



## Operational Update

August 2019

# Omega presentation team

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# Agenda

- Operational Highlights
- Key Growth Areas
  - Allergy
  - Food Intolerance
  - VISITECT® CD4
- Summary

# Operational Highlights

- Cleaned up business
  - Closure of Omega Diagnostics GmbH & Indian manufacturing sites
  - Disposal of non-core infectious disease business for £1.975m
  - Decision made to discontinue autoimmune product range (Sept 2019)
- IDS launch Allergy panel
  - Panel increased to 62 allergens
- Food Division returns to growth (+7%)
  - China-specific Food Detective panel developed and first order received
- VISITECT® CD4 Advanced Disease
  - CE marked
  - Regulatory files submitted for both WHO PQ and ERPD
- VISITECT® CD4
  - First order received from Nigeria
  - Nigerian study – testing completed

# Key Growth Areas – Allergy

- Allergy development
  - Expanding the menu to approximately 80 allergens
    - Focus on 5 screening assays over next 12-18 months
- Allergy commercialisation
  - Short term focus on existing installed base
  - Align allergy and autoimmune
  - Focus on key selling features
    - Random access
    - Smaller footprint
    - Speed to result
    - Results aligned to market leader

Allergy Expertise



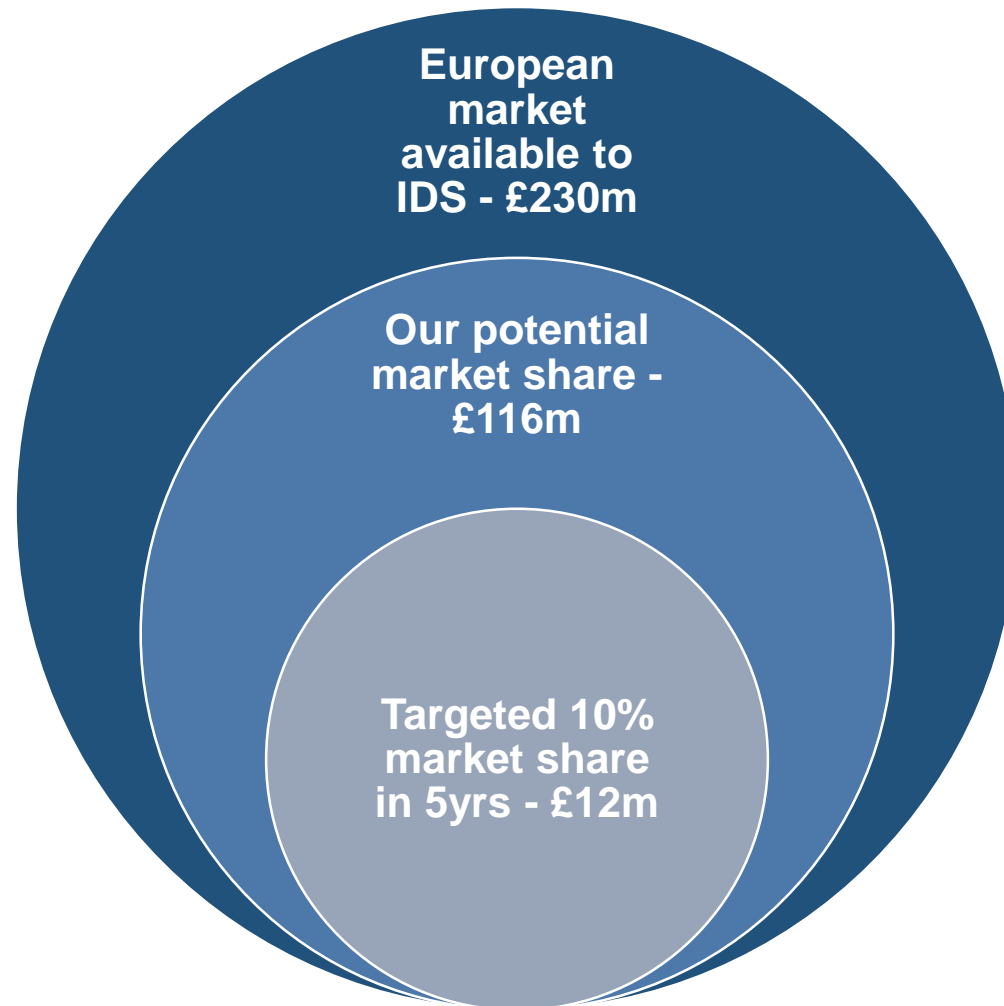
Automated System



Significant Global Opportunity



## Allergy – Europe market opportunity



## Key Growth Areas – Food Intolerance

- Chinese Strategy ahead of plan
  - 1st order received for 20,000 tests - September delivery
  - 2nd order forecast to be 30,000 tests - October delivery
  - Expect CFDA approval for lab testing by end September
  - Expect CFDA approval for self testing by end calendar year
  - Partner spend \$2m
    - Studies to gain approvals
    - Chinese specific app
  - Potential for 0.5m tests within 18 months
- Accessing FoodPrint<sup>®</sup> in North America
  - Growth of 58% from two partners (FY19 v FY18)
  - DTC partner launch delayed due to app development
- New building – move by year end

