SAVASpheres™

Novel magnetic beads…..
for optimal light collection

Background: Magnetic beads (Microspheres)

- Magnetic pigment encapsulated in a polymer shell (to isolate from Biologicals)
- The polymer shell has functional groups such as Carboxyl, Amino, Epoxy (to facilitate linking biologicals)
- Many procedure for polymer encapsulation (patents and know how)
- Sizes of magnetic beads for biological application range between 0.5 and 50 microns

Background: Applications

- A universal binder to link biological agents (solid phase)
- Introduced to the biomedical field 2 decades ago
- Today, a significant reagent for the Clinical testing Kits
- Used in 90% clinical testing analyzers (immunoassay/DNA)
- Used in testing for any disease (Cancer, endocrine, cardiac)

Background: Applications

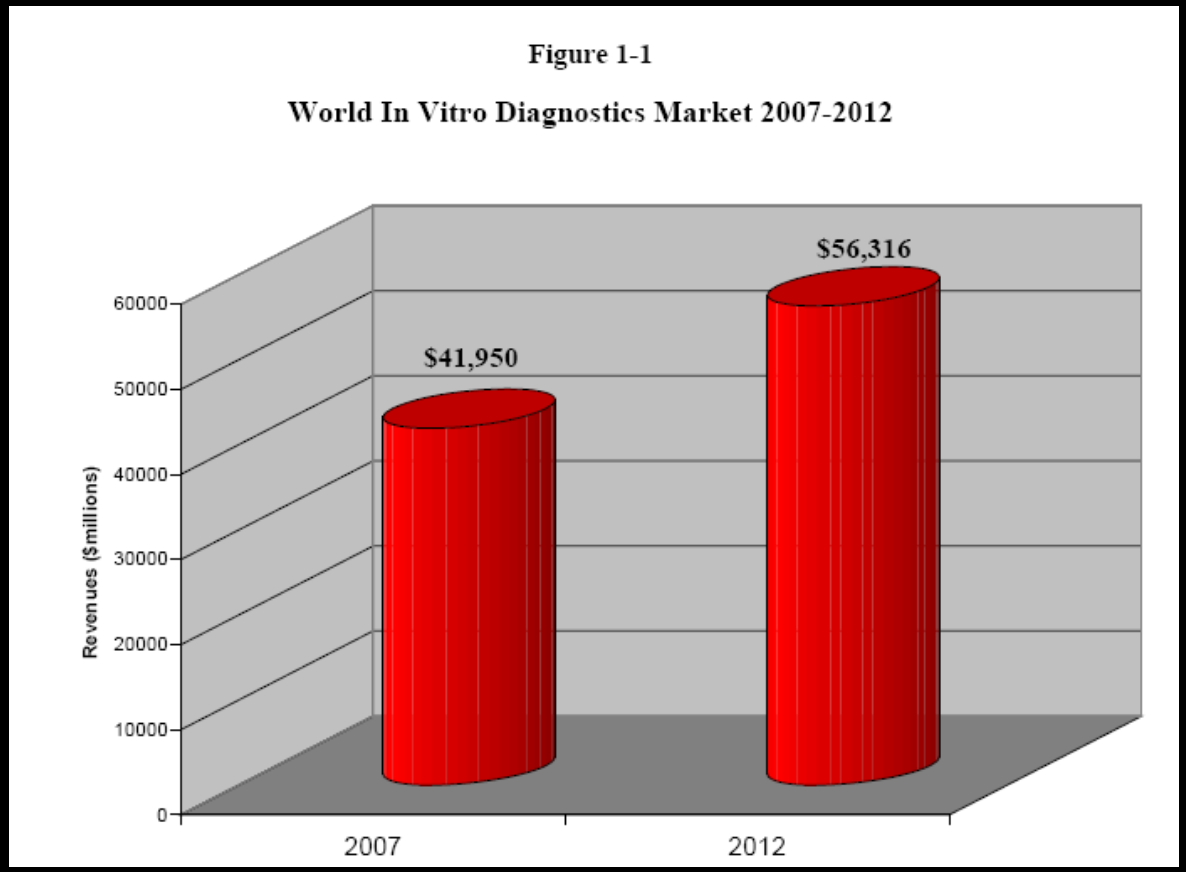
Due to simplicity of use, magnetic particles (MP) are employed in:

- *Clinical In-Vitro Diagnostic Testing*
  - Immunoassays
  - DNA testing
- *Life Sciences Research*
  - Cell & nucleic acid separation
  - Protein purification
  - Sample enrichment

