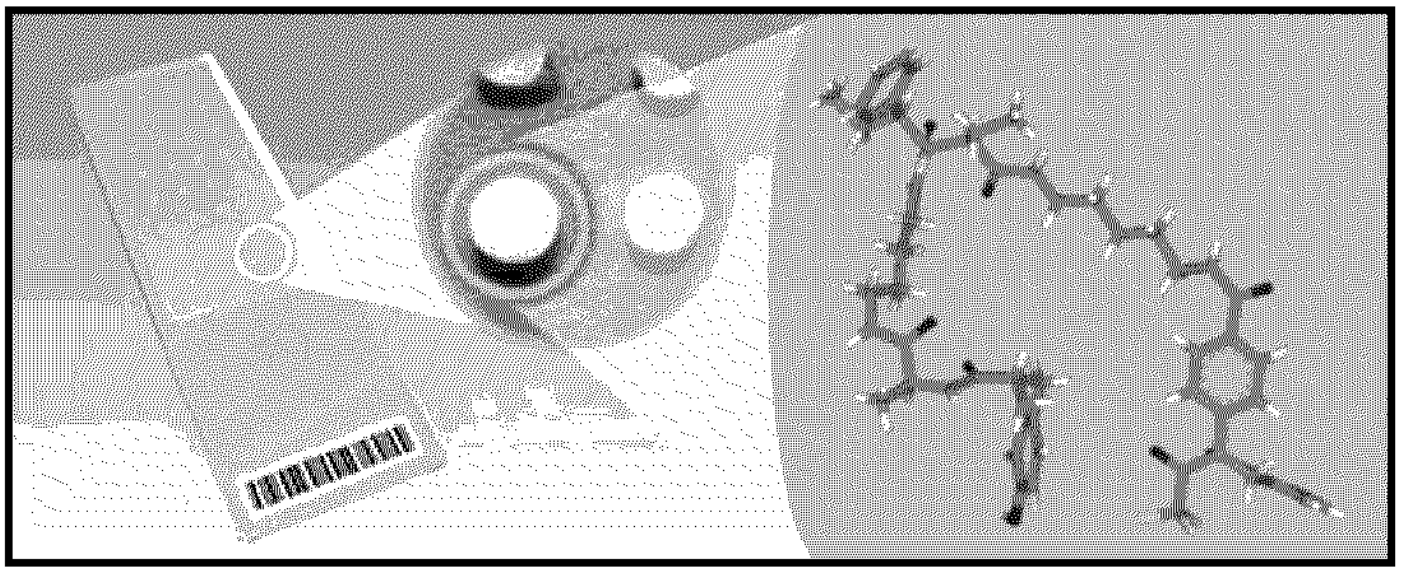
BioLayer Corporation Limited
(ASX:BLS)

Materials Solutions for Life Sciences



Bio-Layer

Important Notice

The purpose of this Presentation is to provide general information about BioLayer Corporation Limited (**BioLayer**). It is not a recommendation that any person makes any investment decision in relation to BioLayer. This Presentation does not contain all information which would be material to the making of a decision in relation an investment in BioLayer. Any shareholder or prospective shareholder should make its own assessment and determination based on all available prior to making any investment decision, and should not rely on the information in this Presentation for that purpose.

Further information about BioLayer and its business and operations is contained in its annual reports and other reports which can be accessed on its websites at www.bio-layer.com. BioLayer does not undertake any obligation to revise the information in this Presentation to reflect any future events or circumstances.

This Presentation contains certain statements (including projections, estimates, opinions and forecasts) concerning the anticipated future performance of BioLayer (**Forward Looking Statements**). None of these Forward Looking Statements is a guarantee or representation as to future performance or any other future matters, which will be influenced by a number of factors and subject to various uncertainties and contingencies, many of which will be outside the control of BioLayer. Accordingly, the combined group's actual results, performance and prospects could differ materially from that expressed in or implied by the Forward Looking Statements.

No representation or warranty, express or implied, is made by BioLayer that the Forward Looking Statements contained in this Presentation will be achieved or prove to be correct. Except for any statutory liability which cannot be excluded, BioLayer, their officers, employees and advisers expressly disclaim any responsibility for the accuracy or completeness of the Forward Looking Statements and exclude all liability whatsoever (including in negligence) for any loss or damage which may be suffered by any person as a consequence of any information in this Presentation or any error or omission there from.

Bio-Layer

Bio-Layer's Business

Bio-Layer is a **materials sciences** company which designs and builds coatings for surfaces used in healthcare applications.

The coatings work in 2 ways:

- By binding, orienting and protecting antibodies which improve their function at lower cost
- By binding (and releasing) specific proteins

Our business is based on:

1. **Licensing and royalties in targeted markets**
2. **Developing the technology for novel applications in new related markets**

Applications:
Immunoassay, Bioseparations, *In Vivo* applications

Bio-Layer

Targeted Markets

Stage 1: Research Immunoassays ($US 1b)

- Low barrier to entry
  - smaller innovative companies
  - less regulated market
- Deals already completed with 2 Life Science companies

Stage 2: Diagnostic Immunoassays ($US 5b)

- Higher volume products
- Highly regulated market
- Bio-Layer is in advanced discussions with 3 of top 8 IVD companies

Stage 3: Future Applications

Bio-Layer

The Diagnostic Immunoassay Market

	Sales ($US)	Industry	Eg.	Product formats	# Prods	Time to market	Sales/ product ($US)
Diagnostics (IVD)	**5.0B**	**Few dominant players**	Tier 1: **J&J (OCD)**, **Roche**, Bayer, **Beckman**, Dade Behring, Abbott Tier 2: **bioMerieux**, **Bio-Rad**, **BD**, Sysmex, DPC, **Olympus**, etc.	Few formats, standardised, high volume, automated assays	~200 per manufacturer	12 – 24 mths	5.0m p.a. (1.0m – 50.0m)

Bio-Layer

Bio-Layer's Current Focus: Immunoassay

What is an Immunoassay?

A test for a disease marker conducted using antibodies which specifically bind the marker (or target) and generate a signal. The signal indicates the marker's presence, or can be measured to determine its quantity, which correlates with the disease.

