

BBI Solutions Company Showcase

Paul Williams
8th July 2015

Agenda

- Introduction to BBI Solutions
- Next generation diagnostic testing
- Responding to a changing landscape

*“Our vision is to create
a world where
everyone has the
opportunity for a
better quality of life”*



Introducing BBI Solutions

- Leading experts in immunoassay design, development and manufacturing services
- Leading supplier of critical biological raw materials and labels to the POC and Lab IVD market
- Served the global diagnostics industry for **over 50 years**
- BBI Solutions is the trusted partner of the major IVD manufacturers while also supporting the development of new and start-up companies
- BBI has a record of **delivery on the results** customers need

“We have successfully completed more than 250 different lateral flow projects”



Our History at a Glance

1986

The BBI Group was established in 1986 with only 10 staff.



<£1m

Turnover <£1M

2000

BBI achieved an MBO in 2000. An IPO in 2004.



2004

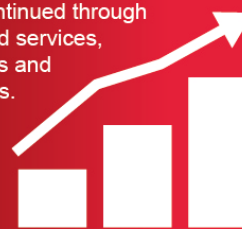
2005/6

First new entities set up - BBI Research & BBI Healthcare.

BBI Research

BBI Healthcare

Growth continued through product and services, acquisitions and new entities.



£85m

2008

In 2008, the BBI Group was sold to Alere for £85m. Alere are a global POC leader.



Today we have established substantial growth since 1986

£52m

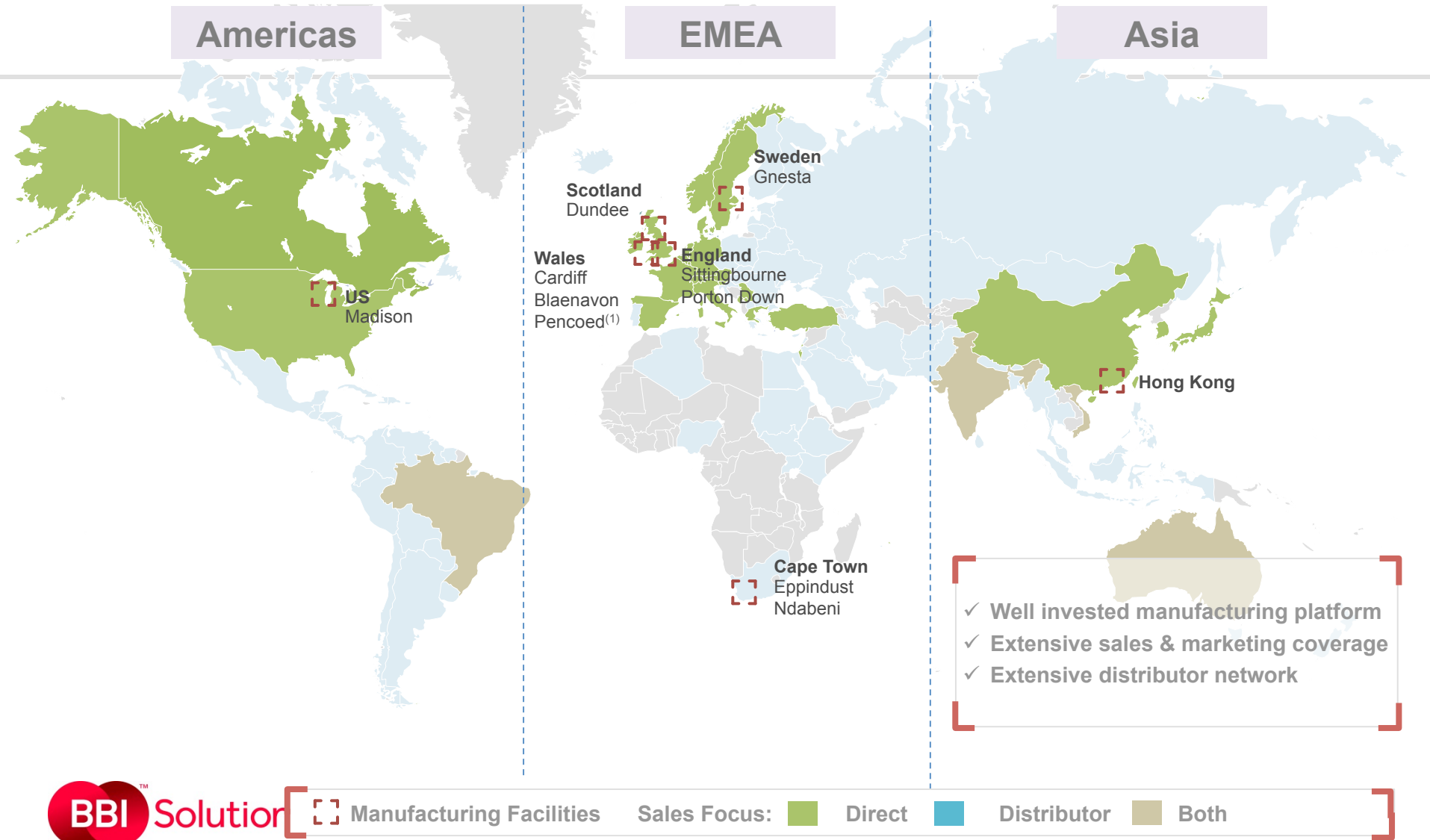
Turnover of £52M

400+ staff including PhD's in chemistry and biology



A Global Footprint

An established global platform with world class manufacturing sites



Solution

Manufacturing Facilities

Sales Focus:



