



2012 Annual General Meeting

22nd November 2012

Mr. Lou Panaccio
Executive Chairman

Overview



Objective

Develop compelling multiplexed test solutions for the \$4BN global molecular diagnostic testing industry using our silica bead based AmpaSand technology platform.

Developments to date

- Pap Type™ HPV detection and genotyping test (TGA, CE-IVD)
 - Projected Global Market \$500M+
- RTI-plex™ Respiratory pathogens test
 - Projected Global Market \$200-500M
- Sirocco high volume testing instrument
- QPlots analytical software

Pipeline tests

- STI-plex™ and Gen-plex™ for sexually transmitted infections
 - Projected Global Market \$350-500M

Target Market – Pathology Laboratories



- Genera's tests are intended to be used by diagnostic pathology laboratories.
- Pathology laboratories are in the business of providing information (obtained by analysing patient specimens) to clinicians who use the information to treat their patients.
- The laboratory business is very competitive and dominated globally by large commercial enterprises.
- These businesses face continual margin pressure:
 - Payers seek to squeeze reimbursement.
 - High fixed cost operating structures.
- What factors will a laboratory consider when assessing a new, or replacement, test?
 - Cost per test
 - Labour cost per test
 - Turn around time
 - Test performance
 - Clinical validation
 - Clinician demand
 - Information provided
 - Ease of use
 - Equipment requirements

Target Market – Pathology Laboratories



Why do we believe that diagnostic laboratories will want to use Genera developed diagnostic tests?

Clinical data

- The first test developed by Genera – PapType (HPV) has been independently tested by Prof Jack Cuzick and his team at the Wolfson Institute of Preventative Medicine in London and compared to other commercially available HPV tests. PapType's ability to genotype HPV is a significant point of difference and the trial suggests that the accuracy of predicting a patient's risk of disease can be increased with the use of the genotyping data.
- PapType is about to be used in Prof Cuzick's next trial (Predictors 3), this involves 6000 patients and will compare Genera's test with virtually all other commercial molecular tests.
- PapType – ability to genotype
- RTIplex – more extensive analyte panel

Operational Performance

- Multiplexing
 - Combining multiple tests into a single reaction
 - Provides more information per test, allows more informed clinical management
 - Results in single assay timeframe
 - Reduces reagent costs
 - Streamlines laboratory workflows
 - Allows for higher volume batch processing
 - Reduces manual handling
 - Cost per test reduced
 - Multiple assays on one platform reduces instrument requirements/bench space
 - Suited to 'coned' reimbursement models.

Target Market – Pathology Laboratories



Why do we believe that diagnostic laboratories will want to use Genera developed diagnostic tests? (cont.)

Sirocco

- Automated platform allows different tests to run on one instrument
- Allows high volume processing
- Reduces manual handling steps

Processing Time

- Faster than competing systems
- PapType on Sirocco v HC2 – 5 hours v 8 hours

Cost

- AmpaSand bead based tests are relatively inexpensive to produce

Overall Market Size

Table 4.2: World Market for Molecular Diagnostics, 2011 - 2015 (\$M)*

	2011	2012	2013	2014	2015
Blood Screening	918	1056	1215	1397	1606
HIV/HCV Testing	847	915	988	1067	1152
STD Testing	546	611	685	767	859
Oncology Testing	488	576	680	802	947
HPV Testing	353	406	467	537	617
Hospital Infections	116	136	159	186	217
Genetics	480	557	647	750	870
Total	3,748	4,257	4,841	5,506	6,268

* Business Insights Ltd 2010

World Market HPV Testing



HPV Market Segment

Table 4.6: Molecular Diagnostics HPV testing market, break up by competition (\$M)*

	2011	2012	2013	2014	2015
Digene HPV (Qiagen)	282.3	284.0	280.0	268.3	277.7
Aptima (Gen Probe)	15.0	40.6	70.0	107.3	154.3
Quest HPV Test	16.1	17.8	19.5	21.5	23.6
Cervista	24.7	32.5	42.0	53.7	74.1
Others	14.7	30.9	55.1	85.8	87.4
Total	352.8	405.8	466.6	536.6	617.1

** Business Insights Ltd 2010*

Achievements



- R&D Activities continue on test, software and automation development.
- PapType – TGA approved and CE marked.
- Scoresby manufacturing facility TGA approved – ISO quality management.
- RTIplex developed in collaboration with Healthscope.
- Prof Cuzick trial # 1 completed (1099 specimens)
- Solid Phase version of PapType developed.
- Sirocco automation platform developed.
- Prof Cuzick trial # 1 updated with Solid Phase version of PapType.
- QPlots analytical software updated to operate with Sirocco.
- Additional UK clinical trials (6000 + 1500 specimens) about to commence.
- Salamao & Zoppi test validation and new test development agreement signed.
- TGA registration process for PapType (new) and RTIplex underway.
- Patents granted – IP position strong.
- Manufactured sufficient PapType and RTIplex test kits for clinical trials and validation purposes.

Work Plan



March 2013

- Complete update of QPlots software and final sign off on RTIplex with Healthscope.
- Install and successfully validate Sirocco instrument and PapType & RTIplex tests in Brazil.
- Complete UK clinical trials using Sirocco instrument
- Exchange Sirocco validation and collaborative agreements for 3 key sites; Australia, Europe & USA.

March – June 2013

- Enter into commercial agreement with SZD.
- Install and successfully validate Sirocco instrument – key site #1.
- IVD company engagements.
- Commence supply of RTIplex for Australian influenza season.

June – September 2013

- Install and successfully validate Sirocco instrument – key site #2 (3?).
- SZD – supply PapType, RTIplex (?)
- IVD company engagements.
- Key site #1 – commercial discussions.

Work Plan (cont.)



Strategy

- Direct engagement with diagnostic laboratories.
- Sirocco and test validation agreements.
- Leverage diagnostic laboratory interest in existing tests and Sirocco platform, together with test development potential, underpinned with strong clinical data and IP position to facilitate commercialisation discussions with IVD companies.

Capital Requirements

- Existing R&D activities - \$160K per month
- Sirocco placements at 3 key sites - \$750K - \$1M.

Contribution Analysis

Sirocco instrument running 400 tests per working day.

Revenue	100,000 tests per annum @ \$15	=	\$1,500,000
COGS	100,000 tests @ \$5	=	(500,000)
Equipment		=	(250,000)
Contribution		=	\$ 750,000

Summary



- Genera has shown that its AmpaSand platform can be used to successfully develop diagnostic tests that can compete in the growing multiplexed MDx market.
- Test data obtained by Prof Jack Cuzick who is recognized as a world leader in cervical cancer confirms the clinical performance of PapType and the benefits of genotyping HPV.
- Sirocco demonstrates that Genera diagnostic tests can be automated and operate in high volume laboratories.
- Genera believes that direct engagement with diagnostic laboratories is the most appropriate way to facilitate commercial discussions with IVD companies
- Possible Commercial Outcomes:
 - IVD company acquires Genera
 - IVD company acquires rights to AmpaSand Platform, PapType and/or RTIplex
 - IVD company and Genera develop JV
 - Genera installs Sirocco in diagnostic laboratories and supplies diagnostic tests directly



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