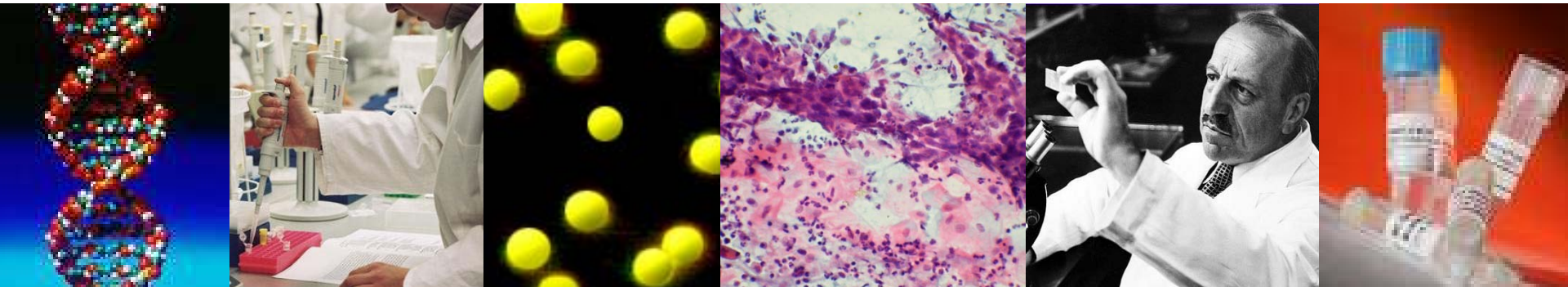


Advanced Molecular Diagnostic Systems

Company Annual General Meeting – November 26th 2008

Allen Bollands, Chief Executive Officer



Genera Biosystems: Technology for Molecular Diagnostics

GBI's core business:

Development of MDx tests using its proprietary DNA testing platform – coded AmpaSand™ beads

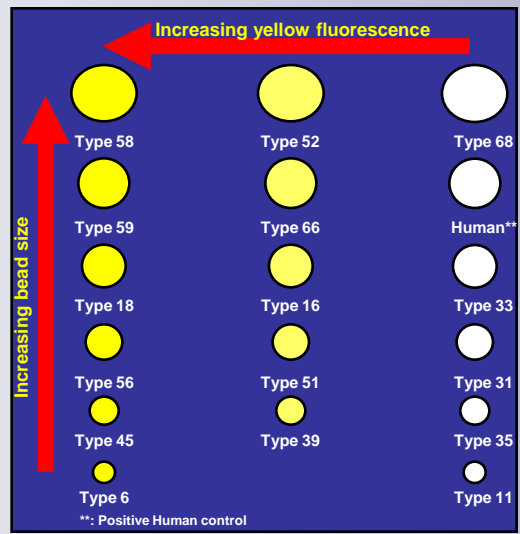
- AmpaSand can be used for any DNA detection assay
- Lead AmpaSand-based product: **PapType™** HPV Detection and Genotyping test

PapType HPV Detection and Genotyping test

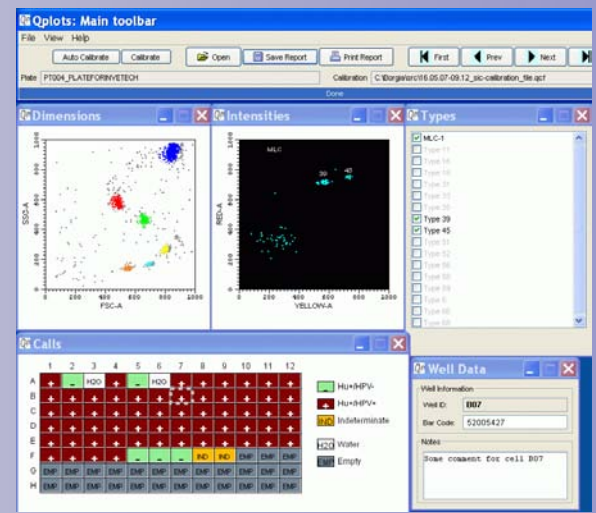
Biochemistry



AmpaSand beads



QPlots Software



Specially designed chemical reagents to facilitate the detection of HPV in cervical smear specimens

