Advanced Molecular Diagnostic Systems

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The ASX Company Announcements office: - Chairman's AGM Address

2008 has been a landmark year for Genera Biosystems Limited (Genera). Despite an extremely tough environment for capital raising, hard work and perseverance saw the Company successfully list on the ASX in June 2008.

Much of the Company's efforts prior to June 2008 related to preparing for listing. However, a number of other initiatives were undertaken in this period which focused on establishing a firm foundation for commercialisation of Genera's products.

One significant initiative related to obtaining a 'Freedom To Operate' opinion in relation to the PapType product from the Company's US patent attorneys.

'Freedom To Operate' had been a contentious issue for new entrants into the HPV testing market, and receiving the advice that we have 'Freedom To Operate' in December 2007 was a significant event for Genera. We also took the opportunity to strengthen our intellectual property portfolio with the filing of additional provisional patents.

A further milestone in the first half of this year was an agreement with Sonic Healthcare, under which Sonic will assist Genera with studies required by global regulatory bodies.

This agreement also sets out supply terms for the potential sale of PapType to Sonic Healthcare. Genera is already seeing great benefit from this strong working relationship. Sonic is the world's third largest corporate pathology operator and the leading private operator in Australasia and Europe.

Sonic Healthcare's leading cervical screening experts have been enthusiastically supporting Genera's efforts to bring PapType to market. This has been both very encouraging and gratifying for Genera.

Also prior to the IPO, Genera's operational team prepared a detailed project plan for the fitting out of a GMP-certified manufacturing facility and the various steps necessary to obtain TGA and CE-Mark approval for PapType.

We were able to hit the ground running and we are on track to achieve these milestones as per our market release in August 2008.

Immediately following the ASX listing of Genera, the Company entered into a commercial arrangement with Gribbles Pathology (Gribbles) for the supply of PapType. Gribbles, which is the third largest pathology operator in Australasia, collaborated with Genera on the development of PapType and is very familiar with the product. Gribbles has validated PapType on their laboratory equipment to NATA and National Pathology Accreditation Advisory Council standards. While HPV testing is yet to achieve Medicare reimbursement in Australia except in a very narrow range of circumstances, use by Gribbles has demonstrated the commercial viability of the product and provides an important third party reference point.

Turning now to the current year.

Genera is in sound condition from an operational perspective. We have tight management and financial controls in place and a passionately

engaged group of employees who are diligently focussed on delivering the Genera business plan.

The Genera team has a high level of confidence in our platform technologies – AmpaSand and QSand. Specifically in relation to PapType, we are confident that we have a product that provides substantial ease of use benefits to pathology laboratories, whilst the ability to simultaneously detect and genotype all 14 High Risk types of HPV provides significant actionable clinical data when compared with competitor products.

In October, Genera was delighted to release the results of a 100 sample trial using archival material from women who had had equivocal pap smears. This pilot study was undertaken in partnership with the Royal Women's Hospital in Melbourne.

This study indicates that PapType shows an improved pre-cancer detection rate in this population sample as compared with Qiagen's Hybrid Capture 2 (HC2). HC2 is currently the only cervical cancer screening test approved by the US FDA.

Genera is tracking well against the Business Plan that was set out in its corporate presentation in August 2008. Genera is in the process of moving its facilities to Scoresby and we are targeting an official opening in March 2009.

We are on target for GMP certification early in the 2nd quarter of 2009, together with clinical validation of PapType sufficient for TGA and CE Mark certification. We expect that TGA registration and CE Mark for PapType will then follow shortly thereafter.

Once these registrations are achieved, full commercial sale of PapType will be possible in Australia, Europe and other markets that rely on the CE Mark registration process such as Latin America and effectively, China.
With solid progress being made towards product registration, increasing focus is now being directed towards establishing PapType as a significant commercial product.

In this context, it is important to understand the market for HPV testing.

For many years the HPV testing market has been growing at around 40% annually and this growth is expected to continue for years to come as the market grows towards its likely ultimate size of approaching 100 million tests per annum in the developed world. This growth is being driven by increasing recognition of the role that HPV testing can play in cervical cancer detection.

Genera is well placed to push into the European and the United States markets.