Examples:

- **Cancer**: AFP, CEA, PSA, CA-125, etc.
- **Fertility**: hCG, LH, FSH, testosterone, etc.
- **Thyroid**: TSH, fT4, TG, etc.
- **Viral**: HBsAg, anti-HCV, anti-HIV, H5N1, etc.
- **Bone**: PTH, osteocalcin, VitD, etc.
- **Anemia**: B12/folate
- **Cardiac**: Troponin T/I, CK-MB, myoglobin, NT pro-BNP, etc.
- **and many more**

Key Players...

PHILIPS

MILLIPORE

BD

BECKMAN COULTER

invitrogen

Ortho-Clinical Diagnostics
a Johnson-Johnson company

Roche

Bio-Layer

Current challenges in Immunoassay

- Surfaces for immobilising capture antibodies are too variable
  - Batch to batch variation
  - Resulting in high cost of quality, and
  - High cost of maintaining supply
- Maturing business – company strategies shift to product differentiation & cost saving
  - Assay sensitivity as a powerful differentiator
- Long clinical validation
  - Pressure on product development time
- Translating assays from one format to another, eg. from lab test to PoC test
  - Bio-Layer coating can be applied to many formats, eg. beads, plates, membranes

Bio-Layer

Where are we now?

- 1 Licensing Agreement (Life Science)
- 1 Development Agreement (Life Science)
- 1 Feasibility Study underway (IVD)
- 2 Term Sheets in advanced discussion (IVD)
- 2 Development Contracts - both imminent (IVD & LS)

What are we targeting?

Company	Time to Start up	Time to License & Royalty stream
IVD 1	Q4, 06	Q4, 06
IVD 2	Q1, 07	Q3, 08
Life Science	Q1, 07	Q3, 07
IVD 3	Q1, 07	Q3, 08
IVD 4	Q2, 07	Q4, 08

Bio-Layer

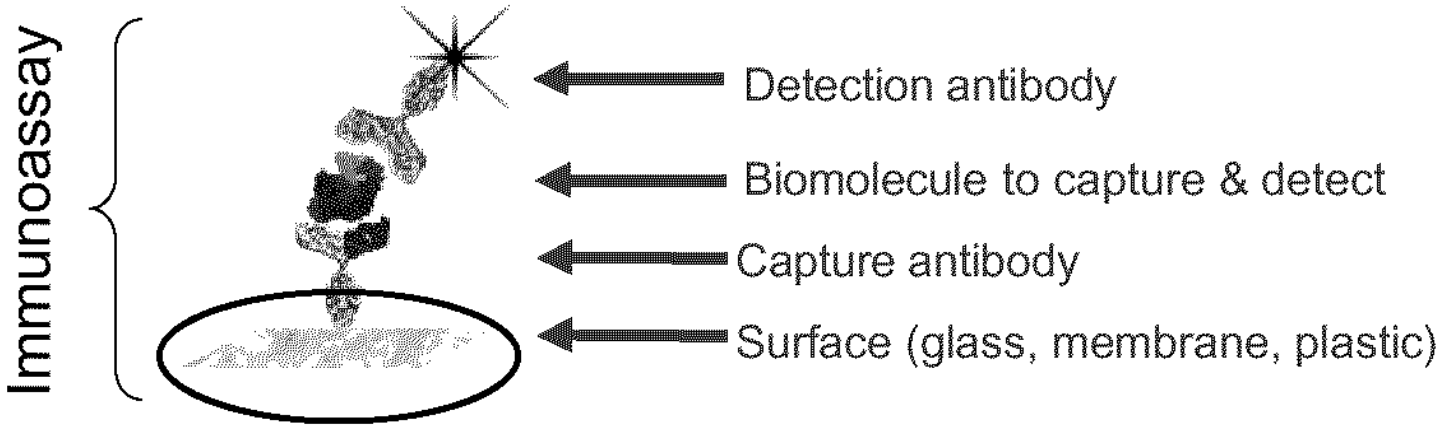
Targeted deal structure

Steps		Timeframe (mths)	Revenue per product ($ '000)
Lead-up	**Getting the foot in the door** • Demonstration/feasibility • Contract negotiation	2 – 6	$0 – 50
1.	**Client Commitment** • Joint Development agreement	0 – 12	$100 – 200
2.	**License to Use/Cost Recovery** • IVD product • Research product	 6 – 18 0 – 6	 $200 – 400 $10 – 50
3.	**Collect Royalties** • IVD product (ave sales $5M p.a.) • Research product (ave sales $200K p.a.)	 - -	 $100 – 500 p.a. $8 – 20 p.a.

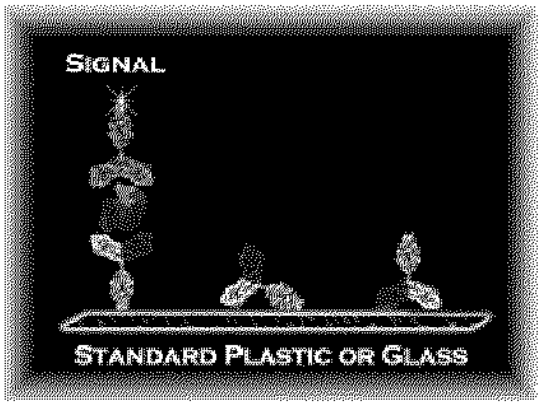
Bio-Layer

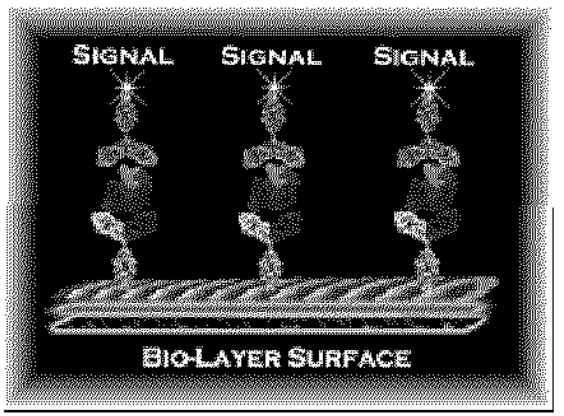
What do Bio-Layer products do?