Background: Biomedical Market

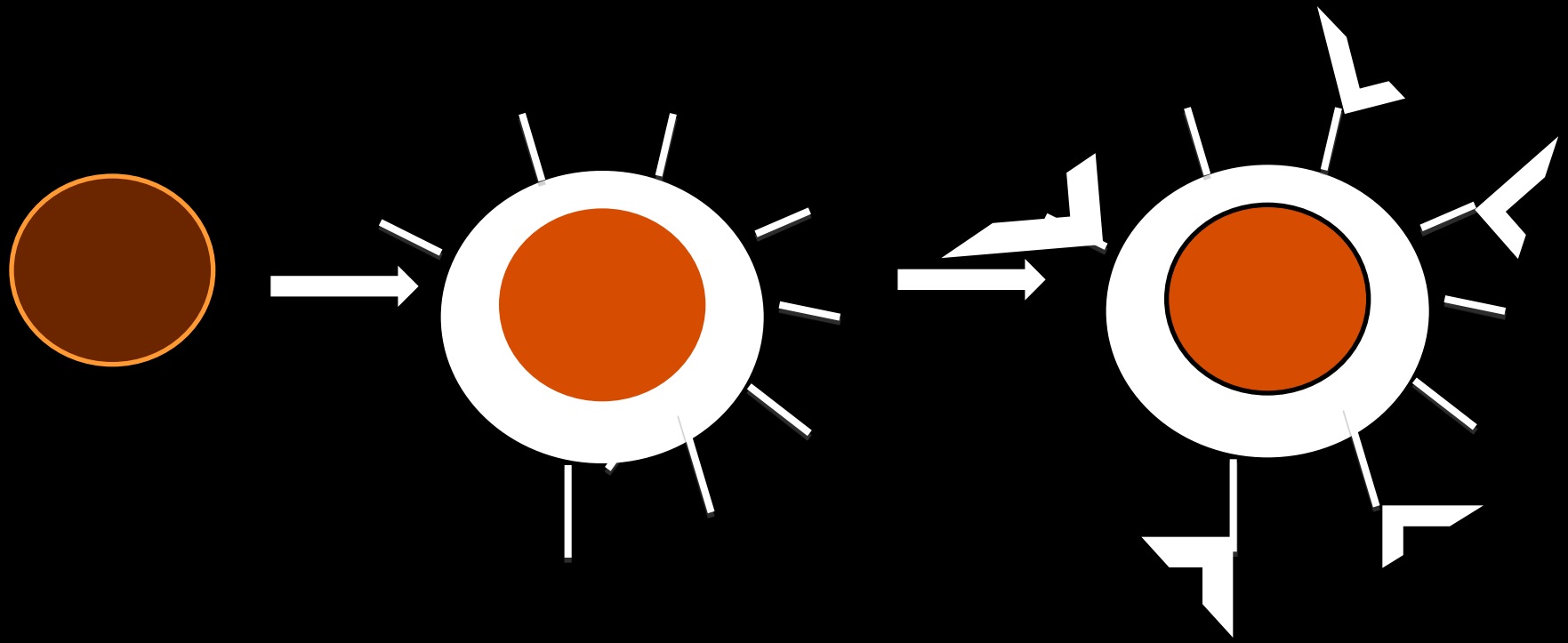
- Global IVD market estimated at $42.9 billion in 2007, expected growth to $56 billion by 2012
- Immunoassay testing market is 28% of the IVD testing
- Immunoassay analyzers that employ both MP and light reactions represent more than 80% of this market
- Estimated MP market of about $1 billion

The In-Vitro-Diagnostics Market



Source: The Kalorama Report, 2010

Novel Paramagnetic Beads



SAVASpheres™

Silver-Plated Magnetic Beads

SAVASpheres™

SAVASpheres™

SAVASpheres™: Silver-Plated MP

- Silver plated and polymer encapsulated
- Manufactured by a simplified process
- Beads of various sizes (0.5-50 micron)
- Scaled up batch-sizes to commercial lots
- Development, supported by NRC through IRAP grants (4 in total)

SAVASpheres™

Color conversion: silver plating

- A proprietary electroless silver-plating process
- Controlled silver thickness, controlled reflectivity-density
- No impact on magnetic properties
- Chemical/mechanical stability
- Post-plating protection (passivation)

SAVASpheres™

Polymer encapsulation (coating)

- Proprietary polymer encapsulation process
- Minimum of three polymer layers:
  - brightness
  - functional group density
  - ion leakage/ion capture
- A combination of electrostatic-covalent bonding
- A hydrophilic polymer surface - minimizes non-specific binding
- Tailored surface functionality – multiple linking

SAVASpheres™

Features

- Silver-layer with no impact on magnetic moment
- 80% magnetic material - quick magnetic response
- No deterioration/peeling in salt high solutions
- No ion leakage (assessed by enzyme)
- Tailored functional surface group (Amino, Carboxyl):
  - to influence colloidal status
  - to influence background

Commercialization

Current competitive products

- All contain dark iron oxide material
- Manufactured by magnetic material encapsulation or magnetic pigment insertion in latex particle
- Several small Companies (~ 30), three main players
- Prices range from $900-$1500/gram of solids
- Developed for color measurements
- Current Clinical Analyzers employ light measurement

SAVASpheres™

Competitive Advantages

- All commercial paramagnetic particles are dark
- 90% of Immunoassay Analyzer use light measurements
- Maximize light collection by white color conversion
- ~ 80% loss of generated light - low testing sensitivity
- High magnetic moment, easy manipulation
- Hydrophilic surface - optimal specific and low background
- Chemically robust surface chemistry - long term stability
- Simplified manufacturing process - less costly

SAVASpheres™

Compared with beads of all major suppliers, a consistent up to 7 folds improvement in light signal collection with SAVASpheres,

- Increased testing sensitivity
- Higher test output

Posters 41 and 42, Oakridge, AACC, 2007

Potential Markets

- Clinical *In-Vitro-Diagnostics* testing that employ MP/light
  - Ten (10) first-tier global IVD test manufacturers
  - Thirty (30) second-tier IVD test manufacturers
  - Numerous small regional manufactures

  Could be adapted to existing/new tests/machinery

- Life sciences research applications, companies/universities

Commercial Strategy

- A marketing agreement with Merck, signed in 2009
- Two Material Transfer Agreements with 2 other multinationals
- Sales Team

Commercial Strategy

Agreement with Merck

- Executed in 2009, Merck is to receive silver-plated beads
- Merck to encapsulate silver beads by their process
- After numerous trials, Merck-encapsulated beads did meet the specs
- Merck agreed to commercialize SAVASpheres
- In October 2011, Merck shipped SAVASpheres to clients

Commercial Strategy

The Two Material Transfer Agreements

- One in progress (testing)
- The other is on-hold

Commercial Strategy

Internal Sales Team

To Target

- Research Laboratories in Universities
- Small IVD companies

4 Man team is being set up

Internal sales/technical support


i-STAT
EC8+

Thank you

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