

# The LentiVector<sup>®</sup> Gene Therapy Company

Interim results for the six months  
ended 30 June 2020

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September 2020

# Forward-looking statements

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# 2020 Highlights – Summary

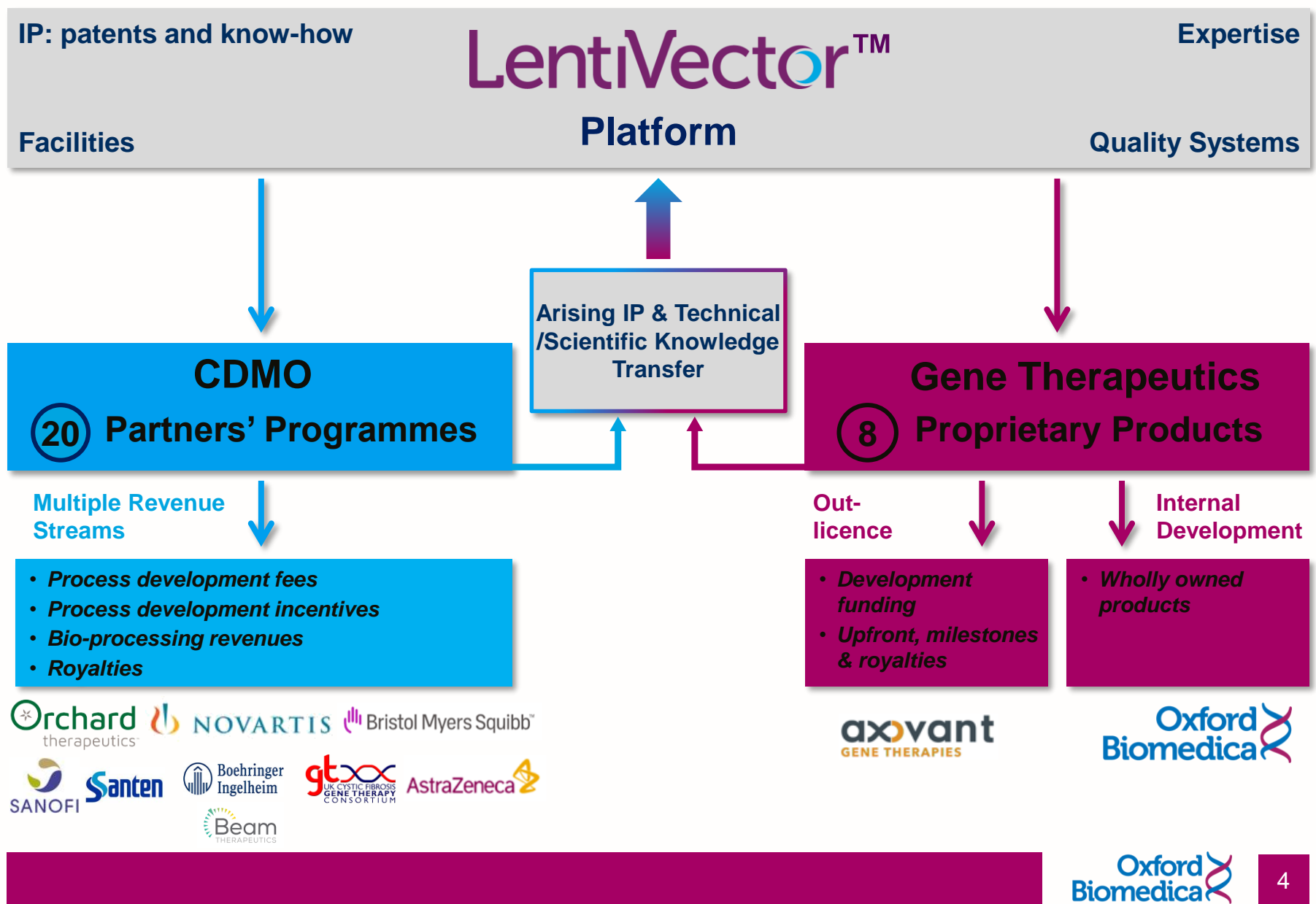
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## Oxford Biomedica has had a very strong 2020 despite the COVID-19 Pandemic

- The number of CDMO Partner Programmes has grown > 50% from 13 to 20
- Underlying revenues in bioprocessing and commercial development grew by 24%
- New partnerships signed with Juno/BMS, Beam Therapeutics and AstraZeneca
- Oxbox received MHRA approval for three GMP suites with the fourth expected soon
- Successful £40.0 million placing with new and existing investors

**Curing patients as a fully integrated gene therapy company**

# Strategy: Leveraging our LentiVector® delivery platform





**CDMO**

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

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# CDMO: 2020 Highlights

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## **Juno Therapeutics / BMS Partnership**

- In March 2020, the Group signed a \$227 million licence and five-year clinical supply agreement with Juno / BMS for initially four CAR-T and TCR-T programmes

