hVIVO plc

Investor Presentation

November 2018

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hVIVO – Uniquely Positioned Clinical Development Services Business in Airways Disease

Company Profile

- Listed in UK on AIM (HVO)
  - Established in 1989 - spin out from Queen Mary University, London
- Headquarters, London
  - Quarantine unit opened 2011
  - c. 130 employees
- Blue chip institutional investor base

FYE 31-Dec-2017 (HYE 30-Jun-2018) Financials

- Revenue: £10.9m (£4.9m)
- Gross profit: £3.6m (£1.2m)
- Short term deposits, cash & cash equivalents: £20.3m (£10.7m)
  - Committed to driving revenue growth and cash generation leading to sustained profitability
  - Ongoing tight cost control and efficiency programmes
  - Disciplined approach to capital allocation

Significant Know-how and Proprietary Models

- Industry leading clinical development services business
- Pioneer of human disease models based upon viral and allergen challenge
- Industry leading clinical trial platform to accelerate drug and vaccine development in respiratory and infectious diseases

Established Global Customers and Collaborations

Investment Overview

- Revenue generating business providing value-added drug development services in airways diseases
  - Strong fee-for-service pipeline - encouraging level of pipeline contract negotiations for Q4 2018 and beyond
  - An industry leader and trusted partner
- Unique market opportunity in human challenge studies with further opportunities to expand services and increase revenues
- Targeting the creation of significant shareholder value through substantial growth and achieving sustainable profitability from 2019 onwards
  - Focused on operational excellence and building scale
- Aiming to rebuild the business and return to £100m+ market capitalisation

Industry Leader and Trusted Partner

- Over 25 years experience conducting and analysing human models of disease
    - Challenging both healthy volunteers and patients with influenza, respiratory syncytial virus (RSV) or human rhinovirus (HRV)
    - Over 50 studies
    - Over 100 publications demonstrating our extensive experience in virology
    - Experts in virus production, viral challenge and host response related to virus insult
- Established a strong reputation for expertise in providing disease insights and technical execution
    - Enable early indications of efficacy of new products in disease models
    - Identify key biological traits of patients who respond to a novel therapy

Unique Market Opportunity

Human challenge studies

- Concept of human challenge studies not new:
  - hVIVO leading the way in the use of human challenge studies to establish early proof of concept
  - hVIVO expanding concept into product development for airways disease (asthma, COPD, cough) – ability to reduce cost, time and risk of achieving POC considerable – significant interest from big pharma
- Encouraging level of pipeline contract negotiations for Q4 2018 and beyond

Human challenge model - clinical development -

- Provide early proof of concept efficacy data for candidate selection
- Enable accelerated development of pipeline compounds, through early identification of endpoints
- Effectively translate animal data to human endpoints and to relate healthy volunteer data to field outcome
- Require relatively small numbers of subjects, hence lower time and cost, to achieve clinical proof-of-concept
- Lower the subsequent risk of negative outcomes when performing large field-based Phase II and III studies, given that the early detection of efficacy and identification of endpoints can strengthen protocol design and patient selection in the later phase studies

Unique Market Opportunity in Human Challenge Studies

Unlocking the full potential of our platform

- Reducing the costs, timelines and risks to product development in airways diseases
- Consider the current issues with development of novel products for asthma:
  - Regulatory and medical focus is on the reduction of asthma exacerbations
  - Significantly increases the scale required for pivotal clinical trials
    - More patients, longer treatment periods
    - Greater costs – Phase III asthma trials: £40-80m per trial
- Move to development of more target-specific therapies e.g. biologics
  - Failure to understand the right patients can lead to pivotal study failures
    - e.g. Tralokinumab (AstraZeneca) and Lebrikizumab (Genentech)
  - Significant time/cost impact
- Enabling development of products in special populations e.g. elderly

hVIVO is creating a challenge model designed to address these issues in asthma and is progressing this concept into COPD

Strategic Priorities

Driving revenue growth with cash generation

- Strong pipeline of sales negotiations expected to be realised as contracted studies in 2019-2020
- Driving revenue growth and cash generation in turn leading to sustained profitability
- Operational excellence - driving operational efficiency and cost containment as we continue to focus on the core business
- Progress strategic discussions with regards to FLU-v to maximise the strategic options available to the Company and Imutex
- Fund further progression of own/part-owned programmes only through partnering / out-licensing / non-dilutive sources – HVO-001, Imutex, PReP