≈ 65,000 microscopic silica beads per test divided into 17 clusters, each identifiable by size and colour intensity. Each cluster tests for a particular type of HPV

QPlots proprietary interpretive software to “call” the results



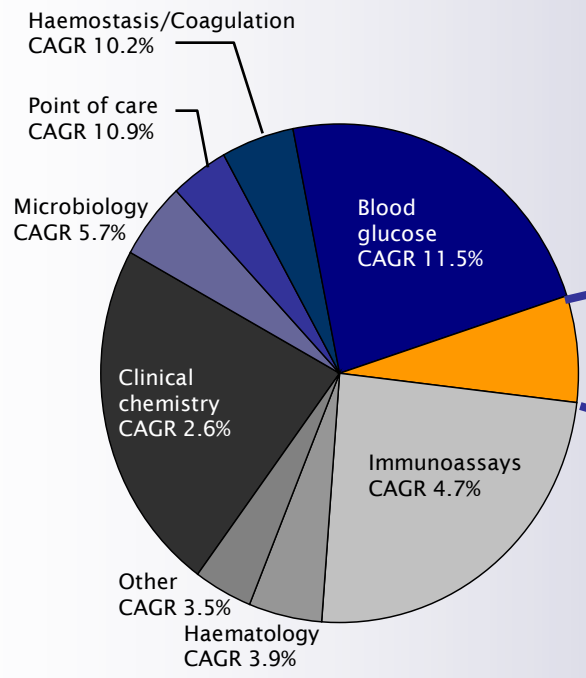
The Molecular Diagnostics Industry

- In Vitro diagnostic (IVD) tests are used by pathology companies to diagnose disease from patient specimens, e.g. blood, urine, sputum, cervical smears.
- IVD test results impact 60-70% of healthcare decisions
- Molecular diagnostics is the fastest growing sub-segment of the IVD industry

In Vitro Diagnostics

Estimated market value: Approx. US\$33bn (2006)

CAGR 2006 - 2010: 7%

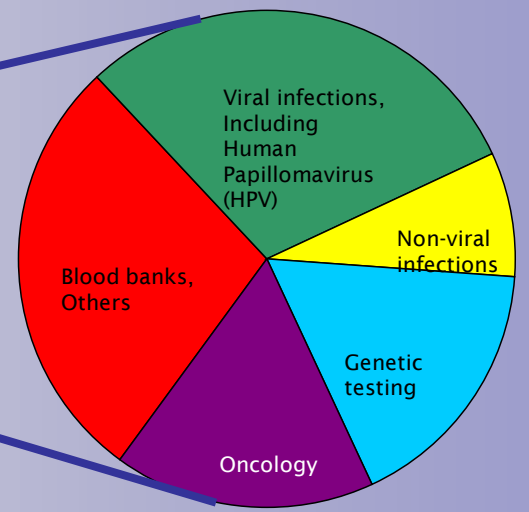


Molecular Diagnostics

Estimated market value: Approx. US\$2.4bn (2006)

CAGR 2006 - 2010: 17%

MDx



Operational overview

- Commercial operations
 - 2 new commercial agreements
 - Outreach commenced on global distribution

- Clinical development
 - Significant new clinical data generated
 - Potential “best in class” performance

- Manufacturing and operations
 - New R&D and manufacturing facility
 - Quality Management System installed

Gribbles: Important commercial validation of PapType



HPV - PCR

An innovative **new** HPV Test which detects individual high risk HPV genotypes enabling better patient management.

*Commercial validation
of platform and
product*

>5,000 patients to date

*Valuable endorsement
for interested parties*



Cerviscreen: The missing link in Women's Health?

Australian cervical screening population

Percentage coverage

2 years: 61%

3 years: 73%

5 years: 86%

14%

60-80%
newly
diagnosed
cancers!



Cerviscreen: The missing link in Women's Health?