An Immunoassay example



Bio-Layer's coatings increase the amount of functional capture antibodies on the solid phase





This is important because it solves immunoassay problems and supports Bio-Layer's Value Proposition

Bio-Layer

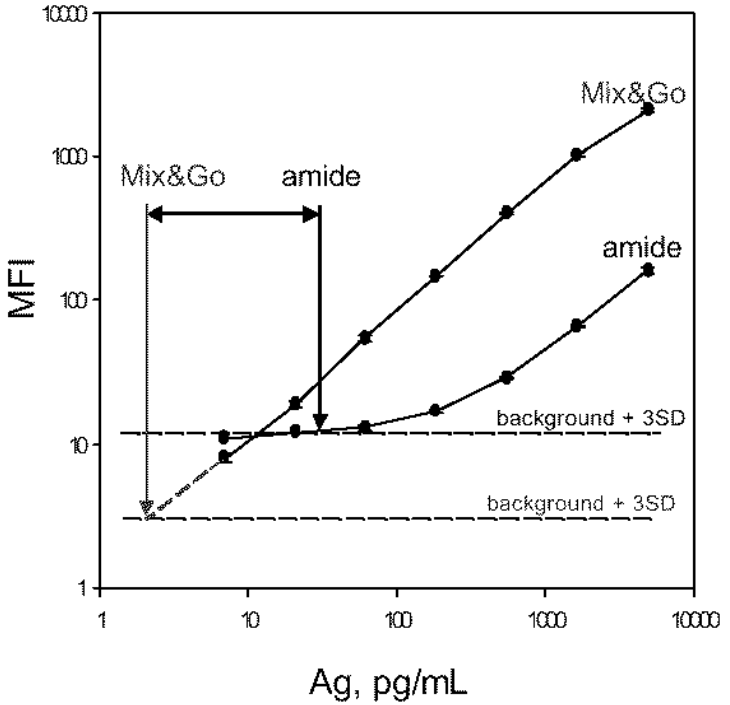
Bio-Layer's Value Proposition

Bio-Layer's products do this	Which has this effect on the customer's product	Delivering this Value to the customer	Cost ?	Revenue ?
More functionalised antibodies on the surface	• Better Signal to Noise ratio • Predictable Ab behavior • Less Ab, same performance	**• More sensitive assays** **• Robust assays** **• Raw material cost saving (rare Abs)**	 Y	Y Y
Standardised, stable surface coatings	Reproducible Ab binding	**Saving on QC, rework and manufacturing scrap**	Y	
Quick, simple coating procedure	• Easily incorporated into SOPs • Scalable • Faster assay development	**• No new plant required** **• Ease of manufacturing** **• Earlier time to market**	Y Y	 Y
Discovery Engine	New high performance surfaces can be developed for different platforms	**Enable new products**		Y

Bio-Layer

Improved Signal to Noise

Cytokine Luminex Bead Assay



= Opportunity to Differentiate!

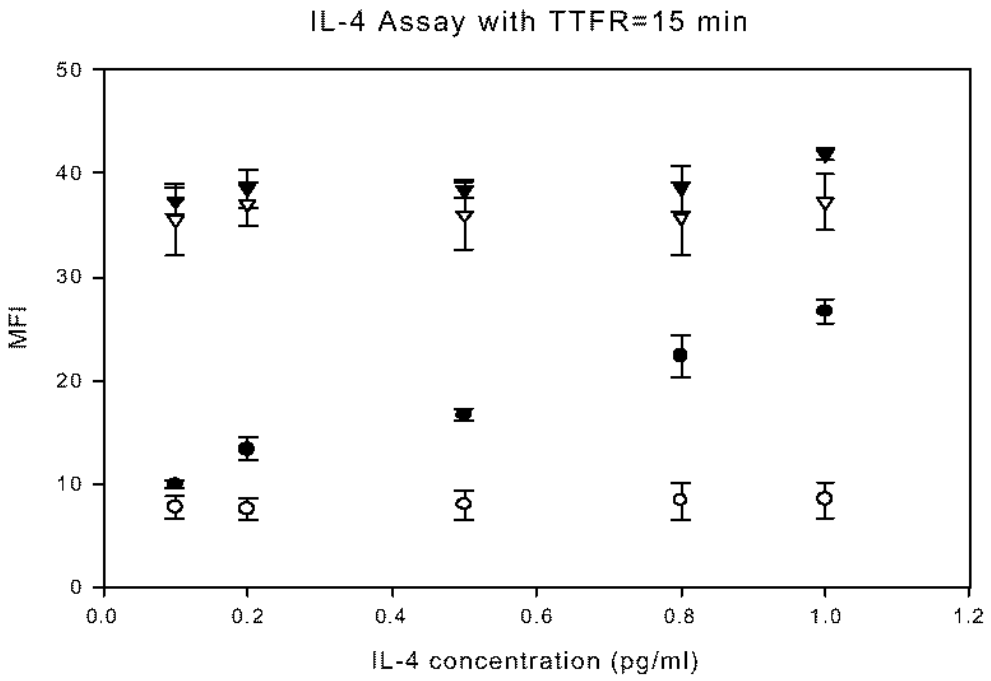
Limit of Detection (LoD) Comparison for Selected Assays

	Mix&Go	*Amide*
IL-4	0.05 pg/mL	0.2 pg/mL
Troponin I	5 pg/mL	50 pg/mL
TNF-a	5 pg/mL	> 250 pg/mL
TSH	<0.001 uIU/mL	0.006 uIU/mL

Bio-Layer has demonstrated sensitivity improvements from 2-fold to 20-fold for over 20 assays tested

Bio-Layer

Sensitivity Improvement under short Assay Times



= Translate to PoC platform!