Direct



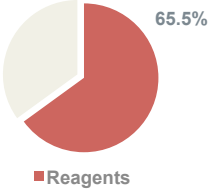
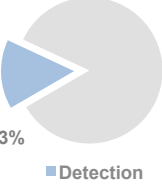
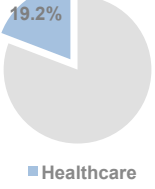
Distributor



Both

BBI Group - How BBI Solutions Fits

A leading supplier of diagnostic reagents, products and services to diverse end markets

Key Product Categories	Diagnostic Reagents	Applied Diagnostics	
	BBI Solutions	BBI Detection	BBI Healthcare
Product Offering	<p>Key Raw Materials (e.g. Enzymes, Proteins, Antibodies) Labels (e.g. Gold) Contract development & manufacturing POC LFD.</p>	<p>Diagnostics for Biothreats, Explosives and Chemicals</p>	<p>Rx and OTC Women's Health and Glucose Products</p>
Key Customers	<p>Major IVD's, Pharma Companion ; Life Science companies.</p>	<p>UK MoD, US DoD</p>	<p>Primary and Secondary Care Channels Major UK Retailers</p>
Revenue Share (2013E)	 <p>65.5%</p> <p>■ Reagents</p>	 <p>15.3%</p> <p>■ Detection</p>	 <p>19.2%</p> <p>■ Healthcare</p>

Our Business - BBI Solutions

High quality raw materials, protein extraction and assay development

	Category	Products and Services	Application	Key Differentiating Factors
Biological Reagents	Human Antigens	<ul style="list-style-type: none"> Native Antigens Recombinant Antigens 	<ul style="list-style-type: none"> IVD immunoassay development Clinical Chemistry 	<ul style="list-style-type: none"> Consistent supplier benefits Portfolio focused on key clinical areas e.g. infectious disease Recognised products within range Direct, ethical access to clinical samples End to end product & service offering Materials can be manufactured to custom specification
	Serum and Plasma	<ul style="list-style-type: none"> Normal & Depleted Serum Disease State Plasma Patient Samples 	<ul style="list-style-type: none"> IVD assay development Calibrators & controls External Quality Testing 	
	Antibodies	<ul style="list-style-type: none"> Monoclonal Polyclonal Recombinant 	<ul style="list-style-type: none"> IVD immunoassay Research/Life Sciences 	
	Enzymes	<ul style="list-style-type: none"> Native enzymes Recombinant enzymes Bulk and Custom manufacture 	<ul style="list-style-type: none"> BGM/Biosensors Immunodiagnosics Clinical Chemistry Pharmaceuticals 	
	Cell Culture Supplements	<ul style="list-style-type: none"> Native Transferrin Growth factors 	<ul style="list-style-type: none"> Bulk Cell culture media Research/Life Sciences 	
Lateral Flow	Gold & Nanotech	<ul style="list-style-type: none"> Colloids Bulk conjugates Custom Conjugation service Proprietary labels 	<ul style="list-style-type: none"> Lateral Flow Tests 	<ul style="list-style-type: none"> End-to-end link between POC and LAB IVD Proprietary know-how Broad range of technologies to employ (e.g. magnetic, gold, latex, fluorescent) Flexible manufacturing capacity for customers Flexible and extensive experience in Immunoassay development
	Contract Assay Development	<ul style="list-style-type: none"> Services – feasibility through to product transfer New development and redevelopment of products 	<ul style="list-style-type: none"> Lateral Flow Tests 	
	Contract Assay Manufacturing	<ul style="list-style-type: none"> Turn-key OEM 	<ul style="list-style-type: none"> Lateral Flow Tests 	

The challenges facing diagnostic companies

High
Sensitivity



Next
generation
DX

Ease of
Use

Faster
Results



Quantitative
tests with
readers

Increased
accuracy

Price

Regulated
Markets

Meeting
Emerging
Market
Demands



Our response

Ease of
Use

Fast
results

Next
generation

Smartphone Mobile Reader Solution

Omega Diagnostics VISITECH App



- 35.3 million people living with HIV globally – 68% of new cases in sub-Saharan Africa
- Omega Diagnostics wanted to make their VISITECH CD4 RDT assay more accessible, affordable and easy to use
- Worked with BBI joint venture Novarum to develop the VISITECH CD4 Reader App
 - **Easy to use:** without training, multi-lingual on-screen instructions
 - **Accessible:** in the field or at home
 - **Visible:** data sharing with local and central government databases
 - **Better patient care:** proactive treatment based on reliable results