Australian cervical screening population

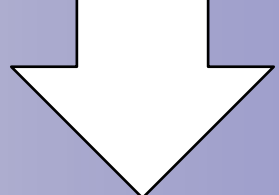
Percentage coverage

2 years: 61%

3 years: 73%

5 years: 86%

**Cerviscreen
targeting these
women from 3Q09**



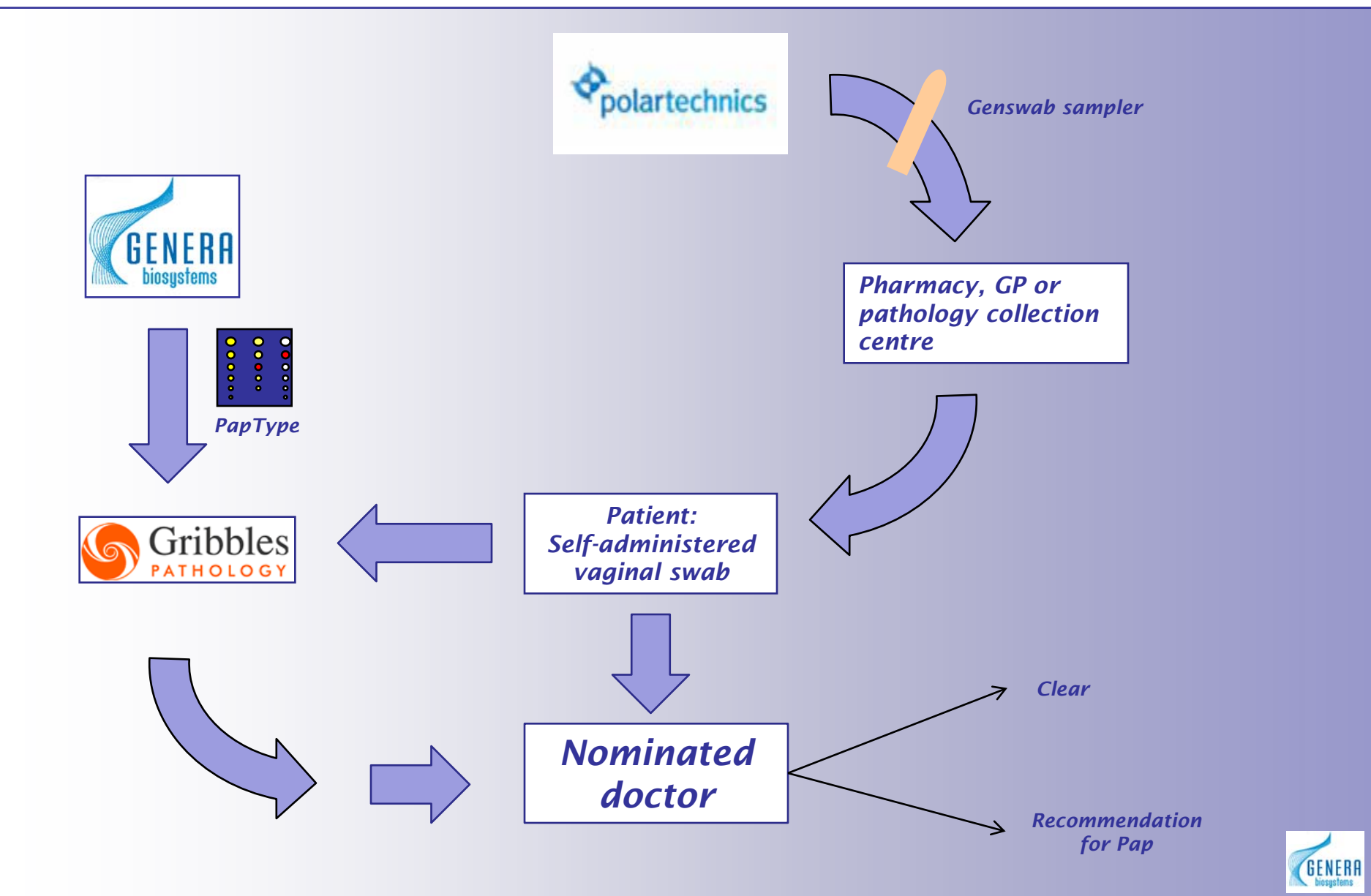
“Self collection with HPV testing is a promising tool for secondary prevention of cervical cancer”
Phil Castle, National Cancer Institute, USA