Amide signal

Amide background +2SD

Mix&Go signal

Mix&Go background +2SD

LOD (pg/mL)	Mix&Go	Amide	Improvement
3.5 Hours	0.05	0.2	4x
15 Min	< 0.1	1.0	10x

Bio-Layer

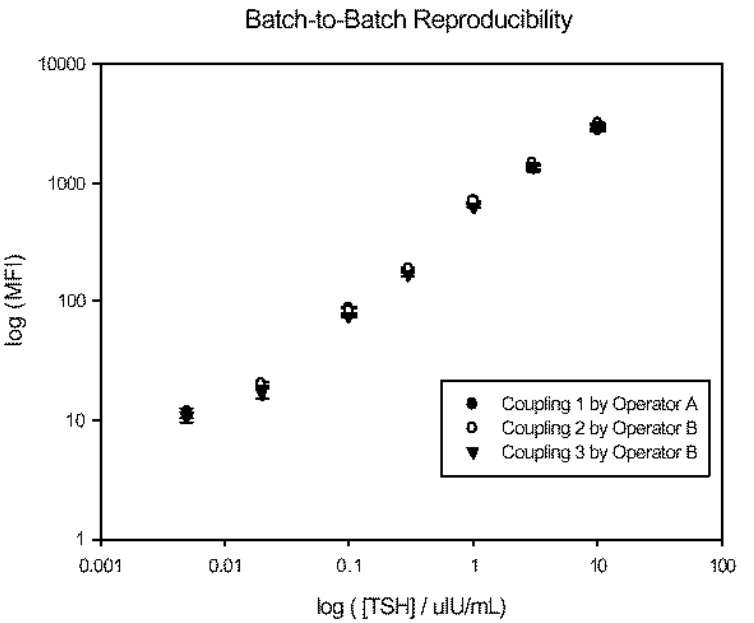
No Coupling Batch Variations

= Cost Savings!

Loading Variation from 3 operators

% CV over 3 coupling	IL-3	GM-CSF	CA125	G-CSF	IL-18	IL-1a	MIP-1a	VEGF	Average
Amide Coupling	9.4	11.6	8.7	8.0	15.8	13.1	8.7	4.9	10%
Mix&Go Coupling	0.5	3.6	3.9	2.0	4.3	3.6	1.0	7.6	3%

Variation from 3 different αTSH couplings

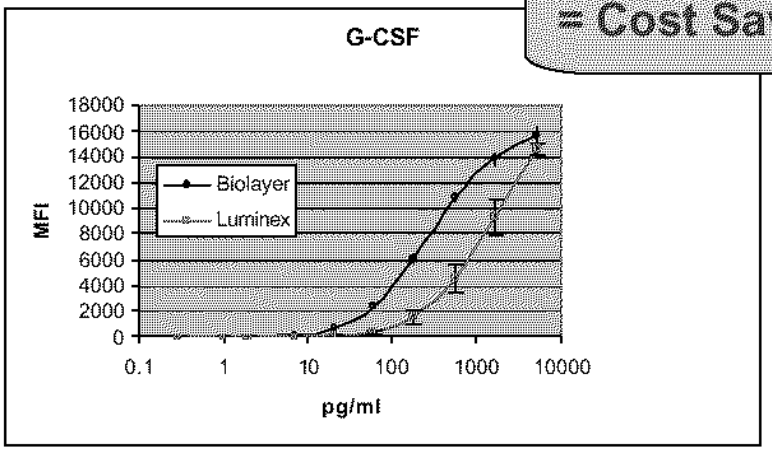


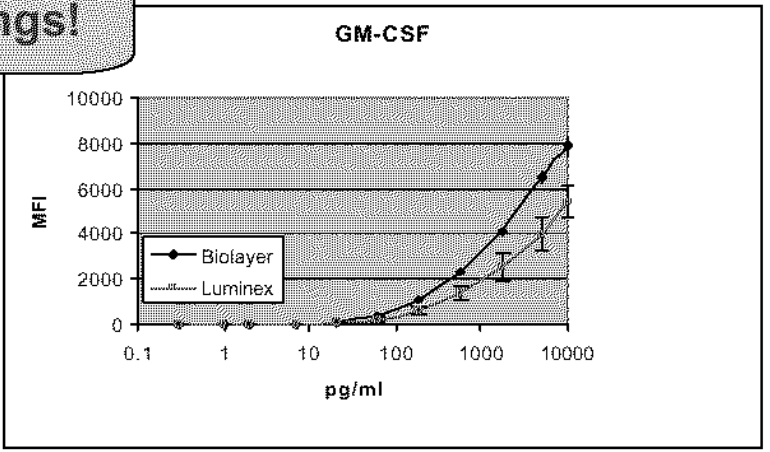
Bio-Layer

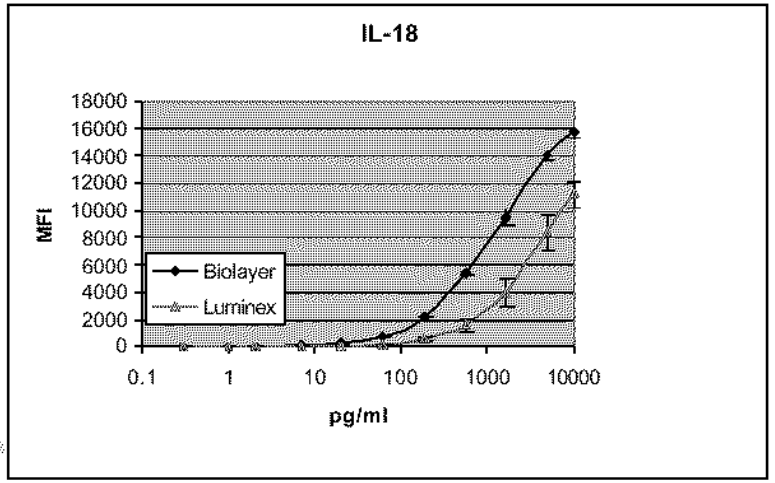
No Coupling Batch Variations

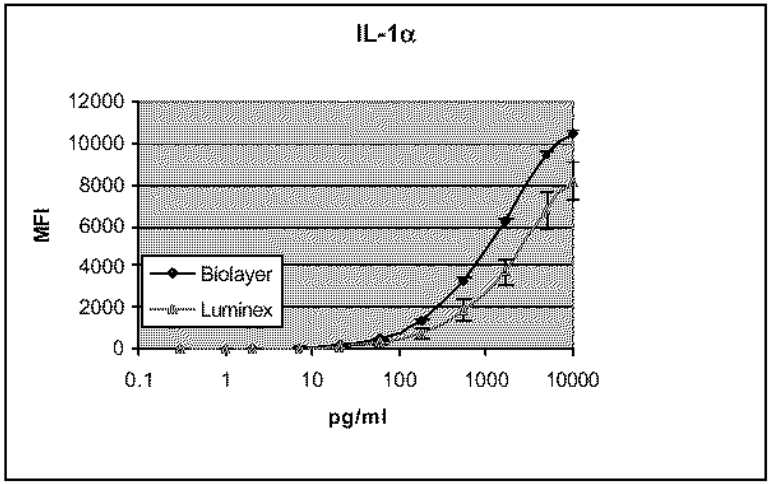
Assay Variation from 2 different couplings

= Cost Savings!



