

# A life saving cell and gene therapy company Interim results for the six months ended 30 June 2021

September 2021

#### **Forward-looking statements**

This presentation does not constitute an offer to sell or a solicitation of offers to buy Ordinary Shares (the "Securities"). Although reasonable care has been taken to ensure that the facts stated in this presentation are accurate and that the opinions expressed are fair and reasonable, the contents of this presentation have not been formally verified by Oxford Biomedica plc (the "Company") or any other person. Accordingly, no representation or warranty, expressed or implied, is made as to the fairness, accuracy, completeness or correctness of the information and opinions contained in this presentation, and no reliance should be placed on such information or opinions. Further, the information in this presentation is not complete and may be changed. Neither the Company nor any of its respective members, directors, officers or employees nor any other person accepts any liability whatsoever for any loss howsoever arising from any use of such information or opinions or otherwise arising in connection with this presentation.

This presentation may contain forward-looking statements that reflect the Company's current expectations regarding future events, its liquidity and results of operations and its future working capital requirements. Forward-looking statements involve risks and uncertainties. Actual events could differ materially from those projected herein and depend on a number of factors, including the success of the Company's development strategies, the successful and timely completion of clinical studies, securing satisfactory licensing agreements for products, the ability of the Company to obtain additional financing for its operations and the market conditions affecting the availability and terms of such financing.



#### Oxford Biomedica delivers record first half

- Revenues grew by 139% to £81 million with operating EBITDA of £27 million
- Continued large-scale commercial manufacture of AZ's adenovirus based COVID-19
  vaccine, proving Oxford Biomedica's capabilities extend to other lentiviral vectors
- Partner programmes continued to progress through development including a new three year agreement with Boehringer Ingelheim
- Planning permission granted for redevelopment of the Windrush Innovation Centre, to be the key hub for next generation platform developments
- Oxford Biomedica welcomed Professor Dame Kay Davies and Dr. Michael Hayden to the Board, strengthening the Group's scientific and translational expertise

#### A life saving cell and gene therapy company



## **Strategy: Leveraging our Viral Vector Expertise**



#### **Expanded Scope of Oxford Biomedica's CDMO**

The global outsourced lenti-, γ-retro- and adenoviral vector manufacturing supply market is forecast to grow to c.\$660m in 2026, increasing c.3-fold to c.\$2.8bn including AAV\*





# Building on our world leading position in lentiviral vectors

#### 1. Oxford Biomedica has the rarest of resources for a viral vector CDMO

Big Pharma validation of technologies and capabilities

JUng | (H Bristol Myers Squibb" **U**NOVARTIS







Proven commercial supply capability in >38 countries



- 2. Oxford Biomedica team is world class in the Industry
  - Delivery track-record, technical expertise, proven deal making, relationship management
- 3. Established operational infrastructure
  - Leverage current facilities, including Quality systems, GMP capabilities and analytics
- 4. Track record of successful expansion into a growing market
  - Yarnton and Oxbox



# CDMO

# Customer-centric Leading provider of scale up solutions and commercial supply

#### **COVID-19 Vaccine and Agreement with AstraZeneca**

- Oxford Biomedica continues large-scale commercial manufacture of AZ COVID-19 vaccine
- In May, AZ committed to an increase in the number of batches required resulting in the Group raising its expectation for cumulative revenues from the contract to be > £100 million by end of 2021
- In the period, the Group agreed to purchase equipment provided to Oxford Biomedica by VMIC to enable longer term use

#### **Boehringer Ingelheim**

- In April, Oxford Biomedica announced a new three-year Development and Supply agreement with Boehringer Ingelheim for the manufacture and supply of various types of viral vectors
- Under the terms of the agreement, Oxford Biomedica intends to manufacture GMP batches for Boehringer Ingelheim to support the development of viral vectors

#### **Building the Future**

- Building work continues at Windrush Court to convert office space into GMP grade laboratories to meet the expected near-term demand in commercial development and analytics
- Fill / finish A is progressing well and expected to be completed during 2021, with approval for use expected in the first half of 2022



## **CDMO Pipeline – Page 1 of 2**

Product	Indication	Pre-Clinical	Phase I	Phase I/II	Phase II	Phase III	Approval		
LentiVector <sup>®</sup> platform									
Kymriah <sup>®1</sup>	r/r ALL / r/r DLBCL								
2nd CAR-T	Cancer (multiple)								
3rd CAR-T	Cancer (multiple)								U NOVARTIS
4th CAR-T	Cancer (multiple)								
5th CAR-T	Cancer (multiple)					Process de	velopment		
6th CAR-T	Cancer (multiple)					and bioprocessing revenues, and royalties		$\left\{ \right.$	
AXO-Lenti- PD <sup>2</sup>	Parkinson's disease								GENE THERAPIES
1st CAR-T / TCR-T	Undisclosed								
2nd CAR-T / TCR-T	Undisclosed								ر <mark>الار</mark> Bristol Myers Squibb
3rd CAR-T / TCR-T	Undisclosed								
4th CAR-T / TCR-T	Undisclosed								l