14%

**60-80%
newly
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Cerviscreen: A new model to enhance access to Pap smears



Partnership discussions in progress

- Primary business development objectives:
 - PapType distribution/licencing partnership for Europe
 - PapType registration partnership for Japan
 - QSand partnerships
- Secondary objectives:
 - AmpaSand platform exploitation
 - Product opportunities
- BioComm Squared
 - Retained for business development
 - Strong access to Japan
- BioJapan, BioPartnering Europe, Eurogin, and individual company outreach.
 - >20 companies so far contacted
 - Active discussions with 5-10

PapType: Attractive competitive profile

PapType feature...

- Enhanced detection of CIN2+
- Simultaneously detects and genotypes
- Detects all 14 HR types
- Provides only clinically relevant information
- Genotypes all HR HPV
- Small specimen volume
- Internal specimen control
- Uses existing laboratory infrastructure and expertise
- Reduced processing time (ESP-PCR)
- Broader multiplexing facility available

Is competitive compared to...

- HC2**
- HC2 AMP CERV**
- HC2 AMP**
- LA I-Lipa GEN**
- HC2 AMP CERV RT-PCR**
- HC2 CERV**
- HC2**
- HC2 AMP LA GEN**
- HC2 AMP CERV RT-PCR**

HC2: Hybrid Capture – Qiagen
AMP: Amplicor HPV™ – Roche
CERV: Cervista/Cervista™ – Hologic
RT-PCR: RT-PCR HPV – Abbott

LA: Linear Array HPV™ – Roche
I-Lipa: Inno-LiPA HPV™ – Innogenetics/Solvay
GEN: Genomica

The above analysis is Genera's opinion based upon publically available information , and internal clinical trial data

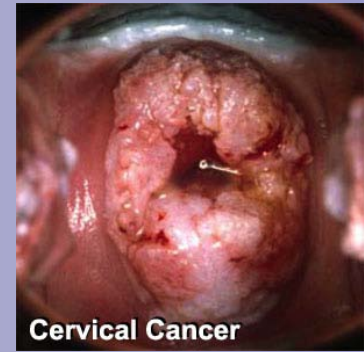


Multiple pathways to commercial success

- European distribution
 - Pick up of PapType by major distribution partner
- Significant uptake of Cerviscreen in multiple markets
 - Agreement is for Australia, EU, SE Asia
 - Possible opportunities in China
- Australian reimbursement for HPV testing
 - Agreements in place for #1 and #3 pathology providers
- Capture opportunities unfolding from Sonic relationship in Europe
- Other:
 - Japanese regulatory partner
 - Platform licencing

Human Papillomavirus (HPV) and Cervical Cancer

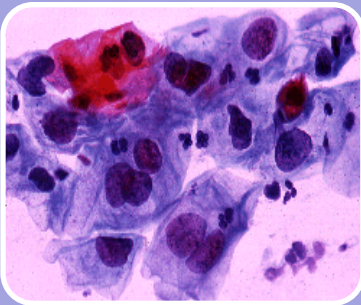
- Cervical cancer is the #2 cancer for women worldwide
 - WW almost 500K cases/year and 250,000 deaths
 - USA 11,820 cases in 2003 and 3,919 deaths
 - Up to 32% of HSIL occur with a normal Pap smear
- Cervical cancers are caused by 14 types of High-Risk HPV
 - “...cervical cancer does not and will not develop in the absence of the persistent presence of HPV DNA.”
- HPV testing improves sensitivity of cervical screening:
 - Combined HPV testing with Pap has a negative predictive value for CIN 2/3 (high-grade cervical lesions) of 99%
- Role of HPV genotyping
 - HPV 16 and 18 are most dangerous
 - Genotyping provides more actionable clinical information
 - Medical and economic value