## **Beam Therapeutics**

- Beam Therapeutics: In August 2020 the Group signed a development, manufacturing and licence agreement with Beam Therapeutics for next generation CAR-T therapies

## **Building the Future**

- Following completion of the first phase of the new 84,000 sqft Oxbox manufacturing facility at the end of 2019, The first two suites received MHRA approval in May 2020 and are now operational
- In September, the 3<sup>rd</sup> GMP suite in Oxbox received MHRA approval with the 4<sup>th</sup> suite expected to receive approval by early in the fourth quarter

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

- In April 2020 the Group joined a Consortium led by the Jenner institute, Oxford University, to rapidly develop, scale up and manufacture a potential candidate for COVID-19.
- In May 2020 the Group signed a clinical and commercial supply agreement with AZ for COVID-19 vaccine production
- Post period end in August, the Group announced an 18-month supply agreement under a three-year Master Supply and Development Agreement with AZ for large-scale manufacture of AZD1222

## **In 2020 the number of programmes has grown > 50% from 13 to 20**

- Oxbox is key to delivering bioprocessing capacity to meet future demand
- Since 30<sup>th</sup> June 2019 Partner Programmes have doubled from 10 to 20

# CDMO Pipeline – Page 1 of 2

Product	Indication	Pre-Clinical	Phase I	Phase I/II	Phase II	Phase III	Approval
<b>LentiVector® platform</b>							
Kymriah® <sup>1</sup>	r/r ALL / r/r DLBCL	[Progress bar: Pre-Clinical, Phase I, Phase I/II, Phase II, Phase III, Approval]					
2nd CAR-T	Cancer (multiple)	[Progress bar: Pre-Clinical, Phase I]					
3rd CAR-T	Cancer (multiple)	[Progress bar: Pre-Clinical]					
4th CAR-T	Cancer (multiple)	[Progress bar: Pre-Clinical]					
5th CAR-T	Cancer (multiple)	[Progress bar: Pre-Clinical]					
6th CAR-T	Cancer (multiple)	[Progress bar: Pre-Clinical]					
AXO-Lenti-PD <sup>2</sup>	Parkinson's disease	[Progress bar: Pre-Clinical, Phase I]					
1st CAR-T / TCR-T	Undisclosed	[Progress bar: Pre-Clinical, Phase I]					
2nd CAR-T / TCR-T	Undisclosed	[Progress bar: Pre-Clinical]					
3rd CAR-T / TCR-T	Undisclosed	[Progress bar: Pre-Clinical]					
4th CAR-T / TCR-T	Undisclosed	[Progress bar: Pre-Clinical]					

Process development and bioprocessing revenues, and royalties



<sup>1</sup> USAN name is tisagenlecleucel

<sup>2</sup> AXO-Lenti-PD formerly known as OXB-102, which OXB out-licensed to Axovant

 *In vivo programmes*  *Ex vivo programmes*

# CDMO Pipeline – Page 2 of 2

Product	Indication	Pre-Clinical	Phase I	Phase I/II	Phase II	Phase III	Approval	
<b>LentiVector® platform</b>								
OTL-101	ADA SCID							
OTL-201	MPS-IIIa							
Other	undisclosed							
CAR-T	Cancer (multiple)							
Factor VIII	Haemophilia A							
Factor IX	Haemophilia B							
CFTR gene	Cystic Fibrosis							
Ocular gene	Inherited retinal disease							
AZD1222	COVID-19 Vaccine							Note 1

Process development and bioprocessing revenues, and royalties



Note 1: Potential scale up and vaccine manufacturing revenues



In vivo programmes



Ex vivo programmes



## Juno Therapeutics / Bristol Myers Squibb agreement signed in Mar-20

OXB to receive sales royalties

Licence to the platform for CAR-T and TCR-T programmes in the field of oncology and other indications

Non-exclusive licence

\$10m upfront and potential to receive up to \$217m in development, regulatory and sales related milestones

Five-year clinical supply agreement where OXB will receive undisclosed process development and batch revenues

 Bristol Myers Squibb™

Press release (03 Jan 2020)  
**Giovanni Caforio, M.D.,**  
**Chairman and Chief Executive Officer of Bristol-Myers Squibb**  
**said:**

*“Together with Celgene, we are creating an innovative biopharma leader, with leading franchises and a deep and broad pipeline that will drive sustainable growth and deliver new options for patients across a range of serious diseases.”*

## Current status and expectations

- Currently working on four active projects – First licence to TCR-T Products
- As part of the agreement Juno / BMS will have access to Oxford Biomedica’s new 84,000 sqft commercial manufacturing centre, Oxbox
- Juno / BMS are able to initiate additional projects in the future
- The Group is eligible to receive up to \$86m in development & regulatory related milestones and up to \$131m in sales related milestones

# 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 £35m plus certain materials costs for large scale vaccine manufacture at 1000L scale

### Timelines and current status

- **April 20:** OXB joined consortium led by the Jenner Institute, Oxford University to rapidly develop, scale and manufacture a potential vaccine for COVID-19, ChAdOx1 nCoV-19. This was licenced in late April to AstraZeneca to enable development, manufacture and distribution of the vaccine globally, vaccine was renamed AZD1222.
- **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 to enable the rapid manufacture of viral vector based vaccines and provides equipment for two GMP suites in Oxbox to further scale up AZD1222 or other viral vector vaccine candidates
- **September 20:** OXB signs 18 month supply agreement under a 3 year master services agreement with AstraZeneca paying £15million capacity reservation fee and potential additional revenues in excess of £35million, scaling up to 1000L production.