# Key Growth Areas - VISITECT® CD4



- VISITECT® CD4 – Commercialisation (10 Countries)
  - Cameroon, Colombia, Ghana, Guatemala, India, Indonesia, Mexico, Nigeria, Russia, Zimbabwe
  - Plan to sell via B2B channels
- Nigeria current status
  - NASCP (MoH) evaluation in six states completed
  - Feedback that the study results were “very good”
  - Evaluation Report about to be submitted to Minister for Health for inclusion in national HIV algorithm
  - Upon MoH approval test is launched nationally and deployed across Nigeria



## Key Growth Areas – Advanced HIV Disease

- 37 million people living with HIV
- c. 1 million people died from AIDS in 2017
- “Despite large increases in ARV coverage over the past decade, death rate has from HIV-AIDS has plateaued” <sup>1</sup>
- WHO definition of Advanced HIV Disease “For adults and adolescents, and children older than 5 years, Advanced HIV Disease is defined as CD4 cell count <200 cells/mm<sup>3</sup> or WHO stage 3 or 4 event.” <sup>2</sup>
- “Approx. one third of adults initiating treatment in LMIC are estimated to start care with AHD-representing a large potential for AHD-related commodities” <sup>3</sup>



<sup>1</sup> Advanced HIV Disease: Opportunity for Impact (CHAI-Unitaid HIV Buyers Symposium, February 2019)

<sup>2</sup> WHO Guidelines for managing advanced HIV disease and rapid initiation of antiretroviral therapy (July 2017)

<sup>3</sup> CHAI Patient Numbers Forecast; AHD percentages based on 951,855 adults from 55 countries (2019)

# Key Growth Areas – NGO Sales Strategy

## AHD Initiative

Unitaid, CHAI, PEPFAR,  
The Global Fund,

\$20M funding for  
HIV/CD4, Crypto, TB

ERPD Required / In-  
Country Registration

PEPFAR included  
“inexpensive lateral flow  
CD4 assay” in guidance

## MSF

Long term / Key advocate  
of CD4 Advanced Disease

Conducting multi-centre  
study in DRC, Malawi &  
Zimbabwe

Requires study  
completion

Deploy in MSF field sites  
Active in many  
challenging countries

## NGOs

UN agencies (UNDP,  
UNFPA, UNICEF, UNHCR)

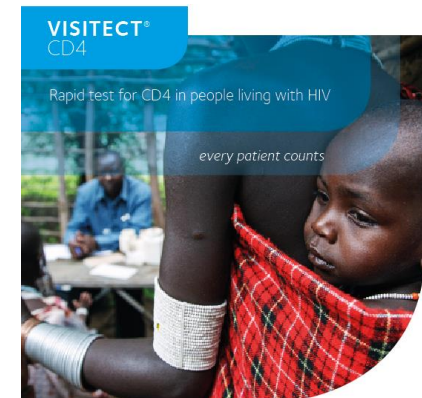
All prospective &  
significant buyers

WHO Prequalification  
required

Advantage is NGOs prefer  
long-term contracts

# Key Growth Areas – B2B Sales Strategy

- 24 countries targeted for Distribution partners
  - Botswana, Cameroon, eSwatini, Ethiopia, Ghana, Kenya, Lesotho, Malawi, Namibia, Mozambique, Nigeria, Rwanda, South Africa, Tanzania, Uganda, Zambia, Zimbabwe, Brazil, Indonesia, Malaysia, Myanmar, Thailand, Vietnam, Ukraine
- Countries identified according to defined criteria:
  - a) Prioritised by Unitaid/CHAI advanced HIV disease initiative, e.g. Lesotho
  - b) HIV prevalence is greater than 2%, e.g. Rwanda
  - c) A strong distribution partner having a proven track record of growing sales, e.g. Brazil
  - d) A group of stakeholders in country actively driving advanced HIV disease agenda, e.g. Vietnam



# Summary

- Financial results for FY19 are in line with management expectations
  - To be announced before the end of September
- Strategic review continuing to reshape the business
- Allergy - commercialisation commenced
- Food Intolerance
  - Returned to growth
  - China ahead of expectations and first significant order received
- Global Health
  - VISITECT® CD4 – first purchase order received from Nigeria
  - VISITECT® CD4 Advanced Disease – good progress with ERPD and WHO approvals
  - Sales strategy is defined and aligns with distinct market opportunity

**VISITECT® CD4 is starting to deliver on potential**

Fighting global  
health challenges  
through innovation



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# Overview

**Omega** provides a range of specialist products, focussed on the delivery in the immunoassay market, within three segments:

- Allergy
- Food Intolerance
- Global Health

**Our Mission:**

**To improve human health and well-being through innovative diagnostic tests and global partnerships.**

# Strategic goals and values



# VISITECT® CD4

## Our Products

- VISITECT® CD4 – used to prioritise patients for ART
  - CE marked in November 2017
  - Commercial launch Q4 2019
- VISITECT® CD4 Advanced Disease – used where immunity is so low = risk of opportunistic infection
  - CE marked in March 2019
  - Commercial launch June 2019

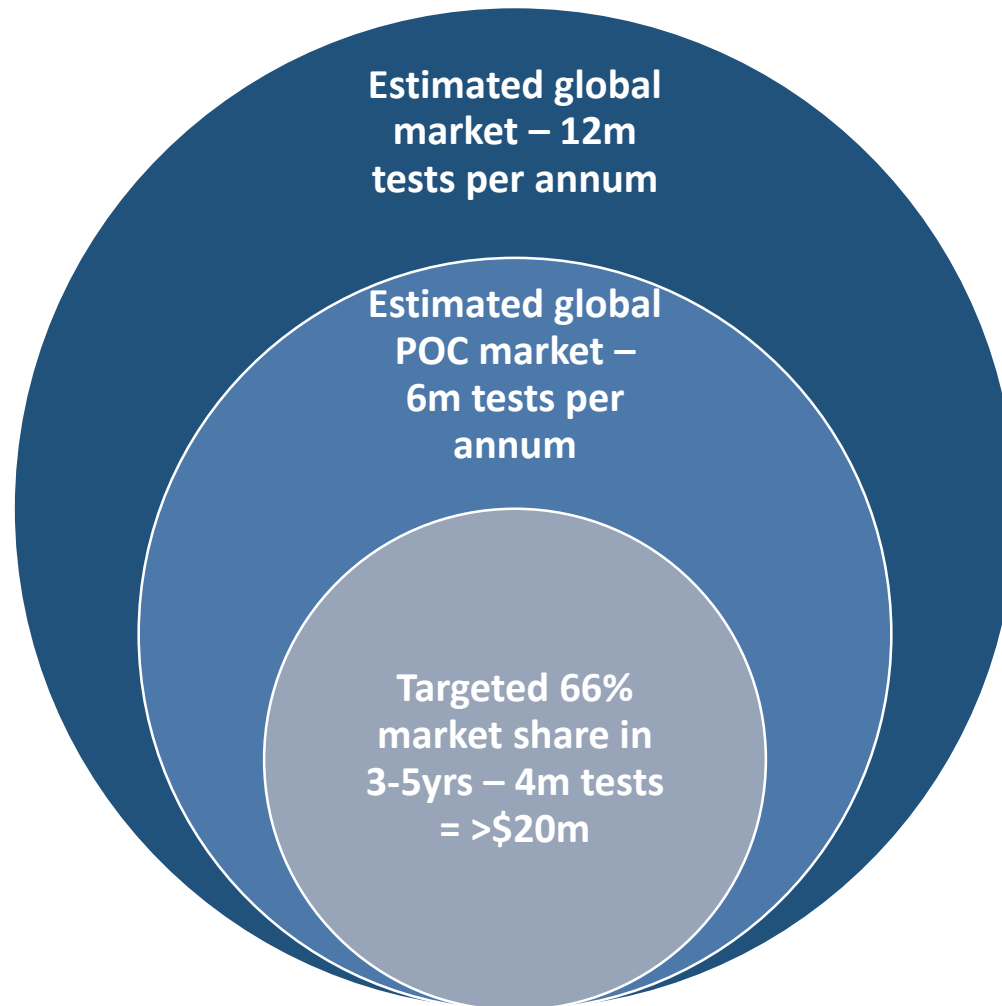
## Key Strengths

- The only instrument-free POCT
- No cold chain
- Affordable and easy to use





# CD4 – market opportunity



Figures based on WHO/UNAIDS Diagnostics meeting April 2018

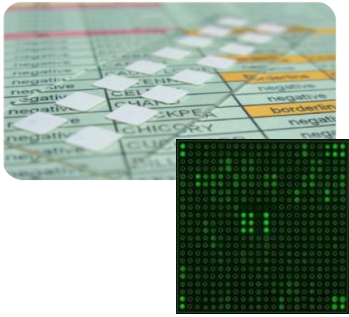
# Food Intolerance



A condition when there is a non-immediate adverse physiological response to particular foods as distinct to an allergic reaction to food

## Our Products

- Food Detective® – designed for use by health practitioners
  - World's only point-of-care food specific IgG test
- FoodPrint® is a product offering significant benefits over traditional plate-based ELISA tests
- CNS Lab Service offered from UK base near Cambridge



## Key Strengths

- Global coverage – over 75 countries
- Global leadership position for Food Intolerance.
  - Grown revenues from £2.3m in 2009 to £8.0m in 2019
- Strong Brand recognition



Cambridge  
Nutritional  
Sciences

# Food Intolerance – market opportunity



US Market estimate \$26m China Market estimate \$20m