Our Re-Focussed Business Model

- Focus on becoming a unique fee-for-service development partner in airways disease
    - Maintaining highly integrated, data driven operations and on-time delivery
    - Maintain industry leading position in human challenge studies
        - Limited competition (main competitor SGS, offers Flu challenge, but as yet has not successfully introduced an RSV challenge model)
        - Currently the only business offering RSV and HCV in asthmatics models
        - Ceasing research & discovery activities to focus only on activities designed to support/enhance service offerings
- Building on our expanded service capabilities in asthma
    - Offers a significantly larger market opportunity for application of hVIVO services
    - Developing additional capabilities to expand into:
        - COPD
        - Special patient populations e.g. elderly
- Leveraging know-how and models to establish, longer term, higher value contracts
    - Aimed at capturing downstream upside on successfully addressing unmet development needs in airways diseases

Strong Fee-For-Service Pipeline

- Large number of opportunities – over 50 potential contract opportunities for 2018, 2019 and beyond
- Mix of virus (Flu, RSV, HRV) and volunteer (healthy, elderly, asthmatic)
- Sales effort focused upon current year contract conversions for studies initiating in 2019 and cultivating opportunities for 2019 and 2020
  - Initiated a new cough model in the clinic in 2018
  - Recently announced three new RSV contracts to a total value of £20m which will run from October 2018 to the end of 2019
  - Ongoing contract negotiations with a large pharma for an HCV challenge study in asthmatic patients
  - Ongoing discussions with large pharm for initiation of two new models initially in pilot studies for first half of 2019, which, if successful, should lead to significant contracts for large challenge studies in late 2019, early 2020
    - RSV in elderly subjects
    - New flu challenge using a different Flu strain
- Currently the quarantine unit will be operating at close to maximum capacity for remainder of 2018 and first 9 months of 2019
  - With additional contracts currently in negotiation expected to extend the level of maximum occupancy into 2020

Future Opportunities

- Build on current pipeline and relationships with large pharma and biotechs to maintain industry leading position
  - Ensure new model pilot studies lead to subsequent investigational product trials
- Expand range of services in patients increasing uptake of asthma model and expanding into COPD
  - Create relationships with asthma and COPD clinicians to obtain access to patients
- Address impact of capacity limitations of 24 bed unit in Whitechapel
  - Run patient based trials at investigator sites to minimise impact on the unit capacity
  - Establish strategic relationships, or acquire additional unit space, with current Phase I units in the UK, EU or US
- Continue to publish papers and data from our investigations to further the position of the Company as a major contributor to the science and understanding of the role of human challenge studies in drug development
- Progress strategic discussions with regards to FLU-v to maximise the strategic options available to the Company and Imutex

The FLU-v Story

Broad Spectrum Stand-alone Influenza Vaccine

Compelling Market Opportunity – FLU-v

- Opportunity to redefine the influenza market with a blockbuster global sales potential

2 **Supportive Regulatory and Academic Environment**

- Key parties are pushing for a universal solution

3 **Unique Solution with Compelling Competitive Advantage**

- Only product to demonstrate efficacy to date; Broad spectrum (A, B and Pandemic Strains), true stand-alone

4 **Excellent Clinical Profile**

- Highly robust Phase II-b field and challenge study results supporting readiness for Phase III

5 **Robust Patent Portfolio in Place**

- Wide-ranging multi-national patents and market exclusivities covering both vaccine components and their homologies

6 **Simple, Cost-effective and Scalable Manufacturing Process**

- Classic synthetic manufacturing process provides significant advantages to biological systems

7 **Innovative Platform for Significant Applications Beyond Influenza**

- Compelling platform for capabilities in the broader antiviral space

Exploring strategic alternatives with regards to both assets, including but not limited to a full sale, a licensing agreement or a non-dilutive funding