AstraZeneca 

Press release (21 May 2020)  
**Pascal Soriot, Chief Executive Officer of AstraZeneca 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”*



## **Gene Therapeutics**

### **Patient-centric**

Leveraging expertise to deliver lentiviral  
vector based gene therapies

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# Gene Therapeutics: 2020 Highlights

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## Axovant Progress

- In January 2020, 12-month data from the first cohort demonstrated a continued favourable safety profile and a 37% improvement in motor function from baseline as assessed by the UPDRS Part III 'OFF' score. This followed an improvement of 29% at six months on the same scale
- Six month data from the second cohort is expected in Q4 2020 with commencement of the randomised, sham-controlled trial in 2021
- In July 2020, Oxford Biomedica signed a three year clinical supply agreement with Axovant




## Proprietary in-house product development

- Internal pipeline review has been completed to identify where future investment will be made
- OXB-302 is the Group's priority candidate and targets haematological tumours with a CAR-T 5T4. Advanced preclinical work is continuing on OXB-302 as the programme moves towards entry into the clinic
- OXB-203, currently in preclinical studies, is targeting Wet AMD and uses Oxford Biomedica's technology to deliver a gene to express afibercept. This programme builds on the demonstrated long term gene expression data seen with its predecessor OXB-201
- The Group is continuing preclinical work on OXB-204 (LCA10) and OXB-103 (ALS) and a new preclinical program, OXB-401 (liver indication), has been initiated

## Sanofi – Ocular assets

- In June, Sanofi informed the Group that it intended to return the rights for the Stargardt's and Usher Syndrome programmes. Once returned the Group will undertake its own internal evaluation to decide whether to commit further resources to them

# Gene Therapeutics pipeline

Product	Indication	Pre-Clinical	Phase I	Phase I/II	Phase II	Phase III	Approval	
<b>OXB Partnered Products</b>								
Axo-Lenti-PD <sup>1</sup>	Parkinson's disease	[Orange arrow]			} Development milestones and royalties			 
SAR422459 <sup>2</sup>	Stargardt disease	[Dark blue arrow]			} In June 2020, Sanofi informed OXB of its intention to return these programmes			
SAR421869 <sup>2</sup>	Usher syndrome 1B	[Dark blue arrow]						
<b>OXB Proprietary Unencumbered Products</b>								
OXB-302	Haematological malignancies	[Blue arrow]						
OXB-203*	Wet AMD	[Blue arrow]						
OXB-204	LCA10	[Blue arrow]						
OXB-103	ALS	[Blue arrow]						
OXB-401	Liver indication	[Blue arrow]						

\* Builds on RetinoStat/OXB-201 – Phase I clinical trial in USA (NCT01301443), Campochiaro *et al.*, Lentiviral Vector Gene Transfer of Endostatin/Angiostatin for Macular Degeneration (GEM) Study. *Hum Gene Ther.* 2017

 *In vivo* programmes  *Ex vivo* programmes

<sup>1</sup> AXO-LENTI-PD formerly known as OXB-102, which OXB out-licensed to Axovant

<sup>2</sup> Out-licensed to Sanofi in 2009

# Axovant licence agreement

## Axovant Gene Therapies initial agreement signed in June 18 with three year clinical supply agreement signed in July 20

Worldwide exclusive  
licensing agreement for  
AXO-Lenti-PD (OXB-102)

Unmet need in Parkinson's disease  
(includes all indications)

Headline  
value  
\$842.5m

\$30m upfront and potentially \$55m for  
specified development milestones, in  
excess of \$757.5m for specified  
regulatory & sales related milestones

Receive 7-  
10% tiered  
royalties  
on sales

axovant  
GENE THERAPIES

**Pavan Cheruvu, CEO Axovant said:**

*"Axovant, together with our parent company Roivant, remains committed to developing innovative treatments for serious degenerative conditions such as Parkinson's disease, and we are excited to partner with **Oxford Biomedica is a recognised global leader in cell and gene therapy. OXB-102 is potentially a best-in-class gene therapy with the potential to transform Parkinson's disease treatment.** This is an area of significant unmet medical need and a major market opportunity. Advancing this high-quality candidate is a key priority for the team at Axovant and we very much look forward to working with Oxford Biomedica."*

