



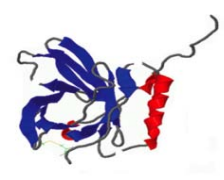
HealthLinx Limited

(ASX: HTX)

An emerging biomarker and diagnostic company with a lead product, OvPlex™, that is a new multi-marker blood test for the early detection of Ovarian Cancer

www.healthlinx.com.au

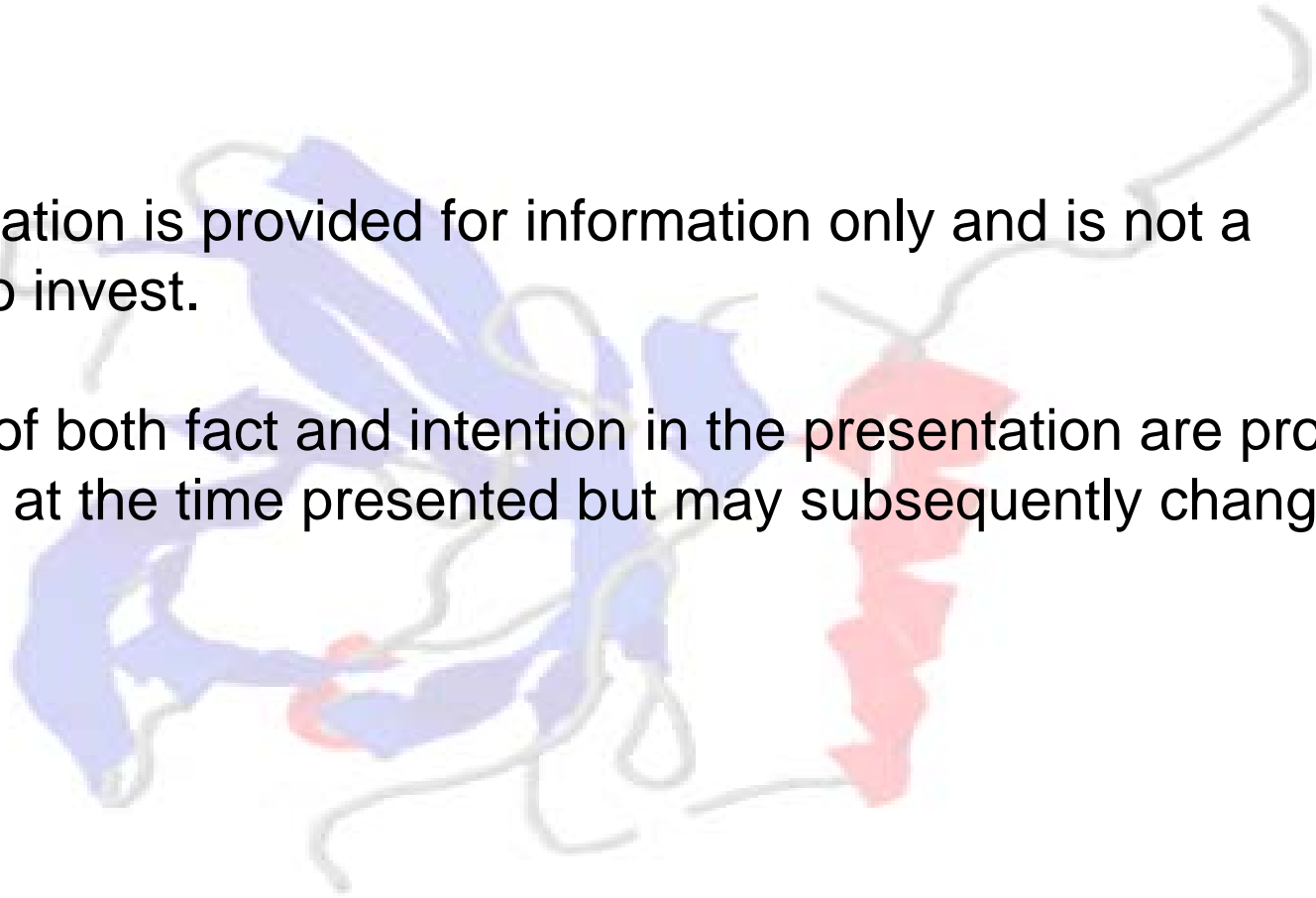
October 2010

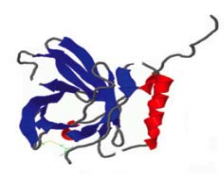


Disclaimer

This presentation is provided for information only and is not a solicitation to invest.

Statements of both fact and intention in the presentation are provided in good faith at the time presented but may subsequently change.

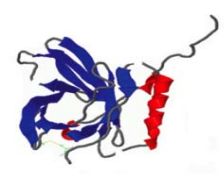




What is a Biomarker?

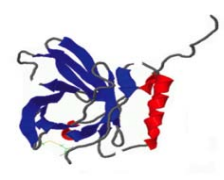
The official NIH definition of a biomarker is: "a characteristic that is objectively measured and evaluated as an indicator of normal biologic processes, pathogenic processes, or pharmacologic responses to a therapeutic intervention."

- This could be;-
 - DNA
 - RNA
 - Protein
 - Imaging markers



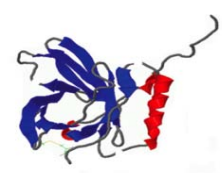
Biomarker Qualification

- Qualification of a biomarker means developing the correlative information that lets us understand its clinical meaning in a given situation
- Qualification often must begin with an initial stage of standardisation of the technology, i.e., need for a reproducible, quantitative test.



