




# ABZENA



Enabling better biopharmaceuticals

**2<sup>nd</sup> February 2016**

**Innovators and Investors Forum**

Julian Smith, Chief Financial Officer

# Important notice

These slides (the "Document") have been prepared and issued on behalf of Abzena plc (the "Company") and its subsidiaries for information purposes only. By attending this presentation and/or accepting a copy of this Document, you agree to be bound by the following conditions and will be taken to have represented, warranted and undertaken that you have agreed to the following conditions.

This Document is for information purposes only and should not be construed as any offer or invitation to subscribe for any securities in the Company nor should it or any part of it nor the fact of its distribution, save as otherwise expressly agreed, form the basis of, or be relied on in connection with, any contract or investment decision in relation thereto.

This Document does not constitute or form a part of any offer or solicitation to purchase or subscribe for securities in the United States of America. The securities of the Company have not been, and will not be, registered under the United States Securities Act of 1933, as amended (the "Securities Act"), or qualified for sale under the law of any state or other jurisdiction of the United States of America and may not be offered or sold in the United States of America except pursuant to an exemption from, or in a transaction not subject to, the registration requirements of the Securities Act. Neither the United States Securities and Exchange Commission nor any securities regulatory body of any state or other jurisdiction of the United States of America, nor any securities regulatory body of any other country or political subdivision thereof, has approved or disapproved of this presentation or passed on the accuracy or adequacy of the contents of this presentation. Any representation to the contrary is a criminal offence in the United States of America.

This Document and any materials distributed in connection with the Document, include statements that are, or may be deemed to be, "forward-looking statements". These forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes", "estimates", "plans", "projects", "anticipates", "expects", "intends", "may", "will", or "should" or, in each case, their negative or other variations or comparable terminology. These forward-looking statements include matters that are not historical facts. They appear in a number of places throughout this Document and include statements regarding the current intentions, beliefs or expectations of the directors ("Directors") of the Company concerning, among other things, the Company's results of operations, financial condition, liquidity, prospects, growth, resource estimates, strategies and the Company's markets. By their nature, forward-looking statements involve risk and uncertainty because they relate to future events and circumstances. Actual results and developments may and often do differ materially from those expressed or implied by the forward-looking statements.

Any forward-looking statements in this Document are based on certain factors and assumptions, including the Directors' current view with respect to future events and are subject to risks relating to future events and other risks, uncertainties and assumptions relating to the Company's operations, resource estimates, results of operations, growth strategy and liquidity. Whilst the Directors consider these assumptions to be reasonable based upon information currently available, they may prove to be incorrect, therefore reliance should not be placed on these forward looking statements. Save as required by law or by any applicable rules or regulations, the Company undertakes no obligation to publicly release the results of any revisions to any forward-looking statements in this Document that may occur due to any change in the Directors' expectations or to reflect future events, new information or circumstances after the date of this Document.

No representation or warranty, express or implied, is or will be made as to, or in relation to, and no responsibility or liability is or will be accepted by the Company, its subsidiaries or by any of their officers, employees, affiliates or agents as to, or in relation to, the accuracy or completeness of the information, data or opinions contained in this Document or any other written or oral information made available to or publicly available to any interested party or its advisers, and any liability therefore is expressly disclaimed, nor have the Company or its subsidiaries independently verified such information, and any reliance you place thereon will be at your sole risk. Neither the Company, its subsidiaries or by any of their officers, employees, affiliates or agents shall have any obligation to update this Document or any additional information or to correct any inaccuracies in it which may become apparent.