## **CDMO Pipeline – Page 2 of 2**

Product	Indication	Pre-Clinical	Phase I	Phase I/II	Phase II	Phase III	Approval
LentiVector <sup>®</sup> pla	tform						
OTL-201	MPS-IIIA						
Other	undisclosed						
CAR-T	Cancer (multiple)					Process dev and biopr	elopment ocessing
CFTR gene	Cystic Fibrosis				re	evenues, and	royalties
Ocular gene	Inherited retinal disease						
AZD1222	COVID-19 Vaccine						

- SANGFI 🖓

Note 1: Scale up and vaccine manufacturing revenues

In vivo programmes



#### **COVID-19 Vaccine partnership**



# AstraZeneca COVID-19 clinical & commercial supply signed in May-20, extended in Sept-20 for up to 3 years

18 month supply agreement under a 3 year master services agreement to GMP manufacture adenoviral vector based COVID-19 Vaccine candidate Follows 1 year supply agreement signed in May for multiple batches at 200L scale

Production will be from up to 3 GMP suites at the new Oxbox manufacturing facility

£15m upfront payment as a capacity reservation fee and potentially in excess of £85m plus certain materials costs for large scale vaccine manufacture at 1000L scale

# AstraZeneca

Press release (21 May 2020) Pascal Soriot, Chief Executive Officer of AstaZeneca said:

"This pandemic is a global tragedy and it is a challenge for all of humanity. We need to defeat the virus together or it will continue to inflict huge personal suffering and leave long-lasting economic and social scars in every country around the world. We are so proud to be collaborating with Oxford University to turn their ground-breaking work into a medicine that can be produced on a global scale"

#### **Timelines and current status**

- April 20: OXB joined consortium led by the Jenner Institute, Oxford University
- May 20: OXB signs initial 1 year clinical and commercial supply agreement with AstraZeneca at 200L scale
- June 20: OXB signs five year agreement with VMIC; VMIC provides equipment for two GMP suites in Oxbox
- September 20: OXB signs 18 month supply agreement under a 3 year master services agreement with AstraZeneca
- December 20: MHRA authorises the Oxford AstraZeneca Vaccine for emergency supply in the UK
- **May 2021:** Following successful manufacturing of 1000L batches and commitment from AZ for additional batches, financial guidance for the September 2020 supply agreement increased to cumulative revenues in excess of £100 million by year end 2021



#### **Boehringer Ingelheim Agreement**



# Apr-21 Signed 3 year Development and Supply Agreement, following earlier partnership agreement signed Aug-18

3 Yr Development and Supply agreement with BI for manufacture and supply of various types of viral vectors OXB to GMP manufacture and supply viral vector products in the future

No financial terms disclosed Follows agreement signed Aug 18 with BI / UK CFGCT / Imperial innovations for lentiviral vector technology to manufacture, register & commercialise a lentiviral gene therapy for treatment of CF

#### Boehringer Ingelheim

#### Dr Clive Wood, Senior Corporate Vice President Discovery Research said:

"Through this collaboration, we are joining forces with some of the top talents in this disease space to propel treatment advances forward. Bringing together our existing expertise as a leader for nearly a century in the discovery and development of therapies that have advanced patient care in respiratory diseases with the gene therapy knowledge of our partners, we aim to unlock unprecedented opportunities for patients with this devastating disease, who are desperately waiting for better treatment options"

#### **Current status and expectations**

- The Group intends to manufacture GMP batches for BI to support the development of viral vectors
- Currently the CF gene therapy product is in pre-clinical development
- Sales of products to treat Cystic Fibrosis in the 7 major markets reached \$2.2bn in 2015 and is forecast to reach \$8.6bn by 2025<sup>1</sup>



# Platform

Driving industrialisation of viral vectors

#### Industrialisation of viral vector manufacturing

- Our expertise, IP and investment make us a world leading producer of Lentiviral vectors
- Multiple elements of IP and innovation is relevant across all viral vector classes

#### Innovation

- Process C is up and running, giving better quantity and quality (includes perfusion and U1)
  - Process C general roll out first half of 2022
- Process D coming on stream a year later
- Ongoing investment in high-throughput automation and robotics to reduce costs by enabling faster screening, analytical testing and streamlining production
- In vivo CAR-T generation for greater patient access and superior efficacy. Off- the-shelf, reduced COGs direct reprogramming of patient's cells

#### **Building the future**

 Windrush Innovation Centre on course for occupancy 2023 – to provide next gen laboratory facilities



