



**A Global leading Lentiviral  
Vector Specialist**

Preliminary results for the year  
ended 31 December 2019

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May 2020

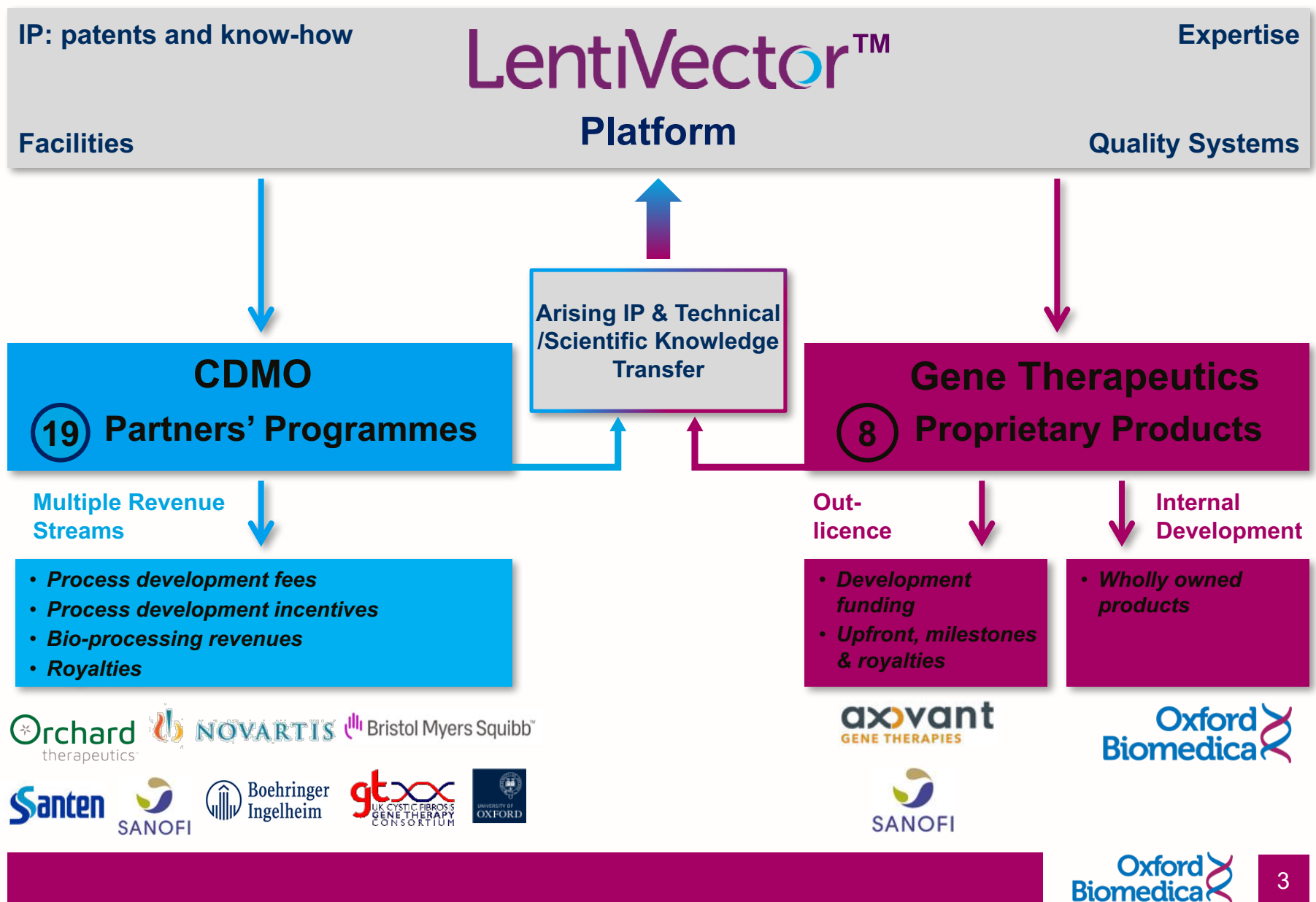
# Forward-looking statements

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# Strategy: Leveraging our LentiVector® delivery platform





**CDMO**

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

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# CDMO: 2019 and post period highlights

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## Novartis Partnership

- In December 2019 Novartis extended its commercial supply agreement by a further five years and extended the collaboration from two to five programmes
- Additional sixth CAR-T programme added in Q1 2020

## 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

## Santen Partnership

- R&D collaboration and option & licence agreement with Santen Pharmaceutical Co Ltd for development of gene therapy vectors for an undisclosed inherited retinal disease signed June 2019

## Building the Future

- The development and fit out of the first phase of the new 84,000 sqft Oxbox manufacturing facility was completed by year end 2019, validation is ongoing with first suite expected to be operational by the end of Q2 2020

## Oxford COVID-19 Vaccine Consortium partnership

- 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 the last 12 months Partner Programmes have more than doubled from 9 to 19