# Helping select, improve, de-risk & manufacture biopharmaceuticals

Licensor of proprietary technologies providing complementary services

Service revenue from range of pre-clinical and manufacturing services

- Acquisition of two US companies in 2015
- PacificGMP & TCRS broaden service offering
- The Group is integrating and consolidating their operations
- Cross-selling and expansion opportunities

Significant income potential from licence portfolio of partner funded “ABZENA *inside*” products

- 11 ABZENA *inside* products already in clinical development
- Three ABZENA *inside* product companies purchased for a total of US\$1.5bn (US\$500m cash)
- Multi-billion \$ sales potential
  - 4 products in later stage clinical studies
  - 5 products partners with major biopharma companies
- Licensing deal for ThioBridge™ antibody drug conjugate (ADC) linker technology has the potential to generate up to \$150 million licence fees and milestone payments and royalties

*Biopharmaceuticals are protein based drugs and include antibodies, antibody-drug conjugates, therapeutic proteins and peptides. ABZENA *inside* products are biopharmaceutical products that incorporate one or more of Abzena's proprietary technologies.*



# Experienced board & executive team

## Non-executive directors



**Ken Cunningham**  
Chairman  
Abzena plc



**Tony Brampton**  
Partner  
Longbow Capital



**Nigel Pitchford**  
Chief Investment Officer  
Imperial Innovations



**Peter Grant**  
Chief Executive Officer  
SkyePharma plc



**Anker Lundemose**  
Chief Executive Officer  
MISSION Therapeutics

## Executive directors



**John Burt**  
Chief Executive Officer



**Julian Smith**  
Chief Financial Officer

## Executive management

**Matthew Baker**  
Chief Scientific Officer

**Campbell Bunce**  
SVP Scientific Operations

**Neil Butt**  
VP Business Development

**Donna Hackett**  
VP IP, Commercial & Legal Affairs

**Naresh Jain**  
SVP (ADC Biomanufacturing) &  
Global Head of Chemistry

**Jim Mills**  
VP Technical Operations

**Gary Pierce**  
President, PacificGMP

**Leigh Pierce**  
Chief Technology Officer  
(Biomanufacturing)

**Sally Waterman**  
SVP Corporate Development

# Broad-based offering from UK & US operations



Bioconjugation for ADC  
Specialised Chemistry  
Cambridge & Coventry UK



Immunology, CLD  
Protein Engineering,  
Cambridge UK



Antibody & Protein  
GMP manufacturing  
San Diego USA



Chemistry & ADC  
manufacture  
Philadelphia USA

- Principal lab and head office facilities at Babraham Research Campus, Cambridge, UK
- Satellite labs in Coventry (UK) at the University of Warwick Science Park
- GMP manufacturing facility for antibodies and other proteins in San Diego, CA, USA
- Custom chemistry and ADC manufacture near Philadelphia, PA, USA

GMP = Good Manufacturing Practice, the standard that must be applied to drugs to treat patients

CLD = Cell Line Development,

ADC = Antibody drug conjugates are antibodies with cytotoxic poisons attached which specifically target tumours and kill them



# Strong support for business strategy from leading sector investors

---

IPO July 2014 and secondary placing in December 2015

Funds being used to achieve step changes in growth trajectory through:

- R&D – investment building expertise & technology
- M&A – two acquisitions announced in 2015



# Abzena operates in the large growing biopharmaceuticals market

Global revenue for biopharmaceuticals \$163bn - CAGR 8%

7 out of the world's top 10 drugs<sup>1</sup>

Outsourced early development services > \$5bn and growing

Innovation thriving as disease mechanisms are better understood

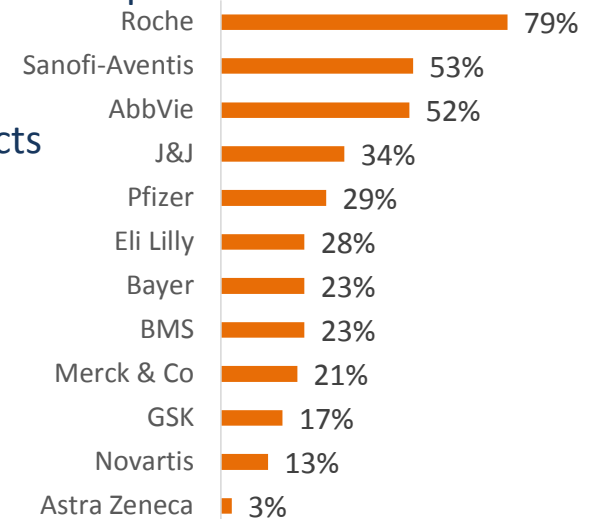
Immuno-oncology products harness the patient's own system