## **Proprietary platform innovation**



# **Gene Therapeutics**

# Patient-centricLeveraging expertise to deliver lentiviralvector based gene therapies

#### AXO-Lenti-PD – Parkinson's Disease Partnered with Sio Gene Therapies

- Work for AXO-Lenti-PD progresses following prior third-party fill/finish issues, two further batches have been manufactured and are undergoing certification
- Enrolment of patients into the AXO-Lenti-PD clinical programme is expected to resume in 2022

#### **Proprietary in-house product development**

- Ongoing internal review realigning priority preclinical targets
- Lead programme: OXB-302 Acute Myeloid Leukaemia, CAR-T therapy for AML targeting 5T4 – clinical trial initiation 2023
- Liver gene therapy liver is an attractive target for Lentiviral vectors due to potential one-off therapy to give life-long benefit
- Deprioritising OXB-203, OXB-204 and OXB-103
- Internal review will be finalised Q4 2021



#### **Gene Therapeutics Pipeline**



In vivo programmes



# OXB-302 – CAR-T therapy for Acute Myeloid Leukaemia (AML)

#### **Tumour Target Antigen: 5T4**

- 5T4 is an oncofoetal antigen specifically expressed on the cell surface of most cancers including AML
- The restricted expression profile of 5T4 on normal tissues combined with its broad expression on tumour cells (including cancer stem cells) make 5T4 an attractive target

#### **CAR-T Cells Targeting 5T4**

- OXB-302 is a 2<sup>nd</sup> generation CAR-T product generated via an optimised lentiviral vector transduction protocol and expansion process to generate more potent cells
- OXB-302 has demonstrated potent *in vitro* and *in vivo* activity against a panel of human solid and liquid tumour cells lines
- OXB-302 has high commercial potential for the treatment of multiple liquid and solid tumours

Factor	Critical Parameter / USP			
5T4	5T4 is expressed on AML primary patient samples			
Profile	5T4 is expressed on AML Leukaemic Stem Cells (LSCs)	~		
	OXB-302 cells kill human AML tumour cell lines			
Efficacy	OXB-302 cells kill human AML Leukaemic Stem Cells			
	OXB-302 are more sensitive than flow cytometry at detecting 5T4 target antigen expression	~		
Safety	OXB-302 showed no impact on haematopoiesis using an industry- standard in vitro model of colony formation	~		



# Financials, Outlook and Newsflow

# H1 2021 Financial Highlights

- Revenue increased by 139% to £81.3 million (H1 2020: £34.0 million)
- Exceptional growth was seen in bioprocessing and commercial development, where revenues increased by 223% to £75.6 million (H1 2020: £23.4 million) largely driven by the highly successful COVID-19 vaccine agreement with AstraZeneca
- Licences, milestones & royalties were £5.7 million (H1 2020: £10.6 million), the reduction of 47% resulting from no significant licence fees arising in H1 2021, whilst H1 2020 saw the £6.2 million Juno licence fee
- Operating expenses decreased by 19% to £23.6 million (H1 2020: £29.1 million) due to the higher recovery of batch manufacturing costs which is reflected in increased cost of goods
- Operating EBITDA<sup>1</sup> and operating profit were £27.1 million and £19.7 million respectively (H1 2020 losses of £0.4 million and £5.8 million respectively)
- Cash generated from operations was £22.2 million compared to £0.9 million consumed in H1 2020
- Cash at 30 June 2021 was £61.3 million (31 December 2020: £46.7 million), an increase of £14.6 million due to operational cash flow generated
- The Group's capital expenditure of £3.5 million (H1 2020: £5.3 million) consisted mainly of purchases of equipment required for the manufacturing and laboratory facilities
- In September, Serum Life Sciences (a subsidiary of Serum Institute of India) made an investment of £50 million in the Group in return for new ordinary shares representing 4% of the outstanding shares



## **Revenue and Operating EBITDA<sup>1</sup>**





<sup>1</sup> Operating EBITDA = Earnings Before Net Finance Costs, Tax, Depreciation, Amortisation, fair value adjustments of assets at fair value through profit and loss, and Share Based Payments



#### **Consolidated statement of comprehensive income**

	For the six months ended 30 June		
	2021 Total	2020 Total	
Devenue	£ 000	£ 000	
Revenue	61,252	33,979	
Cost of sales	(38,372)	(10,314)	
Gross profit	42,880	23,665 🔒	
Bioprocessing costs	(2,947)	(9,195) 🖶	
Research and development costs	(14,708)	(15,168) 🖶	
Administrative expenses	(6,009)	(4,692) 🔒	
Other operating income	441	327	
Change in fair value of available-for-sale asset	1	(703) 🔒	
Operating profit/(loss)	19,658	(5,766) 😭	
Finance income	31	13	
Finance costs	(472)	(373) 🕇	
Profit/(loss) before tax	19,217	(6,126) 😭	
Taxation	(1,148)	(553)	
Profit/(loss) and total comprehensive income/(expense) for the period	18,069	(6,679) 🔒	