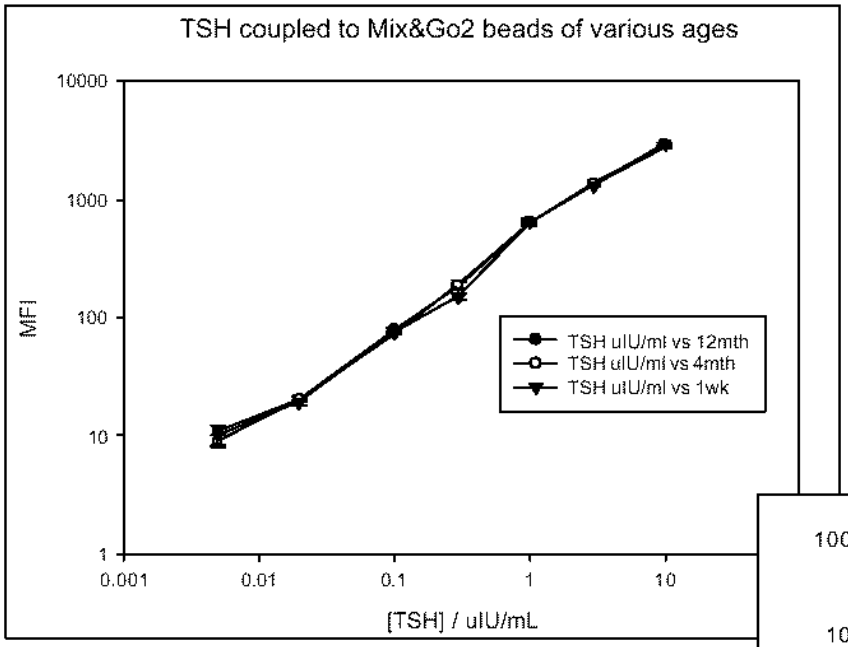






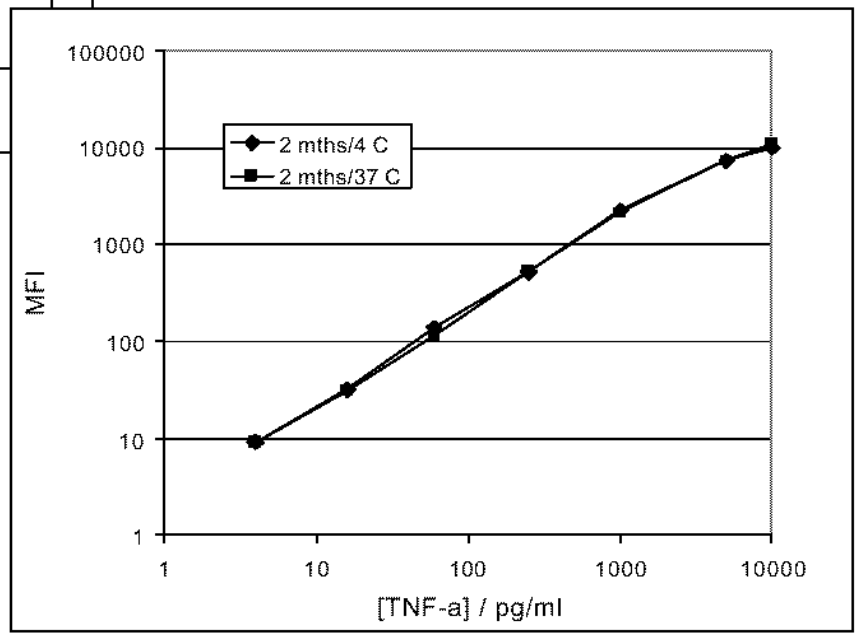
Bio-Layer

Mix&Go Bead & Conjugate Stability



= Manufacturing reproducibility!

= Opportunity to Differentiate!



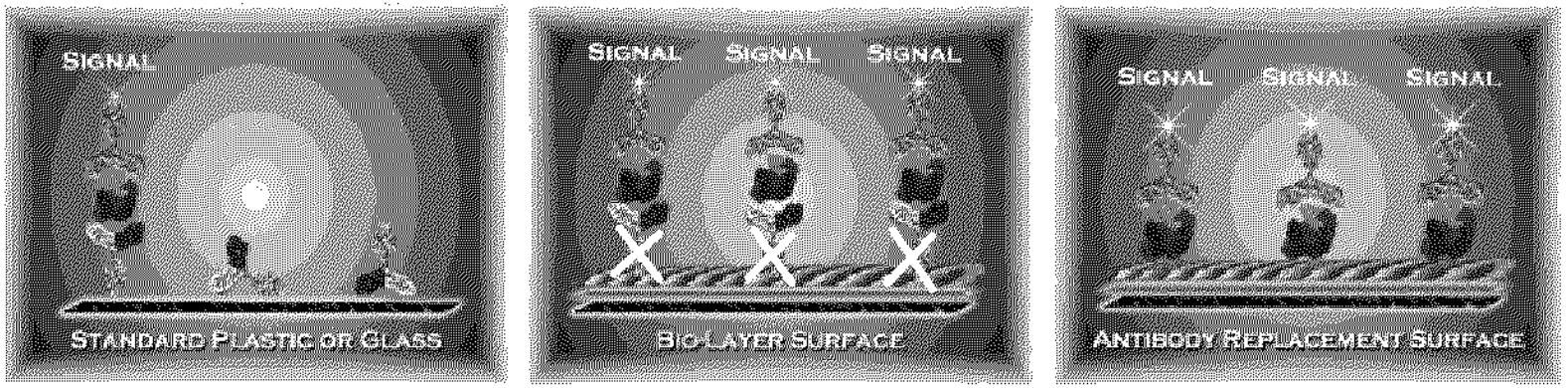
Bio-Layer

Stage 3: Future Applications

Antibody replacement or "*Abiotics*"