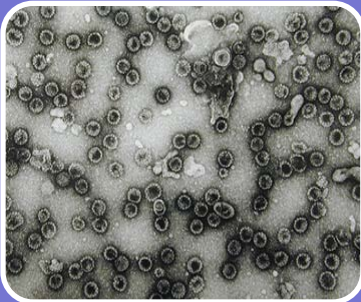
Population screening

- Negative predictive value is key
- Value of True Negatives



Triage of atypical smears

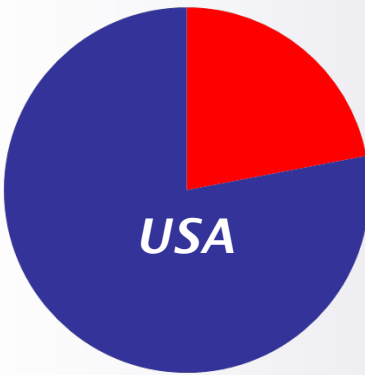
- Positive predictive value is key
- Value of True Positives



Test of cure

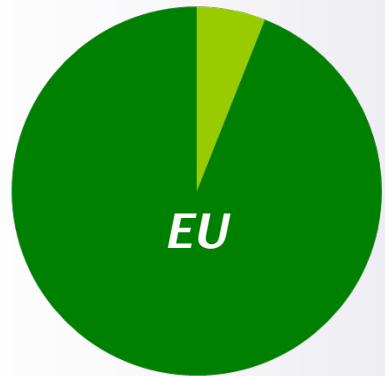
- High sensitivity required
- Value of True Positives

HPV testing: A significant global opportunity



Current tests
~ 8.4m
Penetration rate
~ 22%

- Focussed on Screening;*
- Single dominant player*
- High cost of entry*

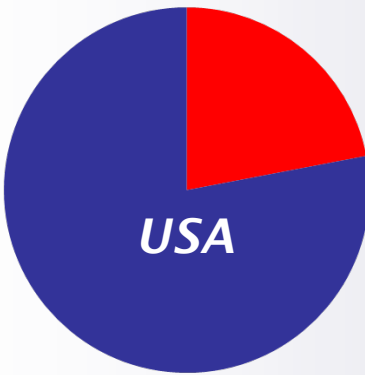


Current tests
~ 2.0m
Penetration rate
~ 6%

- Focussed on Triage;*
- No dominant player*
- Low cost of entry*

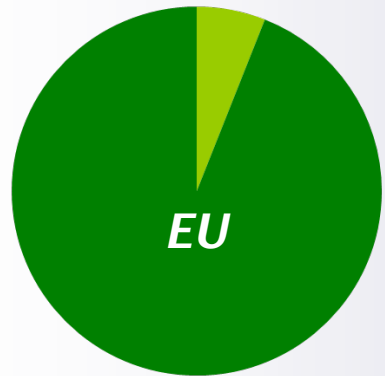


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- No dominant player
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PapType clinical profile ideally suited to Triage

Non-US market opportunity: 51.1m tests/\$664 million

Source: Deutsche Bank, May 2008



PapType: Excellent disease detection in a Triage population

- 100 patients with abnormal smear results
- PapType compared with Hybrid Capture™ in the detection of CIN2+

	<u>PapType</u>	<u>Hybrid Capture</u>
True positives	39	24
False positives	24	24
True negatives	24	25
False negatives	7	27
Indeterminate	6*	0
Total	100	100

**4/6 Indeterminates were HC2 -ve and CN2+. Due to the absence of a cellularity control, HC2 does not return indeterminate results*

Hybrid Capture is a Trademark of the Qiagen Group



PapType™: High level detection of most serious lesions*

	<u>Total</u>	<u>True positive by...</u>	
		<u>PapType</u>	<u>HC2</u>
CIN 3 + ACIS	29	25 (86%)	16 (55%)
CIN 2	22	14 (64%)	8 (36%)
Total CIN 2+	51	39 (76%)	24 (47%)

**In women presenting with previously identified abnormal Pap smears*



PapType: Promising as a screening test as well?