## Current status and expectations

- In January 2020, Axovant reported twelve month data from first cohort in the open-label, dose-escalation portion of the ongoing study
- In July 2020, Oxford Biomedica signed a three year clinical supply agreement with Axovant
- The first patient in the second cohort of the SUNRISE-PD clinical study was dosed in April 2019 and Axovant expects to present six-month efficacy data from the six patients dosed in cohort one and two by Q4 2020
- Axovant expects to initiate the randomised, sham-controlled part of the SUNRISE-PD Phase 2 study in 2021
- Sales of products to treat Parkinson's disease in the 7 major markets reached **\$3.1bn** in 2016 and is forecast to reach **\$8.4bn** by 2026<sup>1</sup>

<sup>1</sup> Parkinson's Disease: Global Forecast and Market . Analysis to 2026, Published Global Data Feb 2020



**Platform**

**Innovation-centric**  
Driving industrialisation of Lentiviral  
vectors

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# Platform: 2020 Highlights

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## **Building the future**

- Following signing of a lease in 2019 on the new Windrush Innovation Centre signed in 2019 occupation of the facility continues to increase. Post the capital raise in June 2020 plans for the further expansion and refurbishment of the laboratories at this site have commenced

## **Platform Innovation partnership with Microsoft progressing well**

- AI collaboration to improve gene and cell therapy manufacturing – yield and quality of next generation gene therapy vectors
- Machine learning and cloud computing will be applied to the large datasets generated during process development, analysis and manufacture

## **In House Innovation**

- The Group's continuous improvement programme focuses on developing, refining and enhancing its technology, expanding its IP portfolio
- Examples include the TRiPSystem™, LentiStable™ SecNuc™ and U1/U2 as well as other innovations being developed to enable further scalable cost efficient manufacturing
- Ongoing investment in high-throughput automation and robotics is streamlining production, reducing costs and enabling faster screening and analytical testing

## **Industrialisation of Lentiviral vectors**

- Oxford Biomedica is driving the industrialisation of lentiviral vectors through innovation



# Proprietary platform innovation

**Next generation vectors:  
Regulated/optimal  
expression, targeting**

**Therapeutic vectors  
with tailored attributes**

**Cell and vector  
engineering to  
increase  
bioprocessing  
yield**

**Maximising  
data integration  
and analysis**



**AI and machine  
learning**

**Analytical dev.  
to characterise  
vectors (purity)  
and achieve  
rapid batch  
release**

**Automation**

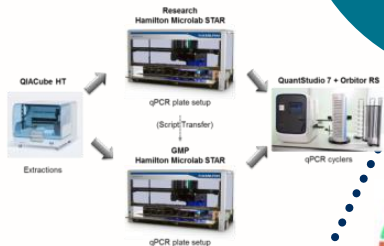
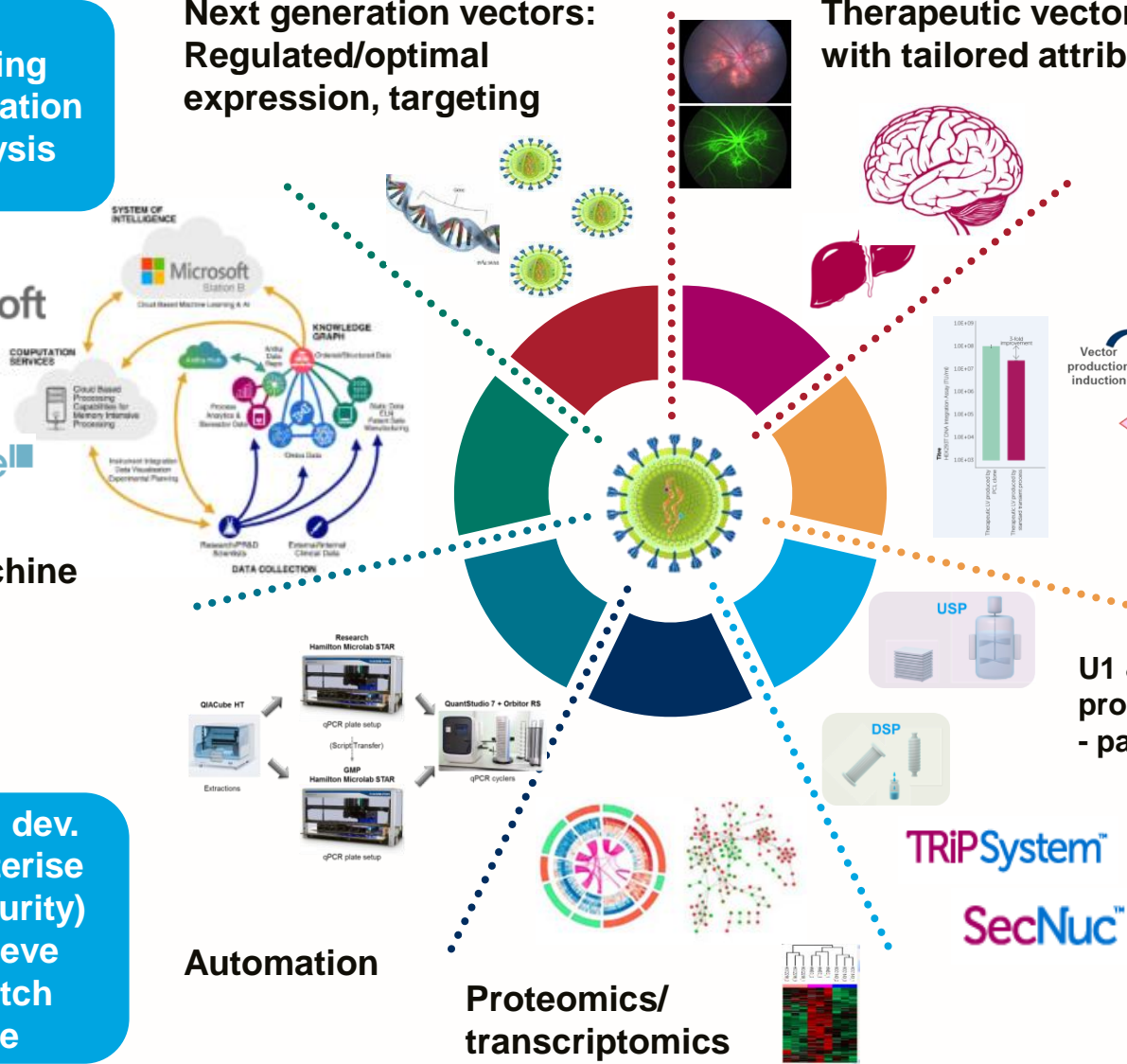
**Proteomics/  
transcriptomics**

