Advanced Molecular Diagnostic Systems

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Thursday 19th November 2009

**CEO Presentation to the Genera Biosystems Limited Annual General Meeting 11 a.m. on 19 November 2009**

Attached is the presentation to be given by the CEO of Genera Biosystems Limited, Dr Allen Bollands at the Company’s Annual General Meeting.

Further details contact:

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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 gonorrhoea.
Operational review

Dr. Allen Bollands,
Chief Executive Officer
• Develop, manufacture and sell Human Medical Test kits for use by commercial pathology laboratories.

• First product: **PapType™ HPV detection and genotyping kit**
  – Detects the HPV virus that causes cervical cancer
  – On sale in Australia through Gribbles pathology
  – TGA approval and European CE marking expected 1st quarter calendar 2010
  – Kit contains:
    • Biochemical reagents
    • AmpaSand™ detection beads
    • Software

• ASX listed (Ticker GBI)
  – 61.6m shares on issue
  – Approx. $53m market capitalisation at 17/11/09
Brief technology review
Core capability: Multiplexed MDx tests

• Molecular Diagnostics (MDx):
The use of information derived from nucleic acids (DNA and RNA) to:
  – Identify disease causing organisms (e.g. bacteria and viruses)
  – Determine risk profile for specific diseases (e.g. breast cancer)
  – Identify patients who may respond to specific therapies

• Multiplexing:
  – Combination multiple tests into single reaction
  – Multiplexing can:
    • Increase the amount of actionable data from a single specimen
    • Reduce the time and resources required to generate required results
What are AmpaSand beads?

- Multiplex PCR reaction detection system:
  - Arrayed clusters of coded silica beads in liquid
  - Bead coding by:
    - Size
    - Colour (1 or 2 colours)
    - Colour intensity
    - Relative count
  - Each cluster (approx. 2,000 beads) detects a different target
  - Detection is by bead colour change
The AmpaSand process

Patient specimen containing unknown pathogens

PCR reaction

Amplified DNA

AmpaSand beads bind to their cluster specific target in the amplified DNA

Bead size and colour “read” by Flow Cytometer

Unhybridised coded beads

Qplots data readout
PapType™
First commercial manifestation of AmpaSand technology
PapType™ HPV detection and genotyping kit

Biochemistry

HPV detection beads

Increasing yellow fluorescence

Type 58
Type 59
Type 18
Type 56
Type 45
Type 6

Type 52
Type 66
Type 16
Type 51
Type 39
Type 3

Type 68
Type 66
Type 16
Type 33
Type 31
Type 11

Type 52
Type 59
Type 18
Type 56
Type 45
Type 6

Type 52
Type 66
Type 16
Type 51
Type 39
Type 3

Type 68
Type 66
Type 16
Type 33
Type 31
Type 11

*: Positive Human control

Software
PapType's role in the cervical screening process
HPV market opportunity

$US 350m today. 40% pa growth 2003-8

Science
- 32% cervical cancer deaths caused by Pap failure
- HPV testing more sensitive than Pap for pre-cancer

Policy
- 2006 consensus guidelines on cervical screening (US)
- Introduction of HPV triage (UK)

Other
- Increasing shortage of cytologists to read Paps
- Introduction of the HPV vaccine

$US 1-2 billion opportunity
## Corporate transactions in the HPV space

<table>
<thead>
<tr>
<th>Date</th>
<th>Acquirer</th>
<th>Target</th>
<th>Notes</th>
</tr>
</thead>
</table>
| June 2007  | QIAGEN [Netherlands]      | DIGENE [USA]            | US$1.6bn deal; 47.9 x LTM EBITDA  
Gained access to Digene’s HPV testing monopoly                      |
| June 2008  | HOLOGIC [USA]             | TWT [USA]               | US$580m deal. TWT not EBITDA positive  
Driven by interest in TWT Cervista HPV portfolio                    |
| July 2008  | SOLVAY [Belgium]          | INNOCENETICS [Belgium]  | US$316m deal; 74% uplift on pre-bid value.  
2-way competitive bidding                                             |

**TWT public filings:** Approaches from 12 potential acquirers in 12 months to transaction; Eight went to due diligence.
Key achievements 2008-9
Summary

• Clinical performance demonstration
  – Pilot 100 patient study
  – Gribbles 1,000 patient study