- 100 patients with abnormal smear results
- PapType compared with Hybrid Capture™ in the detection of CIN2+

	<u>PapType</u>	<u>Hybrid Capture</u>
True positives	39	24
False positives	24	24
True negatives	24	25
False negatives	7	27
Indeterminate	6	0*
Total	100	100

No increase in false positives

**Due to the absence of a cellularity control, HC2 does not return indeterminate results
 4/6 Indeterminates were HC2 -ve and CN2+. PapType patients would have been retested; HC2 patients would have been discharged.
 Hybrid Capture is a Trademark of the Qiagen Group*



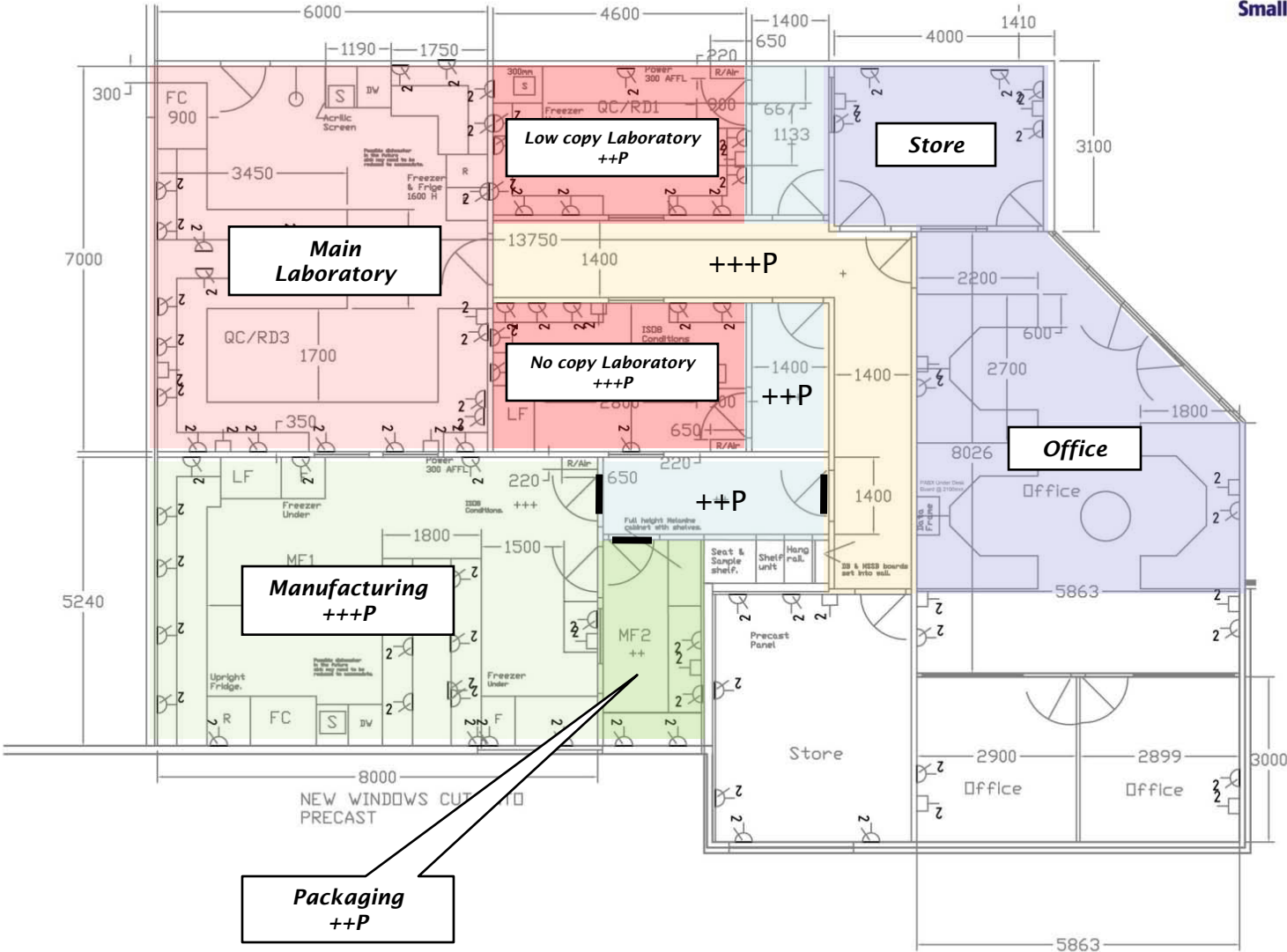
Eurogin: Key outcomes support Genera business plan