Bio-Layer can create surfaces that specifically bind any protein

An Immunoassay example:



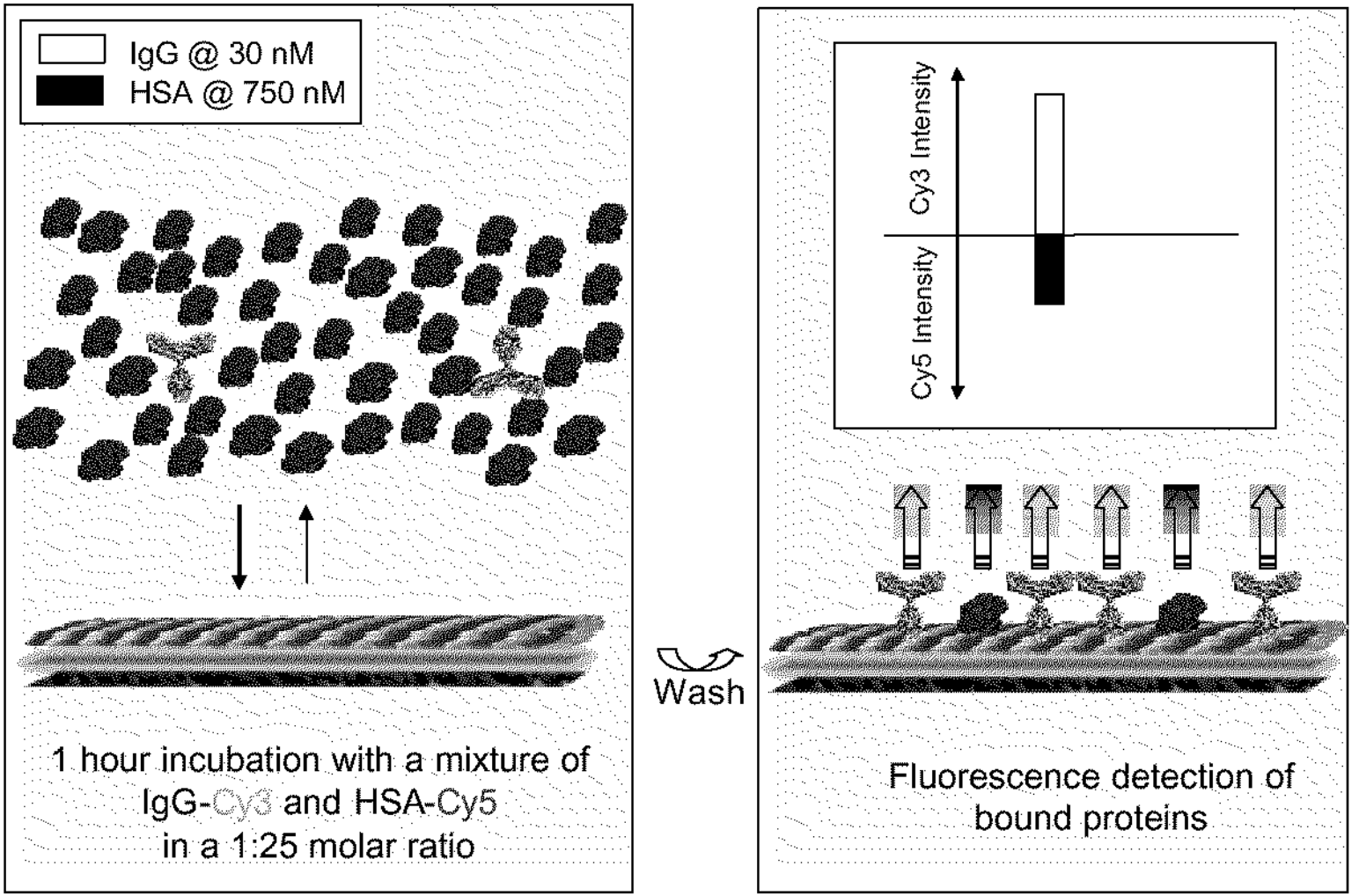
A <u>fully synthetic surface</u> leading to a paradigm shift in immunoassays:

- Eliminates biological variability
- Cost effective substitute for rare/expensive or poor quality antibodies
- Overcome IP barriers, e.g. closely held patents on HepC
- Increased robustness (durability, usability, utility, etc.)