Outlook and 2018 Newsflow

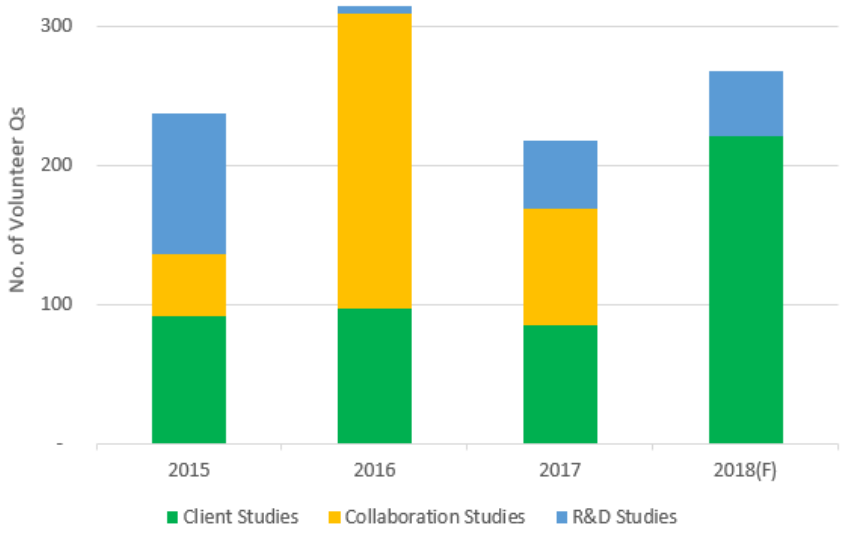
- Committed to a strategy of driving revenue growth and cash generation and in turn leading to sustainable profitability
- Ongoing cost control and efficiency programmes
- Disciplined approach to capital allocation, supporting/enhancing service offerings
- Successfully convert growing number of sales leads into contracted work
- Strategic alternatives for further development of Imutex assets
- Board expectations remain unchanged for the full year – higher level of sales for H2 vs H1
- Full impact of operational actions to be realised in 2019

NEWSFLOW		
Programme/work	**Partner/collaborator**	**Event**
FLU-v 004 - Phase IIb field study	Imutex / UNISEC	Full and final results published by NIAID – expected Q4 2018
FLU-v 003 - Phase IIb challenge study	Imutex / NIAID	Full results published by UNISEC – expected Q4 2018
Initiation of new RSV elderly model	Large pharma	Q4 2018
Initiation of new Flu model	Large pharma	Q1 2019
Initiation of new Asthma study	Large pharma	Q1 2019
AGS-v Phase Ib study mosquito-borne illness vaccine platform	Imutex / NIAID	Final results expected by Q1/Q2 2019

To become the partner of choice for companies developing products in airways disease

Appendices

Financial Highlights H1 2018



	H1 2018	H1 2017	2017
Revenue	£4.9m	£3.9m	£10.9m
Gross profit	£1.2m	£1.0m	£3.6m
Gross margin	24.0%	25.6%	32.7%
Other income	£1.5m	£0.1m	£1.5m
R&D expense	£(2.8)m	£(2.8)m	£(6.1)m
Administrative expense	£(4.9)m	£(6.1)m	£(11.4)m
Loss on provision of services to JVs	£nil	£(0.7)m	£(0.8)m
Share of loss of associate & JV	£(0.4)m	£(0.6)m	£(1.6)m
Taxation – R&D tax credit refund	£0.9m	£1.4m	£1.9m
Loss for the period	£(4.4)m	£(7.7)m	£(12.9)m

Revenue

£4.9m

from client studies completing in H1'18

Gross Profit

£1.2m

lower utilisation in H1'18, but building from Q4'18

Other Income

£1.5m

£1.4m from DARPA cost share

Loss for period

£(4.4)m

Tightening cost base – turning point for becoming profitable

- Growing sales pipeline starting to convert - £11.9m contract signed post period end, commencing in Oct '18
- Driving operational efficiency and cost saving initiatives, focusing on the Company's core business
- Driving revenue growth and cash generation – exercising tight cost control & efficiency programmes to ensure we achieve profitability in 2019
- R&D expense – Prioritised spend completing a smaller no. of previously initiated projects – Includes £1.3m for flu contagiousness project, with cost share from DARPA

hVIVO

Balance Sheet: 30 June 2018

	30 June 2018	30 June 2017	31 Dec 2017
Non current assets	£17.5m	£19.6m	£18.0m
Current assets	£18.1m	£26.4m	£26.8m
Non-current liabilities	£(1.6)m	£(3.3)m	£(2.3)m
Current liabilities	£(4.6)m	£(4.3)m	£(9.2)m
Net assets	**£29.3m**	**£38.4m**	**£33.4m**
Cash at bank and on short term deposits	£10.7m	£15.4m	£20.3m
Contract assets (Accrued income)	£nominal	£nominal	£0.4m
Contract liabilities (Deferred income)	£(2.2)m	£(1.3)m	£(5.8)m

- Cash of £10.3m, prioritising spend and extending cash runway from building client clinical study pipeline, together with operational efficiencies and cost savings initiatives reducing cash burn and extending cash runway
  - £2.5m R&D tax refund received in July ‘18
  - Targeting cash flow positive in H2’18
- Non-current assets movement primarily relates to share of loss of PrEP Biopharm and Imutex
- Current assets reducing with cash
- Current liabilities movement primarily due to timing of new contract signatures and recognition of contract liabilities
- Non-current liabilities relate to unwinding of provisions against onerous leases and dilapidations