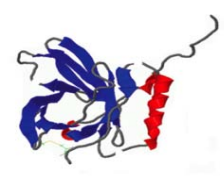
Post Qualification

- **Development and use of a diagnostic test**
 - Assay is designed and built
 - Test assay in clinical environment for “intended use”
- **Validation of biomarker assay**
 - Assay is taken into clinic for validation within diseases target
 - $n=?$ Samples are screened and analysed for;
 - analytical validation
 - assay variability
 - assay reproducibility
 - assay clinical cut off



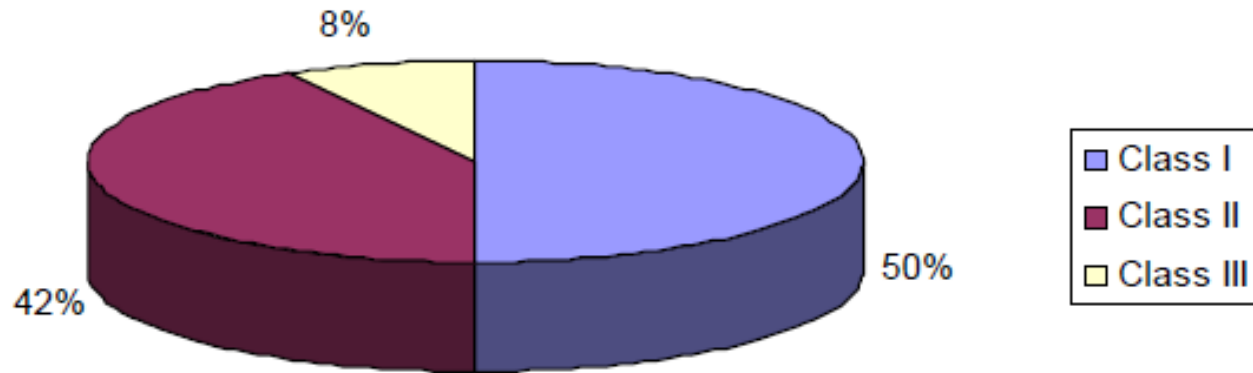
Regulatory Pathway

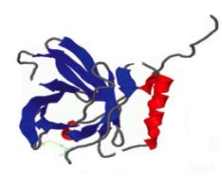
- **PMA (Pre market Approval)**
 - This is a long process
- **510K**
- **Pathway is a “Risk Based” model**
 - **Class III: most complex, high risk**
 - e.g. cancer diagnosis or screening
 - » *Premarket Application [PMA]*
 - » *Safety, effectiveness*
 - **Class II: more complex, moderate risk**
 - e.g. prognosis, monitoring in already diagnosed cancer patients
 - » *Premarket Notification [510(k)]*
 - » *Substantial equivalence*
 - » *Special controls*
 - **Class I: common, low risk devices**
 - » *Most exempt from premarket submission*
 - » *General controls*



Regulatory Pathway

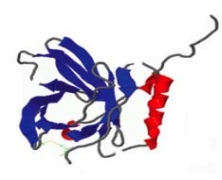
Percentage of IVD Devices by Product Class





Major Elements of IVD Submission

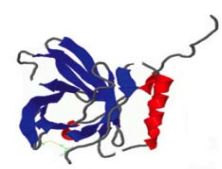
- Intended use/indications for use
- Device description
- Analytical Validation
- Clinical Validation/Clinical Utility
- Instrument and software validation, if applicable
- Label Use



Companion Diagnostics (CDx)

Regulators Perspective

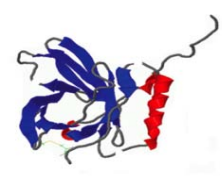
- Allows for the stratifying of patient populations
- Allows for greater efficacy of drugs
- Reduces health cost burden
- Increases the potential of health outcomes to relevant patient population
- Increases drug data for regulatory approvals
- Biomarkers assist in increasing safety and/or efficacy of therapies



Companion Diagnostics (CDx)

Regulators Perspective – cont.

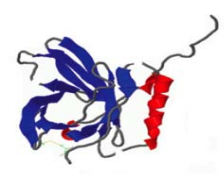
- In 2009 revised label use of Vectibix Erbitux that patients with KRAS mutation **did not** respond to treatment and the ***“use of these drugs is not recommended for patients with KRAS mutation”***
- In early 2010 FDA establishes a roundtable discussion group on CDx’s
- FDA proposes new Rx-CDx Guidance within 12 months
- In 2010 FDA halts ChemGenex Omapro Leukemia drug approval even with excellent data “due to inadequate CDx availability”



Companion Diagnostics (CDx)

Drug Development Impact

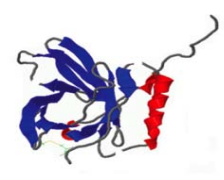
- Parallel development of therapeutic and diagnostic
- Improved controls during Clinical Trials
- Greater Clinical Trial endpoints
- Mitigating risk of clinical trial subjects
- Targeted patient population for drug post approvals
- Insurance companies increased confidence in reimbursement levels for drug and diagnostic
- Joint Regulatory Submission and complimentary data sets



Companion Diagnostics (CDx)

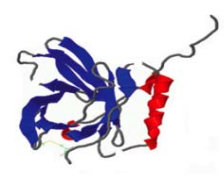
- New methods to better manage a patient's disease or pre-disposition toward a disease
- Aim is for optimal medical outcomes/benefits to patients
- Combines therapeutics and diagnostic modalities in the treatment of a patient

- Herceptin & HER2
 - 30% of women with Breast Cancer are HER2 positive
 - ELISA test is used to identify these women
 - Herceptin therapy is given only to these women



What's Next?

- Drug development companies and Diagnostic companies need to co-exist
- Partnering activity should be on the increase
- One value adds to the other;
 - In the development pathway
 - Post market launch
 - Reimbursement
 - Regulatory approvals
- Increases health outcomes to patients
- Reduces Healthcare costs



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