**LentiStable™**

**Packaging and  
producer cell lines**

**U1 & U2 – increase  
productivity & quality  
- patents filed**

**Large scale  
bioprocessing:  
Increase yield  
and improve  
purity**



**TRIPSystem™  
SecNuc™**



# Financials, Outlook and Newsflow

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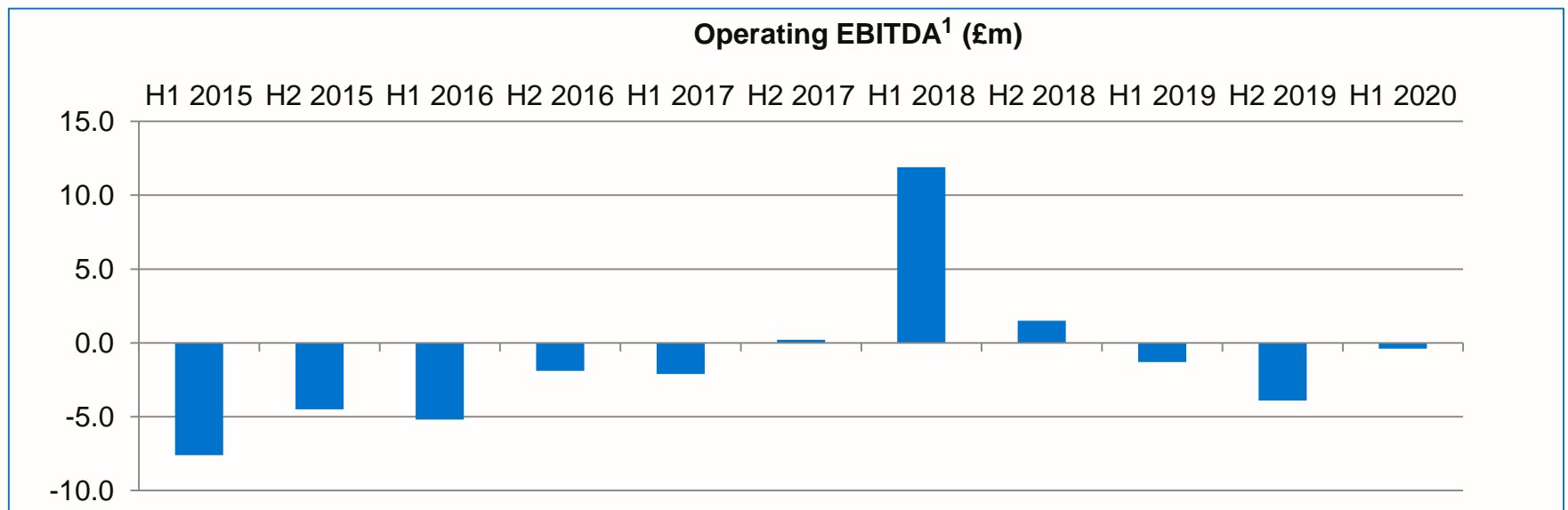
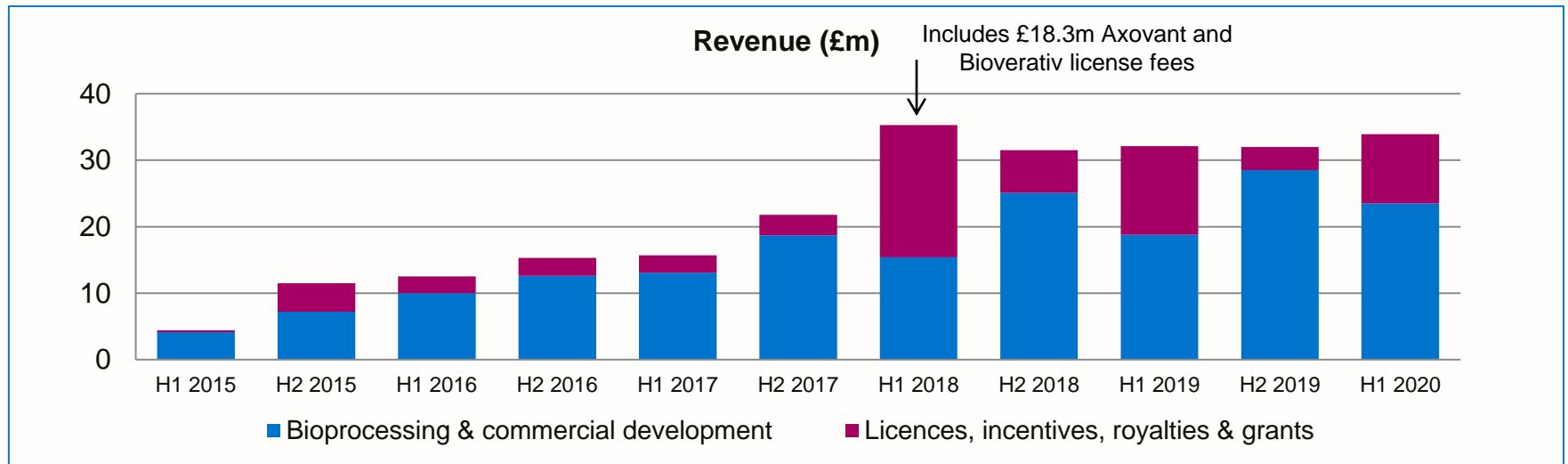
# H1 2020 Financial Highlights