At present, around 8.4 million HPV tests are performed annually in the United States and around 2 million in Europe. Only a small number are performed here in Australia. The United States is the most developed market as guidelines and reimbursement arrangements for HPV testing have been in place in that market for several years. Yet, the United States has only a modest penetration rate for HPV testing of 22%.

Higher growth and more immediate potential for PapType is present in the European Market.

PapType simultaneously detects and genotypes all 14 types of High Risk HPV.

This information has genuine clinical and economic value. Moreover, early results from clinical trials indicate that PapType demonstrates an enhanced ability to detect high grade cervical pre-cancers.

In Europe, guidelines for the use of HPV testing have recently been introduced or modified in a number of markets, with reimbursement expected to grow. For example, the National Health Service in Britain is introducing HPV testing in 2009 in 6 sentinel sites, with the nation-wide introduction of HPV testing expected to follow.

Lower regulatory hurdles, meaning a lower cost of entry, makes Europe the first priority market for Genera.

Growth in the use of HPV testing in Australia is reliant on guidelines and Medicare reimbursement for HPV testing becoming available.

Genera understands that the Medical Services Advisory Committee is currently considering reimbursement of both liquid cytology pap smears and HPV testing. As Genera has an excellent relationship with the largest and third largest pathology companies in the Australian market, it would be extremely exciting if Medicare reimbursement were to be introduced.

Depending on the scope of reimbursement, the Australian market alone could represent an opportunity of several hundred thousand PapType tests per annum for Genera.

In the European market, Genera is actively discussing market opportunities with Sonic Healthcare in the U.K. and Germany.

Sonic Healthcare currently undertakes a modest number of HPV tests using the Qiagen Hybrid Capture 2 product as well as outsourcing. They recognise that having access to PapType, with its compelling competitive features when combined with the market opportunity for HPV testing, may provide an opportunity to win additional share of this high growth market.

We are currently looking to develop additional partnerships for PapType in Europe in order to achieve a broader customer base as quickly as possible.

We have had strong initial interest from several ideally placed potential partners.

Genera also has high hopes for our partnership with Polartechnics and Healthscope in relation to the CerviScreen product.

Cerviscreen is Polartechnics HPV self-sampling device which uses Genera's PapType test to determine whether or not a patient is infected with High Risk HPV.

Many women currently fall outside of traditional Pap screening guidelines, representing a lucrative market opportunity over and above PapType's use in routine testing.

A further commercial development in the coming months may relate to licensing of the AmpaSand platform for the development of molecular diagnostic tests by third parties. A number of international parties have already expressed interest in the platform. Further, Genera continues to develop new tests to run on the AmpaSand platform with a highly innovative combined test for Chlamydia and Gonorrhoea being the next test set for commercial launch. Initial discussions with potential customers suggest that this test has the ability to quickly win market share in this US$350 million market.

As we progress towards commercial success, the Genera Board is acutely aware that the molecular diagnostics industry in general, and HPV testing in particular, are currently the subject of extreme corporate interest. The fast growing nature of the HPV testing market is attracting strong interest from all of the world's leading diagnostic businesses.

Following the acquisition of the industry pioneer, Digene, for US$1.6 billion – a 48x EBITDA multiple – in 2007, interest in companies with HPV assets has only intensified.

During 2008, and more specifically since Genera's listing in June, there have been three deals completed involving the acquisition of companies whose primary assets have been HPV assays.

Transaction values have ranged between US$300 and US$600 million. None of the three targets have been more than a year or two in front of Genera in the commercialisation of their HPV assets, and one of the three (which changed hands for US$345 million) appears to be no more advanced than Genera's current state.

The Board of Genera is committed to "closing the gap" between the valuations that have been applied to international HPV businesses and our current market capitalisation.

In the short term, this involves delivering on the Business Plan and ensuring that institutional investors both in Australia and overseas are aware of the Company and its potential.

We also recognise that a means of creating an outstanding result for all of our shareholders, and other stakeholders, might be to enter into a value-crystallising corporate transaction at an appropriate time. Your Board is taking steps to ensure that we are well prepared for this possibility.

In closing, I would like to reiterate that the coming year will be an exciting one for Genera. The Genera Board has every reason to be confident, and believes that shareholders can be very confident, that Genera will deliver on its potential over the next 12 months or so.

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 gonorrhoea.

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