- **Genotyping of highest risk types will be key**
 - 16,18 most important - 31, 33, 45 possibly also useful
 - ... *the addition of 16 & 18 genotype triage to current adjunctive HPV screening... is a cost-effective screening strategy in the United States*
Anan Vijayaraghavan, McKesson Corp, USA
- **Self-sampling will play a key role**
 - “*Self collection with HPV testing is a promising tool for secondary prevention of cervical cancer*”
Phil Castle, National Cancer Institute, USA
- **HPV to replace Pap the principal screening modality**
 - “*...primary screening with a HR HPV test followed by cytological triage of HR HPV positive women... is far more effective than... cytology*”
Chris Meijer, Netherlands, Eurogin 2008
 - Vaccination will accelerate transition

Manufacturing: On schedule for a GMP facility in Melbourne

- Good Manufacturing Practice
- Essential elements:
 - Factory designed and validated to appropriate standards
 - Equipment installed and validated as fit for the purposes
 - Product manufacturing processes validated
- Ability to produce multiple batches which meet target specification
- Refit completed end October
- Target TGA inspection early April

Genera Biosystems R&D and Manufacturing facility



Airlock

Interlock

- 2 □ Double Data.
- 2 ⚡ Double power 10 amp

**Packaging
++P**

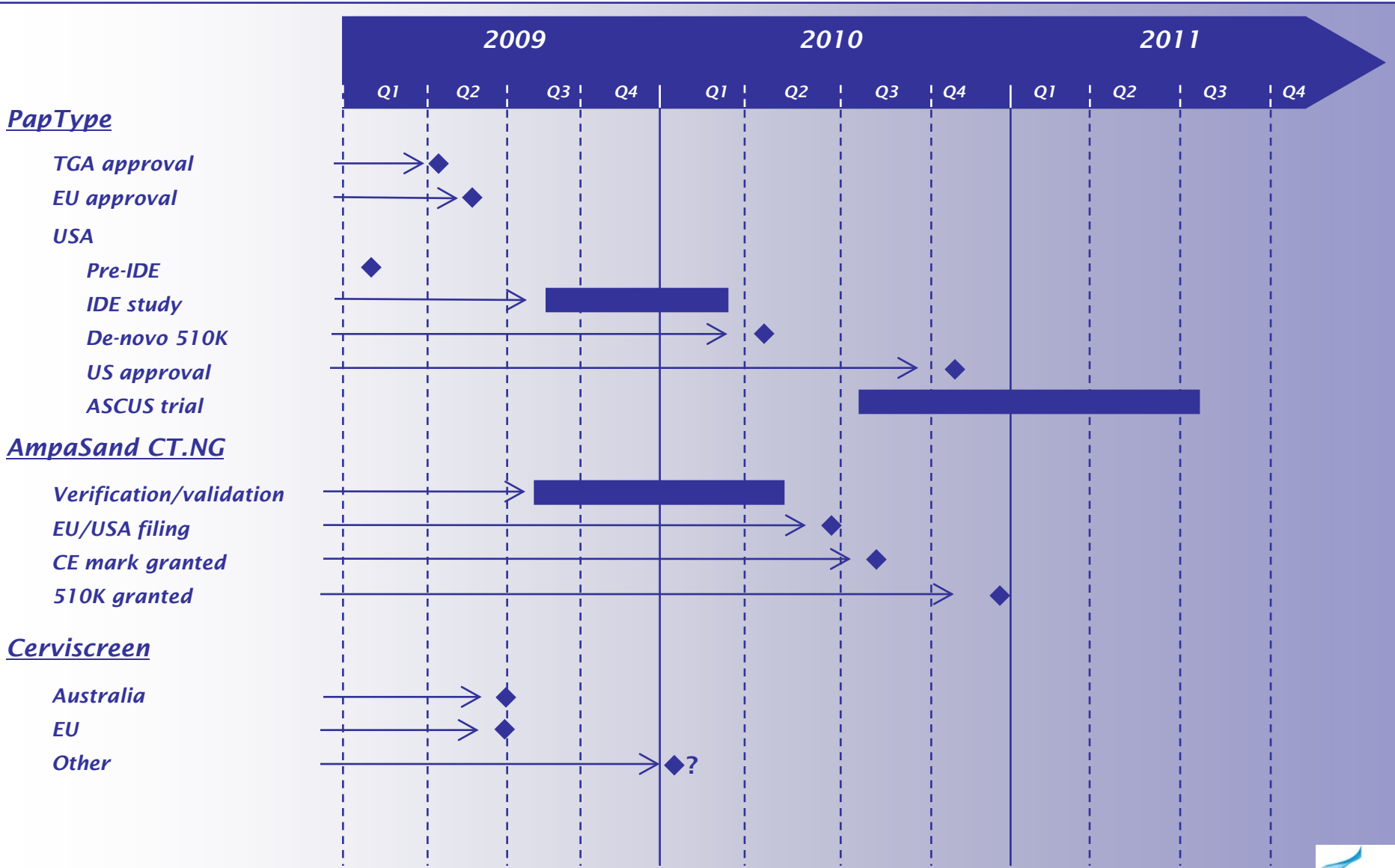
Small Tech Cluster, Scoresby. New home of Genera Biosystems