NB. Downstream products in Bioseparations and *In Vivo* applications

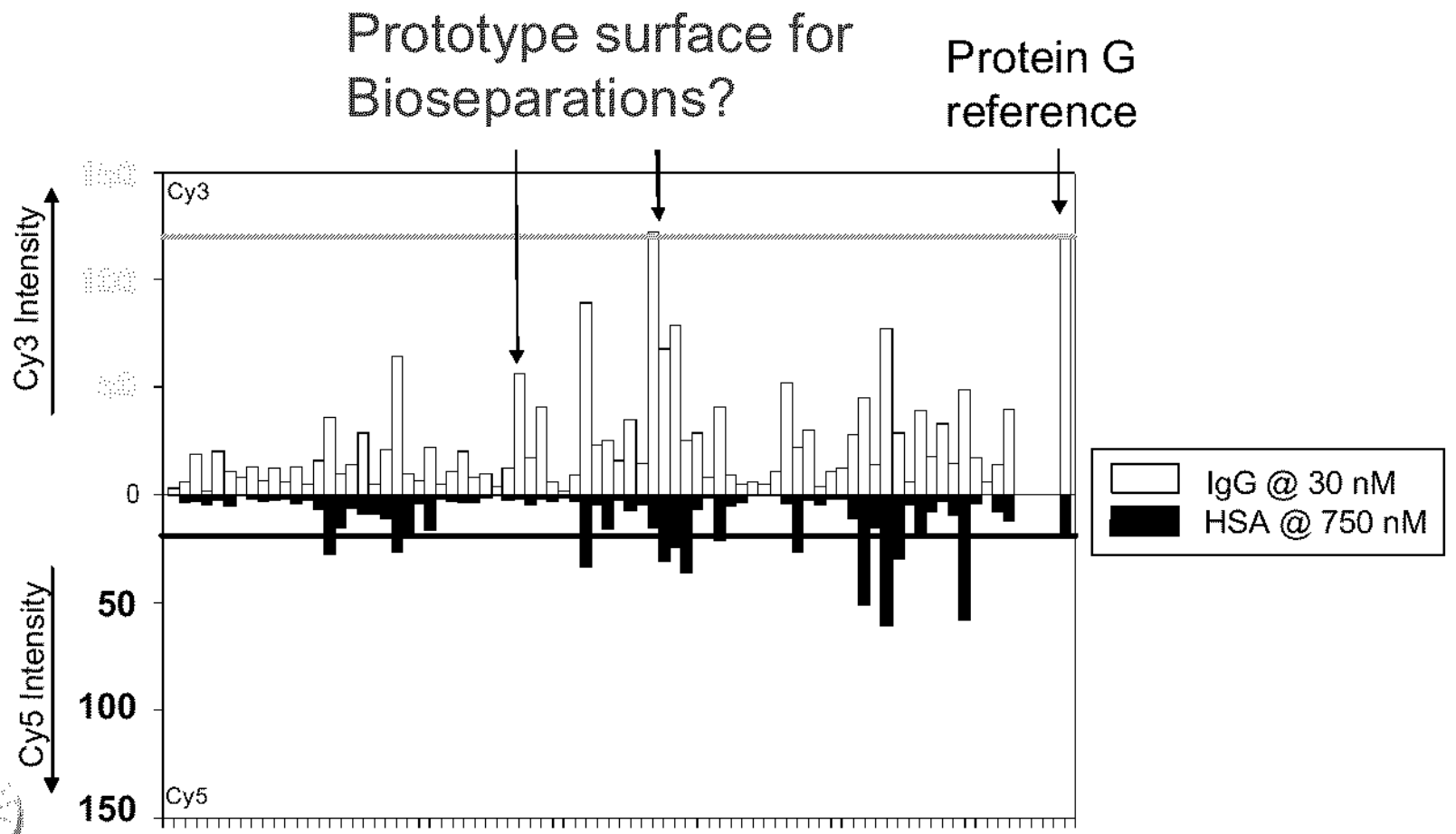
Bio-Layer

Bioseparations require selectivity from a mixture of Proteins



Bio-Layer

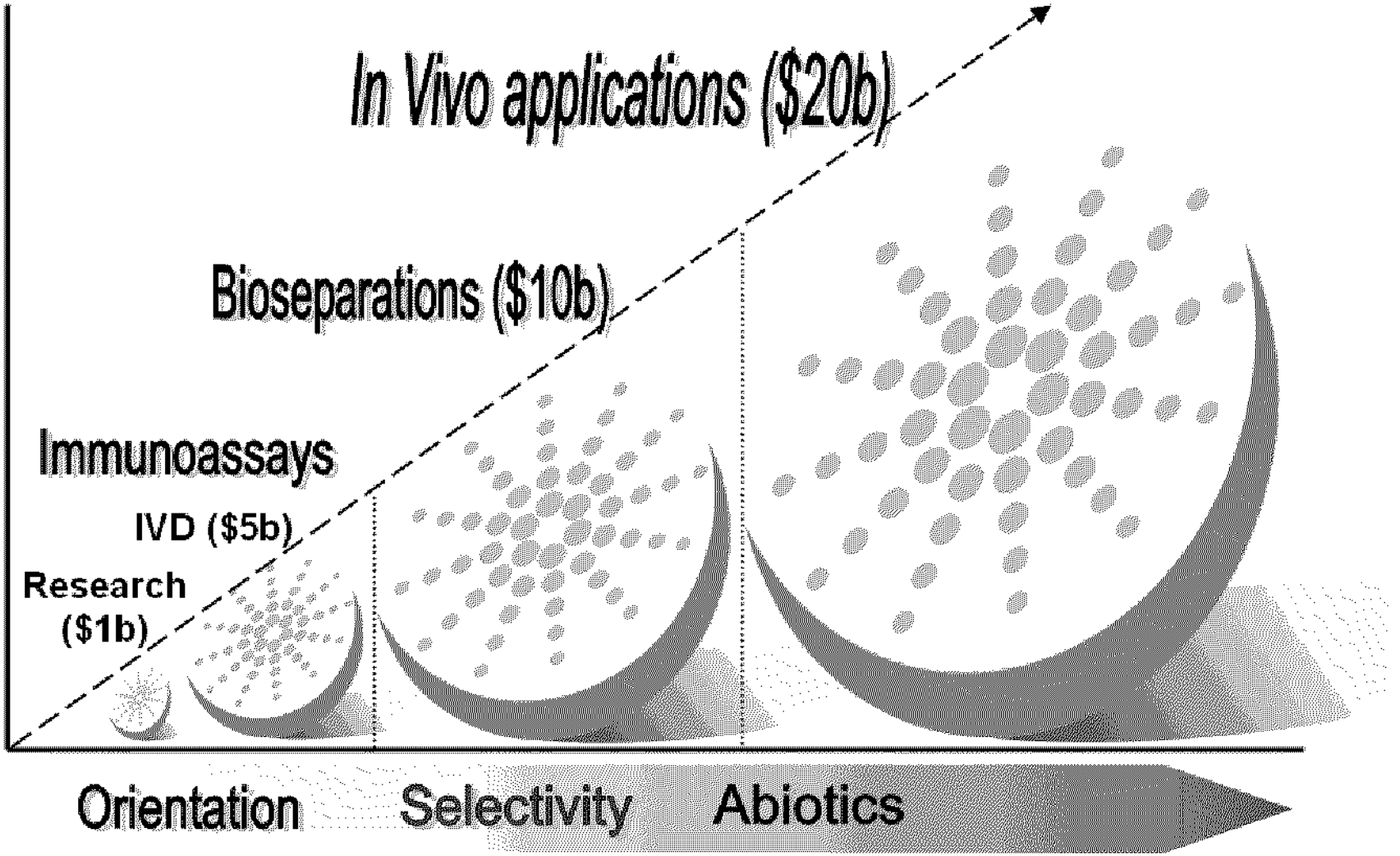
Bio-Layer has a library of synthetic surfaces with selective properties