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- Revenue increased by 6% to £34.0 million (H1 2019: £32.1 million)
- Continued strong growth was seen in bioprocessing and commercial development, where revenues increased by 24% to £23.3 million (H1 2019: £18.8 million)
- Licences, milestones & royalties were £10.6 million (H1 2019: £13.3 million), a decline of 21% as the growing royalties and licence fee revenue from Juno/BMS in H1 2020 was not able to match the large £11.5 million (\$15 million) milestone payment received from Axovant in H1 2019
- Operating expenses increased by 41% to £29.1million (H1 2019: £20.6 million)
- Operating EBITDA<sup>1</sup> loss and operating loss of £0.4 million and £5.8 million respectively (H1 2019 losses of: £1.4 million and £6.1 million respectively)
- Gross proceeds of £40.0 million (£38.6m net) were raised from new and existing investors through a successful placing in June 2020. This enables the Group to continue to leverage the significant opportunities in the growing cell and gene therapy market, and also provide additional resources for the Group's involvement in the manufacture of potential COVID-19 vaccine candidates
- Cash consumed during operations was £0.9 million compared to £1.3 million generated in H1 2019
- Cash at 30 June 2020 was £50.6 million (31 December 2019: £16.2 million)
- The Group's capital expenditure decreased to £5.3 million (H1 2019: £14.9 million) with the completion of the first phase of construction of the Oxbox bioprocessing facility at the end of 2019

<sup>1</sup> Operating EBITDA = Earnings Before Interest, Tax, Depreciation, Amortisation, Fair value adjustments of available-for-sale assets and Share based payments

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



<sup>1</sup> Operating EBITDA = Earnings Before Interest, Taxation, Depreciation, Amortisation, Revaluation of investments and Share-based payments