2009 objectives: Major value inflexion milestones

- 1Q09
 - Further clinical data on Triage population
- 2Q09
 - Australian Register of Therapeutic Goods listing
 - Finalisation of distribution partner(s)
 - CE marking and European launch
- 3Q09
 - Launch of Cerviscreen as a pharmacy product
- Other
 - Commence US clinical trial (subject to FDA endorsement of strategy)
 - Commence AmpaSand CT.NG
 - Clinical data on screening population
 - Clinical data on UK Triage population









Proposed timeline



Timetable assumes standard processing times from regulatory authorities and adequate access to capital



Strong demand for HPV assets as yet unsatisfied

<u>Date</u>	<u>Acquirer</u>	<u>Target</u>	<u>Notes</u>
June 2007	 Netherlands	 USA	US\$1.6bn deal; 47.9 x LTM EBITDA Gained access to Digene's HPV testing monopoly
June 2008	 USA	 USA	US\$580m deal. TWT not EBITDA positive Driven by interest in TWT Cervista HPV portfolio
July 2008	 Belgium	 Belgium	US\$316m deal; 74% uplift on pre-bid value. 2-way competitive bidding
October 2008	 USA	 USA	US\$345m deal. Using Surface Plasmon Resonance - unproven in human diagnostics

- **TWT public filings**

Approaches from 12 potential acquirers in 12 months to transaction;
 Eight went to due diligence.

- **Potential partner response to GBI story supports suggestion of ongoing demand.**

“We need an HPV test in Europe in the next 6-12 months. We can't wait for the in-house programme”
 Major Dx Vice President, November 2008



Conclusions

- Clinical data on PapType indicates potential Best in Class
 - Impressive Triage data
 - Critical data in 1Q09
- On target for Australian and European approval 2Q09
 - Catch to European Wave of HPV testing
 - Companies looking for HPV assets
- Very positive response to the Genera/PapType story by potential partners
 - Increase busdev outreach
 - Enhance competitive tension
- Multiple options for commercial success

Thank You

allen.bollands@generabiosystems.com