Bio-Layer

US Provisional Filed

Bio-Layer is at the door of growing technology markets



Market Dynamics

Companies are acquiring technologies similar to Bio-Layer's.
Some examples…

1. Inverness' acquisition of Clondiag for US $32.7m (March 2006)
   - Clondiag had a platform technology and no products
   - Clondiag's business was customising system components for their partners
     - support transfer of existing assays or set-up new assays onto client platforms
     - carry out feasibility studies and assay kit development on behalf of partners who licensed the technology
   - Inverness worked with Clondiag beforehand, checking the applicability of its technology to their products (PoC diagnostics)

2. Roche Diagnostics' acquisition of Igen for US $ 1.2b (2003)
   - Roche licensed Igen's ECL detection technology for its *Elecsys* automated immunoassay platform, launched ca. 1995.
   - ECL was the most sensitive and fastest technology at the time, giving Roche an important point of differentiation
   - The companies worked together to improve the technology and develop assays for a number of years

Bio-Layer

Bio-Layer Team

David Beins BSc(Hon), MBA

- CEO since April 2006
- Doubled sales & profits as GM at Roche Diagnostics Indonesia. Took company from #4 to #1 in the market in 3 years.
- As regional BD manager successfully launched new molecular diagnostics products throughout Asia for Roche Diagnostics Asia Pacific

N Joe Maeji PhD

- CSO and co-founder of Bio-Layer
- Developed and help build a high growth profitable business as Head of Research at Mimotopes. Facilitated key alliances with major pharma companies like Sandoz, Ciba Geigy, Organon and Janssen as Snr Director at Chiron Technologies
- Wrote 6 of Bio-Layer's patent applications

Dominique Gorse PhD

- Head of Research & Discovery and co-founder of Bio-Layer
- Expert in molecular modeling, theoretical chemistry and chemoinformatics
- Responsible for developing new surfaces for immunoassay products, including Abiotics project

Plus 2 other PhDs, 1 medical and 7 qualified scientists

Bio-Layer

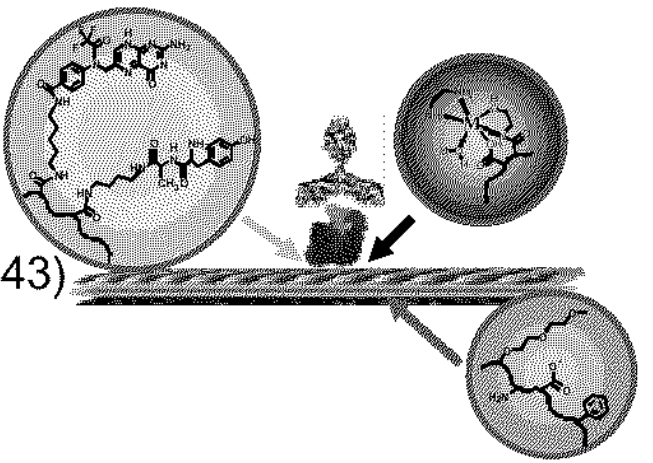
Intellectual Property Estate

- **High Throughput Discovery Patents**
  - Generation of Surface Coating Diversity (PCT/AU03/00566)

    Methods to generate libraries of different surface coatings and screening such coatings to identify novel surface candidates are disclosed.
  - A Method for Designing Surfaces (PCT/AU2004/001747)

    Computational models to design and generate polymeric coating elements that bind proteins in some preferred orientation are disclosed.
  - Use of Metal Complexes (PCT/AU2005/000966)

    Methods and compositions containing metal complexes, and metal, ligand and surface combinations to immobilise proteins are disclosed.
  - Three other US Provisionals filed.

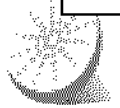


- **Manufacturing Patents**
  - Novel Polymers (PCT/AU01/01638)
  - Methods of Polymerization (PCT/AU02/00043)

Bio-Layer

Board

Bruce Rathie (Chairman) B.Com, LLB, MBA, Grad Dip CSP, FAICD, FAIM	Law, finance, capital markets particularly equity capital markets, Board and business experience and skill. Particular focus on regulatory issues and corporate governance.
Peter Rayner B.Bus, CPA	Twenty five years experience in sourcing funds, analysing and managing business and investment processes. Expertise in accountancy, stock broking and funds management.
Tony Evans PhD, BSc	Very broad science background, long term involvement in both large and small US and Australian listed and private life science based companies from both managerial and Board perspective.
Richard Martin BBus	Proficiencies include finance, business structures and functions attained from over 20 years in public practice as a Chartered Accountant.
Carrie Hillyard BSc(Hon), PhD, FTSE	Biotechnology, diagnostics and venture capital background with product development, management & commercialisation skills.
David Beins BSc(Hon), MBA	Skills in general management, strategic management and business development in the IVD industry.
Steve Erichsen M Mgt	Over 30 years commercial experience in Management, Sales and Marketing across a broad range of industries. Lectures at Undergraduate and Post Graduate level in Marketing and International Business at Macquarie University.



Bio-Layer

Glossary

Antibody: Produced naturally as part of the immune response. The 'stem' (Fc region) is constant for each animal species; the 'arms' (Fab region) bind specifically to a target. Antibodies are used by the IVD industry in immunoassay products and by the pharmaceutical industry in drug discovery and as drugs in their own right.

Abiotics: Using small molecules assembled on a surface to specifically bind a target, such as a protein. In the case of antibody replacement abiotics is synthetically mimicking an antibody.

Bioseparations: Binding one or more specific component(s) from a complex mixture, such as blood, for purposes of purifying the component or to remove a contaminant

Discovery Engine: Bio-Layer's patented high throughput system used to screen multiple surfaces for their ability to bind a specific protein

Immunoassay Market: Worth $US 6.0B globally, split into research and IVD segments. The IVD segment (85%) is highly automated and dominated by few multinational players.

***In Vivo*:** Inside the body

IVD: *In Vitro* Diagnostics, meaning diagnostics in the test tube (outside the body)

Mix&Go™: The brand name for a family of antibody binding products from Bio-Layer. The first version of Mix&Go™ is optimised for Luminex (multiplex) beads and makes them work better and/or reduces cost.

Point of Care (PoC): Diagnostic testing which takes place at the bedside or close to the patient. Characterised by simple to operate desktop or hand held devices which yield the same or similar results as laboratory analysis.

Bio-Layer