• Established manufacturing facility

• Significantly progressed commercial discussions
- PapType significantly outperformed market leading test (HC2) in cervical pre-cancer detection:
  - PapType returns fewer than half the false negatives of HC2
  - Enhanced detection of more serious disease
  - 95% full or partial genotyping concordance with market-leading genotyping assay
  - 95% repeatability in clinical specimens
Significantly fewer false negative results compared to HC2

- PapType returns fewer than half the false negatives of HC2
- False negative = missed cervical disease

**NB:**
- True positive = Specimen returned a positive HPV test, and was also proven positive for cervical disease by histological examination.
- False positive = HPV positive test result but proven disease negative by histological examination
- True negative = HPV test negative and proven disease negative
- False negative = HPV test negative but proven disease positive
## Enhanced detection of the most serious pre-cancerous lesions

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>False negative by...</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>PapType</td>
</tr>
<tr>
<td><strong>CIN 3 + ACIS</strong></td>
<td>327</td>
<td>18 (5.5%)</td>
</tr>
<tr>
<td><strong>CIN 2</strong></td>
<td>204</td>
<td>34 (16.7%)</td>
</tr>
</tbody>
</table>

**NB:**
The acronym CIN means “Cervical Intraepithelial Neoplasia”. Cervical precancer is stratified by level of seriousness, depending upon the appearance of cervical cells under microscopic examination.

CIN1 is considered the least serious; CIN3 the most. The more serious the grading, the less likely it is to spontaneously return to health.

ACIS = Adenomacarcinoma in situ – i.e. actual cancer
95% full or partial genotyping match with Linear Array
PapType vs cytology in 1,000 women

• Population
  – 1,000 women having undergone PapType and cytology testing approximately simultaneously
  – Average age 38.1 years
  – Minimum age 16 years; maximum age 82 years

• Specimen types
  – 74% Liquid-based cytology
    • 63% ThinPrep
    • 37% SurePath
  – 23% cervical swabs
  – 1% high vaginal swabs
  – 2% unknown
• Performs equivalently with both brands of liquid-based cytology
  – *ThinPrep*, Hologic Inc.
  – *SurePath*, Becton Dickinson

• Demonstrated high level of correlation with negative cytology:
  – Strong Negative Predictive Value
PapType: NPV of 99% for cytology positions as a screening assay

- **1000 patients**
  - 829 PapType negative (82.9%)
  - 171 PapType positive (17.1%)

  - 767 cytology negative (92.5%)
  - 53 CIN1 (6.4%)
    - 2 ASCUS
    - 7 CIN2+
  - 171 PapType positive (17.1%)
    - 24 CIN2+ (14%)
    - 147 <CIN2 (86%)
      - 95 cytology negative
      - 52 CIN1
      - 2 ongoing history on CIN2+

Strong correlation of PapType negative result and absence of serious cervical pathology (i.e. CIN ≤ 1). High Negative Predictive Value
Recently completed new custom built manufacturing facility in Scoresby

Australian Therapeutic Goods Administration (TGA) inspected June 2009
  – NO MAJOR NON-CONFORMITIES

Licence to manufacture *in vitro* diagnostic devices received October 2010

Existing infrastructure will give capacity to produce 80,000 – 100,000 tests per months
  – Highly competitive cost base, with improved yield benefits yet to be realised
  – Options for future expansion
• Objective: Licence to strategic partners
  – Single global or multiple regional licences
  – Long term, mutually beneficial relationship
  – Strategic Interest in Women’s Health

• Current status:
  – Active dialogue with multiple organisations
  – Four companies have visited Melbourne facility
  – Three companies provided with beads for evaluation
  – Announcement anticipated 1Q10
**PapType: Positioning, features and benefits**

**Positioning:** *PapType provides the optimum combination of actionable and reliable clinical information for the physician, with ease and speed of use for pathology laboratories*