#### **Partner Programmes / CDMO**

- The Group aims to further increase the number of partner programmes during the year, both through expansion of existing partnerships and new partnership agreements
- Potential extension of the current 18 month manufacturing agreement with AstraZeneca
- Newsflow potentially arising from progress of partner programmes

#### **Proprietary Pipeline**

- Progress internal candidates into our portfolio and towards the clinic
- Potential further updates from Sio Gene Therapies on the progress of AXO-Lenti-PD in the SUNRISE-PD clinical study



## **Positive outlook for 2021**

- The Group expects revenue for the second half to be similar to the first half
- The Group expects total cumulative revenues from manufacture of the AstraZeneca COVID-19 vaccine to be in excess of £100 million by the end of 2021
- Operating EBITDA for H2 2021 is expected to be below H1 2021 as a result of an increase in R&D, administrative and bioprocessing cost lines
- Capex will accelerate in H2 2021 due to commencement of redevelopment work at Windrush Innovation Centre as well as continued laboratory expansion at Windrush Court
- The Group expects to be able to announce further updates on partnering progress and new partnerships during the course of 2021
- With the Group's strong financial position and continued broader market growth, Oxford Biomedica is well positioned to maximise the opportunities ahead

#### A life saving cell and gene therapy company



#### **Contact Us**

Oxford Biomedica plc Windrush Court Transport Way Oxford OX4 6LT

John Dawson Chief Executive Officer Stuart Paynter Chief Financial Officer Catherine Isted Head of Corporate Development & IR

> +44 (0) 1865 783 000 IR@oxb.com www.oxb.com



#### **Balance Sheet**

	30 June	31 December
	2021	2020
	Unaudited	Audited
	£'000	£'000
Assets		
Non-current assets		
Intangible assets	63	73
Property, plant and equipment	70,127	72,304
Trade and other receivables	3,585	3,605
	73,775	75,982
Current assets		
Inventory	8,466	6,912
Assets held for sale	240	239
Trade and other receivables	31,184	37,418
Contract assets	22,746	16,508
Current tax assets	-	126
Cash and cash equivalents	61,275	46,743
	123,911	107,946
Current liabilities		
Trade and other payables	23,290	19,716
Current tax liabilities	2,016	-
Contract liabilities	20,237	27,258
Deferred income	894	1,006
Lease liabilities	818	4,475
	47,255	52,455
Net current assets	76,656	55,491
Non-current liabilities		
Lease liabilities	8,915	9,370
Provisions	6,127	5,839
Contract liabilities	599	1,003
Deferred income	2,186	2,515
	17,827	18,727
Net assets	132,604	112,746
Shareholders' equity		
Share capital	41,307	41,161
Share premium	258,474	258,017
Other reserves	2,291	2,291
Accumulated losses	(169,468)	(188,723)
Total equity	132,604	112,746

.....



#### **Statement of cash flows**

For the six months ended 30 June 2021 2020 £'000 £'000 Cash flows from operating activities Cash generated from/(consumed in) operations (938) 21,205 Tax credit received 994 Net cash generated from/(used in) operating activities 22,199 (938) Cash flows from investing activities Purchases of property, plant and equipment (3, 548)(5, 350)Proceeds on disposal of property, plant and 9 equipment Proceeds on disposal of investments 2,523 Interest received 13 Net cash used in investing activities (3.539)(2,814)Cash flows from financing activities Proceeds from issue of ordinary share capital 483 40.167 (1,533)Costs of share issues Payment of lease liabilities (4, 611)(506) Net cash (used in)/generated from financing activities (4, 128)38.128 14,532 34.376 Net increase in cash and cash equivalents Cash and cash equivalents at 1 January 2021 46,743 16.243 Cash and cash equivalents at 30 June 2021 61,275 50,619



## Segmental analysis



#### **Platform segment**

- Includes revenue received from commercial partnerships and costs of investing in LentiVector<sup>®</sup> technology
- Revenues more than doubled from H1 2020 due to the volume of vaccine batches manufactured for AstraZeneca as part of the COVID-19 pandemic efforts
- Operating results were improved due to the revenue increase of £47.3 million

#### **Product segment**

- Covers product development (discovery, pre-clinical and preparation for clinical studies)
- Costs include employees and directly related internal costs. external project expenditure, and allocation of Group overheads
- Revenues were lower due to a lower level of clinical development activities for customers
- Operating expenses were higher due to increased clinical and pre-clinical product expenditure, and also manpower costs

Operating EBITDA = Earnings Before Net Finance Costs, Tax, Depreciation, Amortisation, fair value adjustments of assets at fair value through profit and loss, and Share Based Payments



H1