# Consolidated statement of comprehensive income

	Six months ended 30 June 2020	Six months ended 30 June 2019	Variance	
	Unaudited £'000	Unaudited £'000	£'000	
<b>Continuing operations</b>				
Revenue	33,979	32,101	1,878	↑
Cost of sales	( 10,314 )	( 16,831 )	6,517	↓
<b>Gross profit</b>	<b>23,665</b>	<b>15,270</b>	<b>8,395</b>	↑
		-		
Bioprocessing costs	( 9,195 )	( 4,116 )	( 5,080 )	↑
Research and development costs	( 15,168 )	( 12,484 )	( 2,683 )	↑
Administrative expenses	( 4,692 )	( 4,028 )	( 664 )	↑
Other operating income	327	463	( 136 )	
Change in fair value of available-for-sale asset	( 703 )	( 1,166 )	463	
<b>Operating loss</b>	<b>( 5,766 )</b>	<b>( 6,061 )</b>	<b>295</b>	↑
		-		
Finance income	13	70	( 57 )	
Finance costs	( 373 )	( 6,122 )	5,749	↓
<b>Loss before tax</b>	<b>( 6,126 )</b>	<b>( 12,113 )</b>	<b>5,987</b>	↑
Taxation	( 553 )	1,945	( 2,498 )	
<b>Loss and total comprehensive expense for the year</b>	<b>( 6,679 )</b>	<b>( 10,168 )</b>	<b>3,489</b>	↑
<b>Basic loss and diluted loss per ordinary share</b>	<b>( 8.69p )</b>	<b>( 14.83p )</b>	<b>6.14p</b>	

# Expected news flow 2020

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## Partner Programmes / CDMO

- The Group aims to further increase the number of partner programmes during 2020
- New facility (Oxbox) fully operational during H2 2020 with production of COVID-19 Vaccine, AZD1222 and other partner programmes
- Novartis CAR-T programmes progress in development in 2020
- Oxford COVID-19 Vaccine further clinical trial data during H2 2020

## Proprietary Pipeline

- Targeting the spin out / out-license of one in-house product candidate during 2020
- Axovant expects to present six-month efficacy data from cohort one and two of their SUNRISE-PD clinical study by Q4 2020
- Progress internal candidates into our portfolio and towards the clinic during 2020

## Positive outlook for 2020

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- Improved financial performance in 2020 building on growth of bioprocessing and commercial development partnerships and benefiting from increased utilisation of Oxbox during the year
- The partnership with AstraZeneca is likely to boost revenues in the year in excess of £10 million subject to successful scale up and regulatory approval of the fourth bioprocessing suite within Oxbox early in the fourth quarter of 2020
- Operating EBITDA for the Group is expected to be in the low to mid-single digit million range for the year on the basis described above
- Group expects an increase in operating expenses due to the number of employees growing to over 650 by year end
- Capex spend in the second half of the year will be higher than the spend in the first half with conversion of the office space within Windrush Court to GMP laboratories and final costs associated with the completion of the installation of the fill/finish line within Oxbox
- Despite the COVID-19 pandemic, the Group is excited about capitalising on its leading global lentiviral vector market position within the dynamic and fast growing cell and gene therapy sector



## Contact Us

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# Appendix

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# Balance Sheet

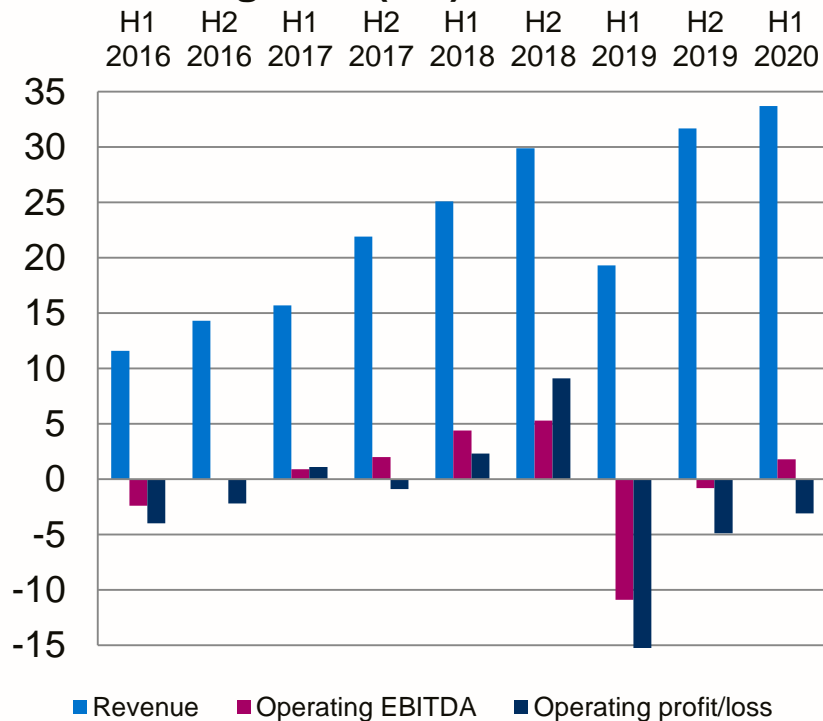
	<b>30 June 2020 Unaudited £'000</b>	31 December 2019 Audited £'000
<b>Assets</b>		
<b>Non-current assets</b>		
Intangible assets	84	95
Property, plant and equipment	66,094	61,932
Trade and other receivables	3,605	3,605
Deferred tax assets	-	359
	<b>69,783</b>	<b>65,991</b>
<b>Current assets</b>		
Inventory	3,174	2,579
Assets held for sale	366	2,719
Trade and other receivables	14,209	16,639
Contract assets	17,185	13,406
Current tax assets	4,858	5,351
Cash and cash equivalents	50,619	16,243
	<b>90,411</b>	<b>56,937</b>
<b>Current liabilities</b>		
Trade and other payables	16,391	14,297
Contract liabilities	13,394	13,156
Deferred income	647	1,006
Lease liabilities	827	482
	<b>31,259</b>	<b>28,941</b>
<b>Net current assets</b>	<b>59,152</b>	<b>27,996</b>
<b>Non-current liabilities</b>		
Lease liabilities	9,789	7,907
Provisions	5,806	5,086
Contract liabilities	1,063	1,695
Deferred income	3,373	3,310
Deferred tax liability	61	359
	<b>20,092</b>	<b>18,357</b>
<b>Net assets</b>	<b>108,843</b>	<b>75,630</b>
<b>Shareholders' equity</b>		
Share capital	40,967	38,416
Share premium	258,701	222,618
Other reserves	2,291	2,291
Accumulated losses	(193,116)	(187,695)
<b>Total equity</b>	<b>108,843</b>	<b>75,630</b>