<table>
<thead>
<tr>
<th>Features…</th>
<th>Benefits…</th>
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<tbody>
<tr>
<td>Simultaneous detection and genotyping</td>
<td>• More actionable information more quickly</td>
</tr>
<tr>
<td>Better detection of CIN2+ compared to HC2</td>
<td>• Reduced risk of undetected cervical disease</td>
</tr>
<tr>
<td>Small specimen volume only</td>
<td>• Reduced number of QNS</td>
</tr>
<tr>
<td>Internal cellularity control</td>
<td>• Reduced false negatives from operator error</td>
</tr>
<tr>
<td>Attractive processing characteristics</td>
<td>• Relatively short processing time and few handling steps</td>
</tr>
<tr>
<td>PapType</td>
<td>HC2</td>
</tr>
<tr>
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</tr>
<tr>
<td><strong>Dects 14 HR and 2 LR types:</strong> 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68 and 6, 11</td>
<td>13 HR types only. No type 66.</td>
</tr>
<tr>
<td><strong>Simultaneous detection and genotyping:</strong> Full genotyping in a single reaction.</td>
<td>Detection only. No genotyping.</td>
</tr>
<tr>
<td><strong>Internal control:</strong> Reduces likelihood of false negatives</td>
<td>No internal control</td>
</tr>
<tr>
<td><strong>Efficient processing:</strong> 6-7 hours total processing and 4 handling post-extraction steps. One well per patient (91 patients/plate).</td>
<td>6-7 hours and 4 handling steps</td>
</tr>
<tr>
<td><strong>Small specimen volume:</strong> 800 µl - Reduces risk of QNS</td>
<td>4 ml</td>
</tr>
<tr>
<td><strong>Objective results assessment:</strong> Automated call via Qplots. High risk Y/N only</td>
<td>Automated call. High risk Y/N only</td>
</tr>
<tr>
<td><strong>Leverages existing lab infrastructure and expertise</strong></td>
<td>Test-specific equipment and expertise required.</td>
</tr>
<tr>
<td><strong>Competitive cost/test:</strong> Attractive manufacturing costs</td>
<td>US$21/test</td>
</tr>
<tr>
<td><strong>Regulatory status:</strong> Australia: RUO. TGA approval 1Q10 EU: CE mark from 1Q10</td>
<td>FDA approved and CE marked</td>
</tr>
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PapType: Excellent operational characteristics

**Digene HC2 High Risk HPV test**
- 90 specimens
  - 6-7 hours
  - HR HPV*: ✓/✗

**Cervista HPV test plus reflex Cervista 16/18**
- 28 specimens
  - 6-7 hours
  - HR HPV: ✓/✗
- 45 specimens
  - 4 hours
  - 16/18: ✓/✗

**PapType**
- 90 specimens
  - 6-7 hours
  - HR HPV: ✓/✗
  - plus full genotyping

*: No type 66
The importance of human control

Specimen transfer

Specimen Processing

Human + HPV 16 +

IND Retest

HPV HR - FALSE NEG

HPV HR +
2009-10 outlook
Current position

- Cash as at 6th November 2009 of approx. $4.1m
- Quarterly burn rate approx. $800K, reducing to approx. $650K from 1Q10
- Value creating milestones:
  - 4Q09: TGA submission for PapType
  - 1Q10: Company-transforming agreement on PapType
    TGA approval for PapType
    CE-marking/First sales in Europe
  - 1-2Q10: Australian screening study
    PapType vs market leader in US specimens

Strictly confidential
Co-development of RTI-plex™

• Proposal to develop 19-plex respiratory panel under review by a partner

• Proposal:
  – Partner to support initial development costs
  – Genera to finalise regulatory package
  – Preferential supply rates and royalty to partner
  – GBI to retain all other commercial rights

• RTI-plex:
  Simultaneously detection and individual identification of:
  • Respiratory Syncytial virus (RSV)
    – Subtype A, Subtype B
  • Influenza A, B, C
    – Non-specific influenza A
    – Swine and Avian
  • Parainfluenza
    – Type 1, Type 2, Type 3
  • Metapneumovirus
  • Rhinovirus
  • Adenovirus
  • Corona Virus
    – NL63, 229E, OC43, HKU1
  • SARS

Strictly confidential
Future development strategy

- **PapType Rapid**
  - Genera has identified a number of areas where PapType’s operating processes can be improved
  - New technology could reduce processing time by 40%
  - To be performed in conjunction with partner

- **Additional products under consideration**
  - STI-plex – multiplex sexually-transmitted infections
  - Hospital acquired infections

- **AmpaSand application expansion**
  - Multiplex protein detection assays

- **Ultrasensitive optical biosensor**
  - QSand
• ASX-listed company
  – Approx. $55m market cap
  – Strong register
  – Cash for >12 months

• Lead product commercial ready:
  – Very competitive product profile
  – Substantial global market opportunity
  – Strong partner interest
  – Near term milestone/royalty income stream

• Good track record of value creation:
  – Multiple near-term value-inflexion points

• Multiple platform development opportunities
Thankyou

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