Antibody drug conjugates target tumours to kill them with lower side effects



Examples of some currently available biopharmaceutical drugs

## Proportion of revenue attributed to Biopharmaceuticals





# Background overview of the drug development process



## Research services & technology evaluation

Revenue-generating

Optimisation & selection of better candidates

- Immunology
- Protein engineering <sup>L</sup>
- Bioconjugation for ADCs <sup>L</sup>

## Development Services

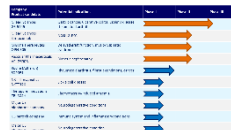
Revenue-generating - growth facilitated by capex

Enabling progression into clinical studies

- Cell line development
- Process development
- GMP manufacture

## Technology Licence Portfolio


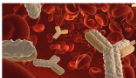
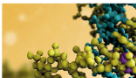
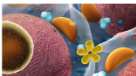







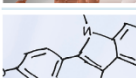
Significant potential future revenue



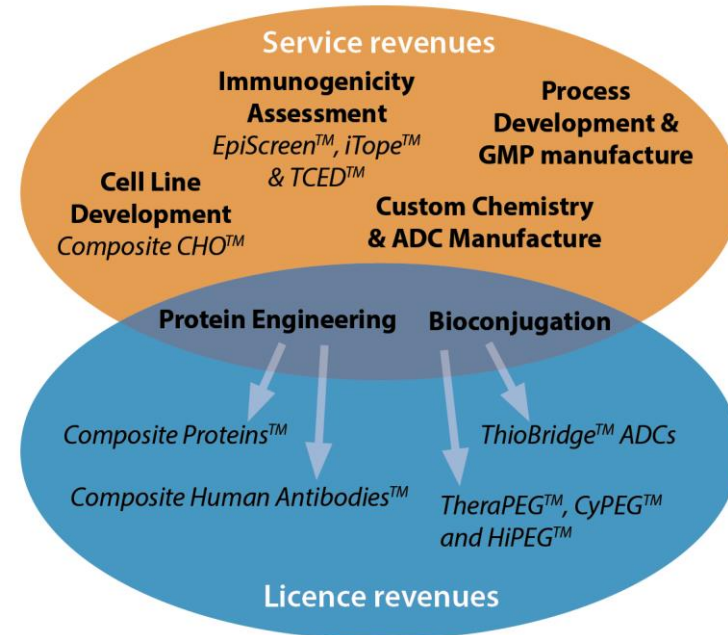
Licences provide potential future value from further development & commercialisation by partners of **ABZENA inside** products through milestones and/or royalties arising from protein engineering and ADC linker technology



# Complementary services and technologies

		Service revenues	Licence revenues
ANTITOPE	 <b>EpiScreen™</b> for assessment of the immunogenicity of biopharmaceuticals	●	
	 <b>Composite Human Antibody™</b> technology to create less immunogenic therapeutic antibodies	●	●
	 <b>Composite Protein™</b> technology to create less immunogenic therapeutic proteins	●	●
	 <b>Composite CHO™</b> to produce cell lines for the manufacture of therapeutic antibodies	●	
	 <b>iTope and TCED™</b> technologies to identify parts of proteins and antibodies that could be immunogenic	●	
POLYETHERICS	 <b>ThioBridge™</b> for linking antibodies that target tumours to cancer drugs	●	●
	 <b>TheraPEG™, CyPEG™ and HiPEG™</b> for linking polymers to therapeutic proteins to extend their duration of action	●	●
	 <b>PolyPEG™</b> a low viscosity polymer to make it easier to manufacture and inject long acting therapeutic proteins	●	●
PACIFICGMP	 <b>Process development</b> to optimise upstream and downstream production as a standalone service or integrated with a manufacturing project	●	
	 <b>GMP manufacture</b> of biopharmaceuticals for Phase I & II clinical studies and non-GMP production using single-use equipment	●	
	 <b>Toolbox of cytotoxic payloads</b> and synthesis of payload-linker combinations for ADCs, and custom synthesis of other reagents and small molecules	●	
TCRS	 <b>Manufacture of ADCs</b> for evaluation and preclinical studies using ThioBridge™ or other proprietary or non-proprietary conjugation chemistries	●	

