

**Selling Biomarkers...
...at Each Step in the Value Chain**

About Bio-Link

- Biotechnology business development company
- Offices in Melbourne (HQ) and Sydney
- Cover therapeutics & diagnostics
- Range of services:
 - Deal strategy & Licensing
 - Technology assessment
 - Intellectual property strategy & auditing
 - Commercial positioning
 - Project management

Selected Biotech Clients



Biotron



MEDICALTHERAPIES 





BIOLINK

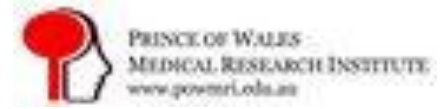
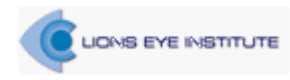
Selected Institutional Clients



HOWARD FLOREY INSTITUTE



CENTENARY INSTITUTE



www.bio-link.com

Principals

- **Paul Field**
– Itochu, Cellabs, University of Technology Sydney, ATP Innovations
- **Christopher Boyer**
– Novartis, Halozyme, NewBiotics, Howard Hughes Medical Institute
- **Christian Toouli**
– Schering Plough Biopharma, Children's Medical Research Institute (Sydney)

Portfolio: Therapeutics

- Small molecule anti-parasitic drugs – PARTNERED (Bayer)
- GVHD cell therapy – PARTNERED (Becton Dickinson)
- Protein and small molecule anti-epileptic drugs – TERMS
- Marine-derived natural chemistries – TERMS
- Protein coagulation modulators – MARKETING
- Small molecule memory enhancement drugs – MARKETING
- Protein wound healing agents – MARKETING

Portfolio: Diagnostics

- Protein biomarker for PD – PARTNERED
- PGx for Li⁺ treatment of BAD – PARTNERED
- Enzyme activity biomarker for cancer – PARTNERED
- PGx for anti-epileptic drugs (CBZ & VPA) – TERMS
- PGx (mRNA levels) for Velcade treatment of MM – TERMS
- Genetic biomarker for hereditary hearing loss – MARKETING
- Protein biomarker for CNS hypoxia – MARKETING
- Epigenetic biomarker for Fragile X syndrome – MARKETING
- Epigenetic biomarker for adolescent depression – MARKETING

Biomarker Development Milestones

- Correlation Discovery (20 – 100 patients, 1st cohort)
- Patent application
- Scientific Validation (50 – 100+ patients, 2nd cohort)
- Peer-reviewed Publication
- Assay validation (proteins, mRNA, epigenetics)
- Clinical validation (100 – 500+ patients, 3rd+ cohorts)
- Regulatory approval
- Reimbursement
- Market launch

Selling is Required at Each Step

- Path to market is the path to wide-scale clinical benefit
- Clinical validation is expensive
- Product development is complex
- Reimbursement is challenging
- Test developers understand the business best
- Downstream deals depend on the same selling points

Market Access / Regulatory Pathways (US)

- Depends on risk associated with the “intended use”
- Main categories (in order of increasing complexity):
 1. Research Use Only (subject to “off-label” abuse)
 2. CLIA-registered in-house (LDT or “home brew”)
 3. Analyte-specific reagents (single moiety; no kits)
 4. 510k medical device (quasi-ANDA)
 5. Premarket Approval (kits; need prospective study)

Biomarker Selling Points: Technical

- Scientifically and clinically validated – large, multiple cohorts
- Easily accessible source (e.g. blood, urine, buccal swab)
- Medically meaningful specificity and sensitivity
- Viable assay format (e.g. radioisotopes, mass spec difficult)
- Platform independent
- Access to quality patient cohorts; medical expertise

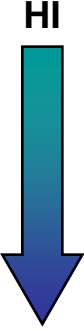
Biomarker Selling Points: Commercial

- Novel, with medical advantages
- Provides *actionable* information for clinicians (alternatives, timing)
- Results support early diagnosis, drug response, and monitoring
- Peer-reviewed publication(s)
- Viable health economics for reimbursement
- Market exclusivity

Market Exclusivity?