# Statement of cash flows

	Six months ended 30 June 2020 Unaudited £'000	Six months ended 30 June 2019 Unaudited £'000
<b>Cash flows from operating activities</b>		
Cash (consumed in)/generated from operations	(938)	1,305
<b>Cash flows from investing activities</b>		
Purchases of property, plant and equipment	(5,350)	(14,928)
Proceeds on disposal of property, plant and equipment	-	2
Proceeds on disposal of investments	2,523	148
Interest received	13	49
Net cash used in investing activities	(2,814)	(14,729)
<b>Cash flows from financing activities</b>		
Interest paid	-	(3,352)
Proceeds from issue of ordinary share capital	40,167	55,306
Costs of share issues	(1,533)	(640)
Payment of lease liabilities	(506)	(471)
Loans repaid	-	(43,589)
Net cash generated from financing activities	38,128	7,254
<b>Net increase/ (decrease) in cash and cash equivalents</b>	<b>34,376</b>	<b>(6,170)</b>
Cash and cash equivalents at 1 January 2020	16,243	32,244
<b>Cash and cash equivalents at 30 June 2020</b>	<b>50,619</b>	<b>26,074</b>

# Segmental analysis

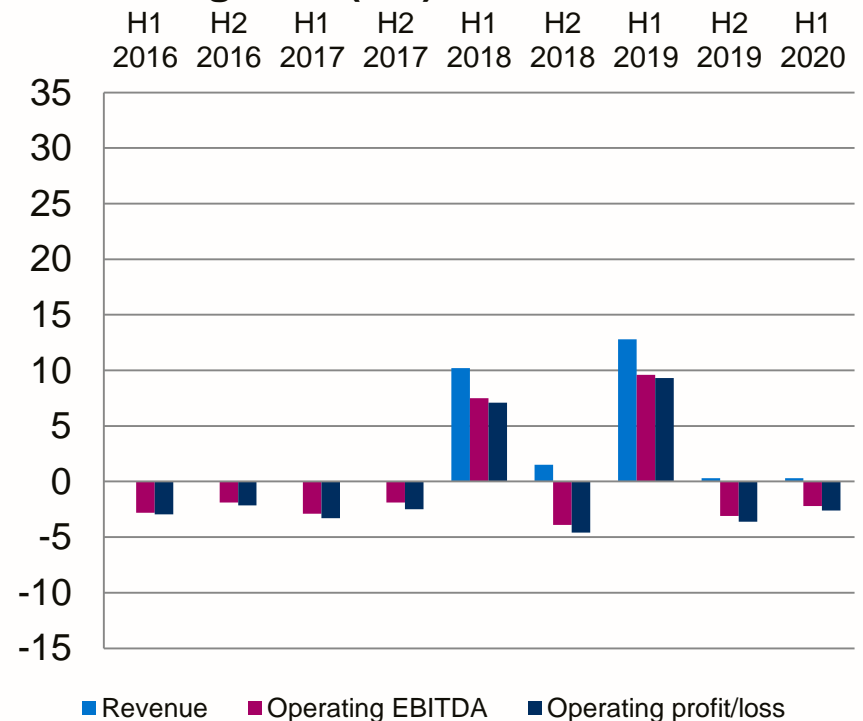
## Platform segment (£m)



### Platform segment

- Includes revenue received from commercial partnerships and costs of investing in LentiVector® technology
- Revenues were higher than H1 2019 due to increase in bioprocessing / commercial development revenues, increased Novartis royalties and Juno/BMS licence fee
- Operating results improved due to the revenue increase of £14.4 million over H1 2019

## Product segment (£m)



### 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
- Results were lower compared to the H1 2019 which was aided by the £11.5 million (\$15 million) Axovant milestone