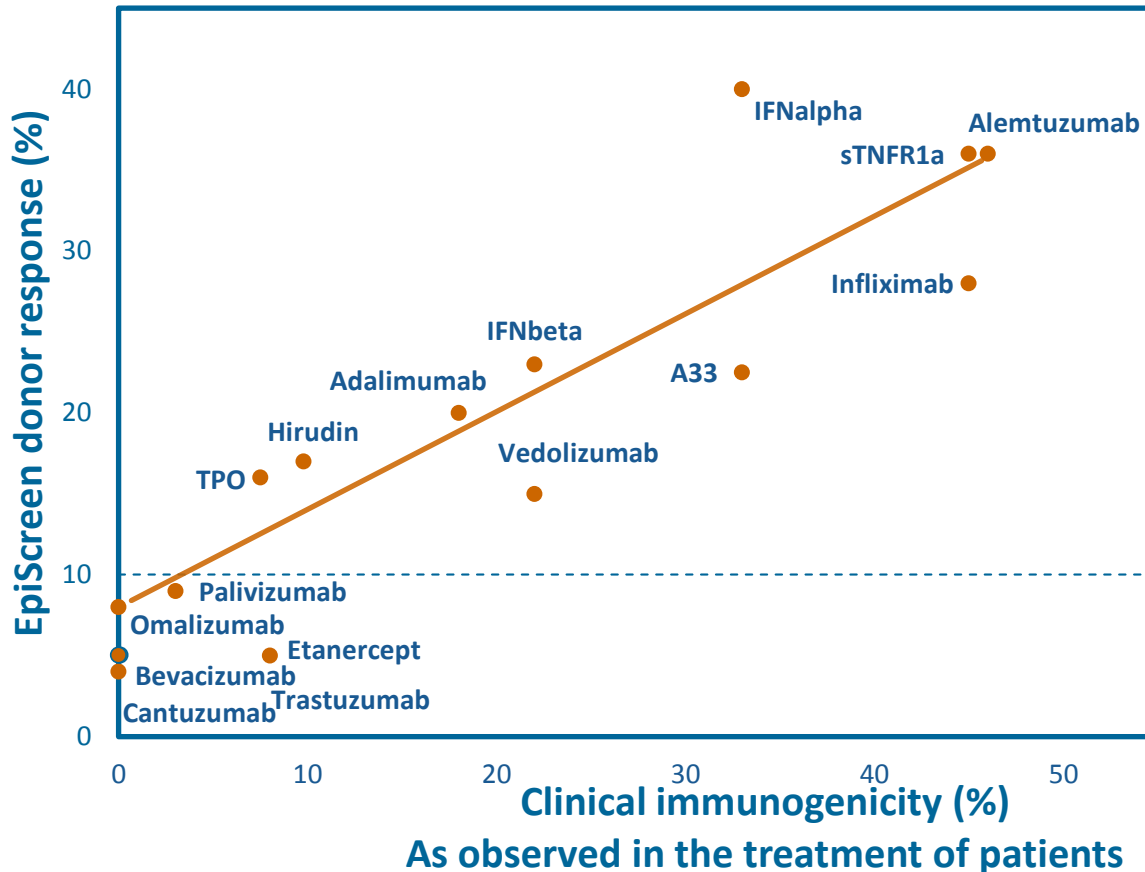
Growing service revenues through organic growth & expansion of offering via M&A



Portfolio of > 40 licence & licence option agreements with potential to deliver significant future licence revenues

# Immunogenicity risk assessment:

## Potential to anticipate outcome prior to clinical studies



Abzena has shown that the results of its immunogenicity assay (EpiScreen™) correlate with the published data on the immunogenicity of well-known products in patients