Our response

Ease of
Use

Increased
accuracy

Emerging
markets

Integrated platform

Simple, fast, accurate testing - Ebola



- 27,000 Ebola cases reported and 11,000 deaths in West Africa to date
- Accurate diagnosis relies on laboratory staff and equipment - delays in diagnosis, difficulty containing spread of the virus
- BBI partnered with Dstl and Atomo Diagnostics to develop:
 - Rapid assay - results in the field in approx 20 mins
 - An integrated platform simplifies the process, reduces the risk of user error and cross contamination
- In field trials in Sierra Leone:
 - 100% detection rate was achieved
 - Low positive - 100% sensitivity and 92% specificity
 - High positive - 100% sensitivity and 97% specificity
- More sensitive and specific than competing tests
- Quarter 3 launch!



Our response

Increased accuracy

Faster results

Emerging Markets

Direct sourcing of patient samples

True diagnostic QC testing



- **Direct sourcing** of patient samples and clinical specimens
- Relevant high and low titre disease state material for true diagnostic QC testing
 - Used to spike higher lower levels
 - Not a broker – we can secure rare early acute phases of infection
- Biobank allows our customers to:
 - **Save time & optimise their success rate** - highly characterised disease state plasma units. Large inventory stored at our facilities
 - **Have confidence in their supply** -
 - We collect directly from hospitals and blood banks.
 - Materials collected with ethics approval and/or donor consent when relevant, storage at a HTA licenced facility
 - Facilities in the UK and Containment Level 3 laboratories in South Africa to process infectious disease state plasma

Responding to a changing landscape

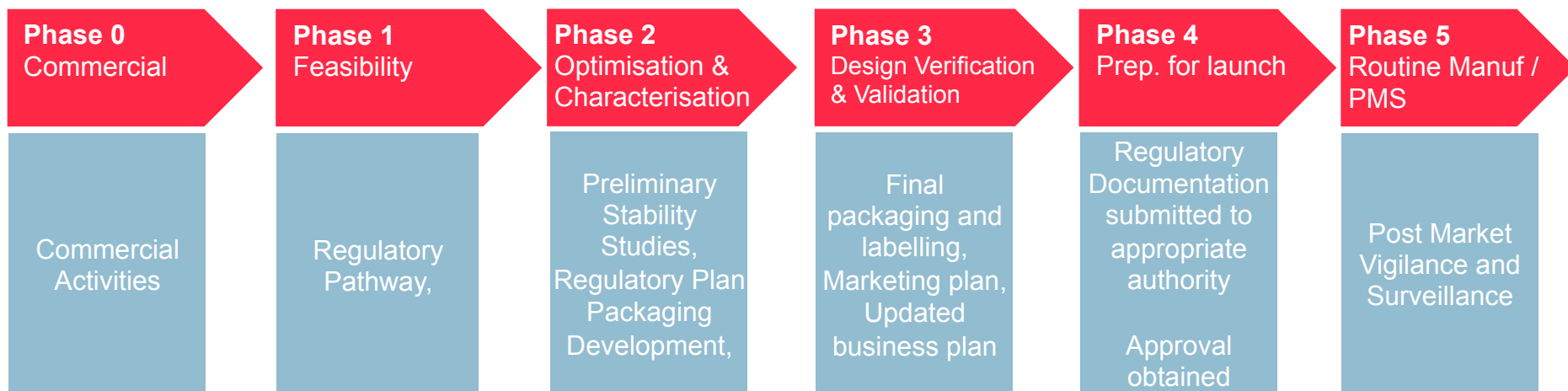
Regulated
markets

Fast
results

End to end contract development and manufacture

Responding to regulatory changes

- Changes to EU IVD Diagnostic Directive – IVDs currently classed as ‘self certify’
- Customers need to start thinking about the following now:
 - How **new** products will be classified at the **start** of the development process
 - Whether **existing** products will meet **new** requirements
- Extended existing service to include full regulatory and post market support:



Summary

- Grown into a true end to end supplier of Immunoassay diagnostic products and services
- Proven track record of collaboration and delivery with some of the world's leading diagnostic partners
- Working with customers to meet changing market and regulatory requirements
- Future focussed – next generation assay development
- Looking for partnerships and commercialisation opportunities for new technologies both in the UK and abroad

“BBI’s commitment and professionalism were key points to achieve the successful result in gaining the GMP Certificate”

Ingrid Jurgensen, Compliance Auditor at
Becton Dickinson

