administration granted Genera a Licence to manufacture in vitro diagnostic devices. This certifies Genera's compliance to ISO 13485:2003 the internationally recognised quality system standard for design and manufacture of medical devices.

These milestones have culminated in Genera filing for listing on the Australian Register of Therapeutic Goods for *PapType* this week. This significant achievement has been announced to the ASX this morning, and represents a major milestone in Genera's journey towards commercial success.

Turning now to the future, we believe that the coming six months promises to be an exciting period for the *PapType* product and for Genera more broadly.

Genera is on track to attain TGA registration for *PapType* and CE Marking by the end of the 1st Quarter 2010. We are highly confident of delivering on this milestone.

In order to achieve these registrations, we will first have to complete a 'Repeatability & Reproducibility' study that will

demonstrate how results obtained using *PapType* do not vary within or between laboratories or technicians.

This study is commencing shortly and will, in part, be conducted at two of Sonic Healthcare's laboratories in Sydney. Genera expects this study to be completed by the end of December 2009.

Genera is also finalising plans for the commercial launch of *PapType*. During the course of the year we have kept the market abreast of our progress with strategic discussions with major international diagnostics companies with a strong interest in women's health.

These discussions have been undertaken with a view to entering into a global licensing deal, or a series of regional licensing deals, with a partner or partners who are well placed to maximise the commercial potential of *PapType*.

Assisting potential partners with their due diligence investigations into the *PapType* product has been a major workstream for the Genera team in recent months.

Our Scoresby site has been visited by representatives of four possible strategic partners as part of the process of building an understanding of both *PapType* product and the versatility of the AmpaSand platform.

At Genera's 2008 AGM I outlined the extreme corporate interest in HPV testing that had led to three corporate deals, each of between US$300 – 600 million which took place in the second half of 2008 and which were focused on the HPV testing market.

This interest has developed as a consequence of the pivotal role that HPV testing is expected to assume in cervical screening and

underpins the expectation that the HPV diagnostic market is set to achieve a size of US$1 – 2 billion within the next few years

As a consequence, diagnostics companies involved in the women's health market uniformly recognise a strategic need to develop a presence in HPV testing.

The nature and level of interest in Genera's *PapType* test reflects the reality of this market dynamic.

However, major commercial deals are rarely concluded quickly as entry into a significant transaction is a major decision for both parties. Nevertheless, we have been pleased with the progress that has been made over the course of the year, and are confident of concluding a commercial deal in coming months.

The Genera Board will be focused on maximising the short and long term position of our shareholders as a commercial deal takes shape.

While achieving a strong commercial outcome for *PapType* has been the starting point for strategic discussions, we will give appropriate consideration to a full range of transaction alternatives, whether they are focused on the *PapType* product, the AmpaSand platform, or Genera as a whole.

Moving forward, Genera is planning enhancements to both the processing characteristics of *PapType* designed to reduce handling time and the cost of running the test and to prepare for high-throughput operation. This should enhance *PapType*'s appeal to pathology lab customers and increase the product's competitiveness over other products.

Further opportunities for Genera's 1st generation proprietary diagnostic platform *AmpaSand* are now under consideration for

product development. Dr Bollands will talk further about these opportunities in his presentation.

In summary I can confidently say the Genera Biosystems Limited is strongly placed, strategically, operationally and from a product quality perspective, to deliver a material commercial outcome over the next six months or so.

In closing, I would like to recognise that none of Genera's achievements over the last 12 months would have been possible without ongoing shareholder support. All of us at Genera have worked hard to earn the loyalty of our shareholders, and we have been particularly pleased to achieve increased institutional shareholder and stockbroker support during the course of the year.

We look forward to your continuing support which will position the company strongly in our commercial negotiations, and in turn enable Genera to deliver quality outcomes for all our stakeholders.

Finally the Board and I would like to thank the diligence and hard work of Dr Allen Bollands, our CEO, and the staff of Genera without whose endeavours we would not be in this favourable position.

Thanks also to the efforts of our Scientific Advisory Board headed by Professor Susan Garland and to Gribbles Pathology and Sonic Healthcare for their continuing support of our product and company.

The Board of Genera believes that we can all look forward with confidence to the next 12 months.

Mr Fernando Careri
Chairman

19th November 2009

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About Genera Biosystems:

Genera Biosystems Limited (ASX: GBI) is a molecular diagnostics company that develops, manufactures and distributes advanced molecular diagnostic tests. Its first product, PapType™, a test which simultaneously detects and genotypes human papillomavirus, is on sale in Australia through Healthscope. International registrations are expected in 2009. The company has a development pipeline of products including novel tests for Chlamydia trachomatis, and Neisseria gonorrhea.