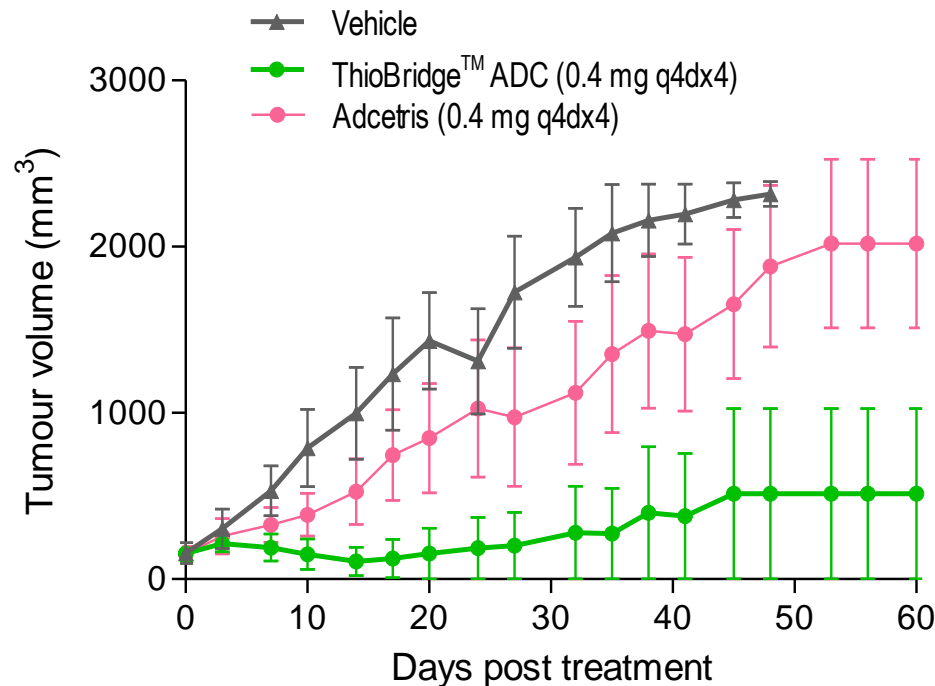
Mean frequency of anti-therapeutic antibodies observed clinically (source PubMed) correlates with observed immunogenicity (% donor response) in *ex vivo* EpiScreen™ T cell assays.  $R^2 = 0.83$ . Baker and Jones *et al.* 2008 Curr. Opin. Drug Disc. Dev, Barker. Current Drug Safety. 2010; 5(4): 272-274

# Wavebag manufacturing process



# Benefits of ThioBridge™ ADCs

ThioBridge™ conjugation technology can produce ADCs which are easier to manufacture with more predictable & stable effects allowing the drug to stay attached to the antibody until it reaches the tumour



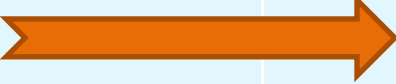





A licensing deal for ThioBridge™ ADC linker technology announced January 2016 has the potential to generate up to \$150 million licence fees and milestone payments with additional royalties on product sales

ThioBridge™ version of Adcetris (a marketed ADC) was more efficacious in an animal model of cancer

Repeat dose study (Karpas299 xenograft)

# Significant potential income from products in clinical development

Company Product candidate	Potential indications	Phase I	Phase II	Phase III
<b>Gilead Sciences</b> GS-5745	Gastric cancer, ulcerative colitis, Crohn's disease, rheumatoid arthritis			
<b>Gilead Sciences</b> Simtuzumab	NASH & PSC			
<b>Opsona Therapeutics</b> OPN-305	Delayed graft function, myelodysplastic syndrome			
<b>Vascular Pharmaceuticals</b> VPI-2690B	Diabetic nephropathy			
<b>Roche (Adheron)</b> SDP051	Rheumatoid arthritis, fibrotic conditions, cancer			
<b>NKT Therapeutics</b> NKT120	Sickle cell disease	<p>Three <b>ABZENA</b> <i>inside</i> product companies purchased for a total of US\$1.5bn (US\$500m cash to date).</p> <p>Their products continue to be developed by their acquirers.</p> <p>Analysts view is this portfolio covers a peak market in excess of US\$10bn p.a.</p>		
<b>Therapure Innovations</b> TBI 304H	Chemotherapy-induced anaemia			
<b>Major US</b> biopharma company	Neurodegenerative conditions			
<b>US biotech company</b>	Immune system and inflammatory conditions			
<b>Major US</b> biopharma company	Neurodegenerative condition			
<b>US biotech company</b>	Cancer			