- Composition-of-matter is strongest patent position
- Validity of US methods patents uncertain (Bilski v. Kappos)
- Combinations of markers may be subject to restriction requirements
- Enforcement can be challenging
- Emerging new tests for same outcome = competition
- Individual \$1000 genome: DTC threatens genetic biomarkers

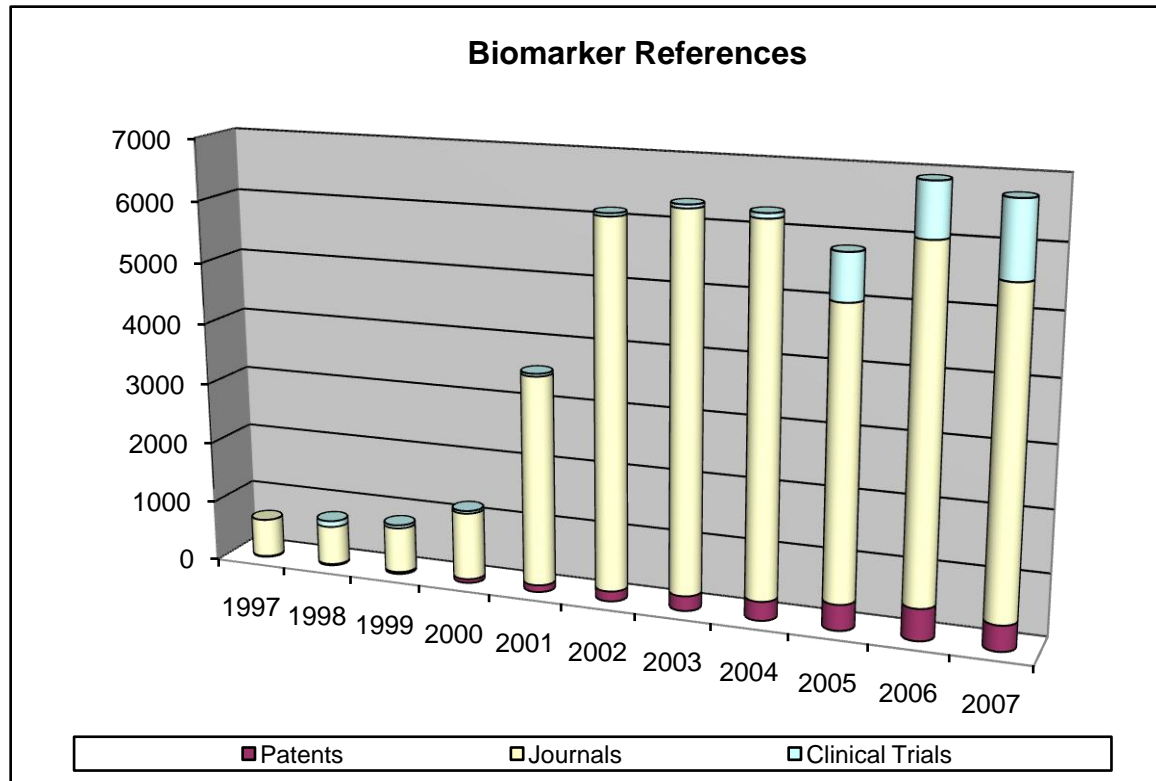
Likelihood of Commercial Uptake for Biomarkers

- 
- Definitive diagnostics for disease (e.g. causative mutations)
 - Markers that monitor patient response to Rx
 - Prediction of patient response to Rx
 - Prognostic markers for disease
 - Markers for predisposition to complex diseases

What are the Markets?

- Pre 2000: classic IVDs (e.g. clinical chemistry, immunoassays)
- Post 2000: high-value “esoteric” Dx (e.g. genotyping, -omics)
- Current IVD Market: ~\$20b growing at 6%
- Current Esoteric Market: ~\$4b growing at 10-15%

Turn of the Century Biomarker Explosion



THOMSON REUTERS

Source: *BIOMARKERcenter*

Who are the Immediate Customers?

- Small diagnostic developers (Athena, Monogram, HealthLinx)
- Platform companies seeking content (Nanosphere, Genera Biosystems)
- Large diagnostic companies (Quest, LabCorp, Sonic, Roche, Abbott)
- Pharmaceutical companies? (patient stratification, companion Dx)
- Reagent suppliers (Millipore, Qiagen, Invitrogen)

Who are the Ultimate Customers?

- Doctors
- Patients (Need-to-know; DTC marketing)
- Private insurance providers
- Government payors (need advocacy groups, lobbyists)

Typical Deal Terms for Early Stage Biomarkers

- Few if any comparables for licensing
- *Theoretically*, deal value = rNPV
- Selling price based on reimbursement, *not* test value
- Early days, few successes » high risk » buyers market
- Typical deal values:
 - License prior to clinical validation: \$1 – 3m
 - Product with \$15m sales pa: \$20 – 50m
 - Monogram Biosciences » LabCorp: \$155m (HIV Rx Response)
 - DxS » Qiagen: \$130m (Victibix companion Dx KRAS)



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Thank you for your attention!