NASH = Non-alcoholic steatohepatitis; PSC = primary sclerosing cholangitis

# Composite Human Antibodies™ in Phase II/III clinical development

## Phase II

### Gilead Sciences: simtuzumab

#### Non-alcoholic steatohepatitis

- Fatty accumulation in the liver
- Incidence increasing: ~6m affected in US
- 3 studies ongoing in 551 patients with & without cirrhosis and in combination with other investigative agents

#### Primary sclerosing cholangitis

- Scar tissue restricts liver function
- Prevalence 2.8% population > 40 years
- 235 patient study ongoing

### Opsona Therapeutics: OPN-305

#### Delayed graft function

- Occurs in ~21% patients in the US after kidney transplant (17,105 in US in 2014)
- 351 patient study ongoing

#### Myelodysplastic syndrome (MDS)

- Low number of blood cells produced
- Incidence 4.8 per 100,000 in US
- 40 patient study ongoing

### Vascular Pharmaceuticals: VPI-2690B

#### Diabetic nephropathy (kidney damage)

- Will develop in ~40% diabetics
- 300 patient study ongoing

## Phase II/III

### Gilead Sciences: GS-5745

#### Gastric cancer (Phase III study initiated Q4 2015)

- 952,000 new cases reported in 2012
- 430 patient study ongoing

#### Ulcerative colitis (Phase II/III study)

- Chronic inflammation of colon & rectum
- Prevalence of 238 per 100,000 in US
- 1600 patient study ongoing

#### Crohn's disease (Phase II study)

- Inflammation of lower part of ileum
- Prevalence of 201 per 100,000 in US
- 175 patient study ongoing

#### Rheumatoid arthritis (Phase II study planned)

- Chronic progressive inflammation of joints
- Affects approximately 1.3 million US adults
- Phase II study details not yet announced

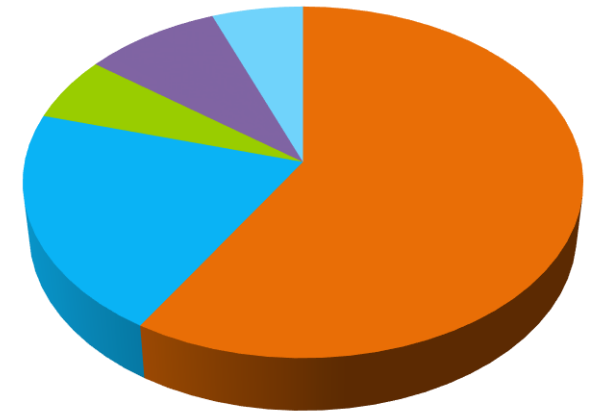




# Financial highlights for the half-year to 30 Sept 2015

- Revenue - £3.5m (\$5.3m)
  - Increased 43% from H1 2015 with service revenues up 47%
  - Small contribution from acquisition of PacificGMP
  - TCRS revenues will start to impact revenues in period to March '16
- Gross profit - £1.6m (\$2.4m)
  - Increased by 31% from H1 2015
- R&D investment - £1.9m (\$2.8m)
- Reported loss increased to £3.5m (\$5.3m)
  - Reported loss for H1 2015 £2.7m (\$4.0m)
- Cash at £7.4m (\$11.1m) at 30 September 15
  - £20m (\$30m) (net of expenses) raised in Dec 15

Service revenue split



- Immunology (£2.0m)
- Protein engineering (£0.7m)
- Bioconjugation (£0.2m)
- Cell line development (£0.3m)
- Biomufacturing (£0.2m)

Abzena plc listed on the AIM segment of the LSE in July 2014 (AIM: ABZA)





# ABZENA

Enabling better biopharmaceuticals



An Abzena company

**POLYTHERICS**

Enabling better biopharmaceuticals



An Abzena company

**ANTITOPE**

Enabling better biopharmaceuticals



An Abzena company

**PACIFICGMP**

An Abzena company

The Chemistry Research Solution