- Oxbox is key to delivering bioprocessing capacity to meet future demand

# 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 spanning Pre-Clinical, Phase I, Phase I/II, Phase II, Phase III, and Approval]					
2nd CAR-T	Cancer (multiple)	[Progress bar spanning Pre-Clinical and Phase I]					
3rd CAR-T	Cancer (multiple)	[Progress bar in Pre-Clinical]					
4th CAR-T	Cancer (multiple)	[Progress bar in Pre-Clinical]					
5th CAR-T	Cancer (multiple)	[Progress bar in Pre-Clinical]					
6th CAR-T	Cancer (multiple)	[Progress bar in Pre-Clinical]					
AXO-Lenti-PD <sup>2</sup>	Parkinson's disease	[Progress bar spanning Pre-Clinical and Phase I]					
1st CAR-T / TCR-T	Undisclosed	[Progress bar in Pre-Clinical]					
2nd CAR-T / TCR-T	Undisclosed	[Progress bar in Pre-Clinical]					
3rd CAR-T / TCR-T	Undisclosed	[Progress bar in Pre-Clinical]					
4th CAR-T / TCR-T	Undisclosed	[Progress bar in 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-III A							
Other	undisclosed							
Factor VIII	Haemophilia A							
Factor IX	Haemophilia B							
CFTR gene	Cystic Fibrosis							
Ocular gene	Inherited retinal disease							
Vaccine	COVID-19						Note 1	

Process development and bioprocessing revenues, and royalties



Note 1: Potential scale up and vaccine manufacturing revenues if successful in clinical trials



In vivo programmes



Ex vivo programmes

# Novartis CAR-T partnership

Novartis partnership in place since 2014. 1<sup>st</sup> commercial supply agreement signed in 2017 and 5 year extension signed Dec 2019 with additional 6<sup>th</sup> programme added Q1 2020

Clinical and commercial supply of vector

Kymriah<sup>®</sup> (tisagenlecleucel)/CTL019 and five additional lentiviral vectors for CAR-T programmes

IP licence

Minimum of \$75 million in vector manufacturing revenues inc. mid single digit reservation fee

Undisclosed process development fees

OXB receives royalties on sales

**NHS**

England

News release (05 Sept 2018)

**Simon Stevens, Chief Executive NHS England said:**

*“CAR-T therapy is a true game changer, and NHS cancer patients are now going to be amongst the first in the world to benefit. Today’s approval is proof-positive that, in our 70th year, the NHS is leading from the front on innovative new treatments. This constructive fast-track negotiation also shows how responsible and flexible life sciences companies can succeed - in partnership with the NHS - to make revolutionary treatments available to patients.”*

## Current status and expectations

- Kymriah<sup>®</sup> approved for r/r ALL & r/r DLBCL indications in US, EU, JP, AU, CA
- Kymriah<sup>®</sup> the only CAR-T available in Asia
- In April 2020, FDA granted Regenerative Medicine Advanced Therapy (RMAT) designation to Kymriah<sup>®</sup>, for an investigational new indication to treat patients with relapsed or refractory (r/r) follicular lymphoma (FL). Novartis expects US regulatory filing for Kymriah<sup>®</sup> in r/r follicular lymphoma in 2021.
- 130 qualified treatment centres and 20 countries worldwide have coverage for Kymriah<sup>®</sup> for at least one indication
- Sales estimate **>\$1.2bn<sup>1</sup>** by 2025

<sup>1</sup> Global Data Pharma eTrack Product Sales/Analyst consensus, extracted Feb 2020



## 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 will receive up to \$86m in development & regulatory related milestones and up to \$131m in sales related milestones



## Gene Therapeutics

**Patient-centric**  
Leveraging expertise to deliver lentiviral  
vector based gene therapies

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# Gene Therapeutics: 2019 and post period highlights

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## Axovant Progress

- Axovant reported 3-month data from first cohort for AXO-Lenti-PD. Progression to the second dose cohort, triggering a \$15 million milestone to Oxford Biomedica on dosing of the first patient
- 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 first and second cohort as well as commencement of the sham-controlled portion of the study is expected by year end 2020

## 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, for which work has now been halted
- 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

# 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						
SAR422459 <sup>2</sup>	Stargardt disease						
SAR421869 <sup>2</sup>	Usher syndrome 1B						
<b>OXB Proprietary Unencumbered Products</b>							
OXB-302	Haematological malignancies						
OXB-203*	Wet AMD						
OXB-204	LCA10						
OXB-103	ALS						
OXB-401	Liver indication						

**axovant**  
GENE THERAPIES

SANOFI

Development milestones and royalties

**Oxford Biomedica**

\* 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> Sanofi are seeking a partner to out-license these assets



**Platform**

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

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# Platform: 2019 and post period highlights

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## Industrialisation of Lentiviral vectors

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

## Platform Innovation partnership with Microsoft

- 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
- Examples include the TRiPSystem™ and LentiStable™ 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

## Building the future

- Lease on the new Windrush Innovation Centre signed for an additional 32,000 sqft discovery and innovation facility next to Windrush Court. Occupation of the facility began during the first half of 2019 with increased utilisation expected during 2020

# Proprietary platform innovation

Maximising data integration and analysis

Patient sample analysis

Next gen. vectors: Regulation, targeting

Cell and vector engineering to increase bioprocessing yield



AI and machine learning

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

Automation

Proteomics/transcriptomics

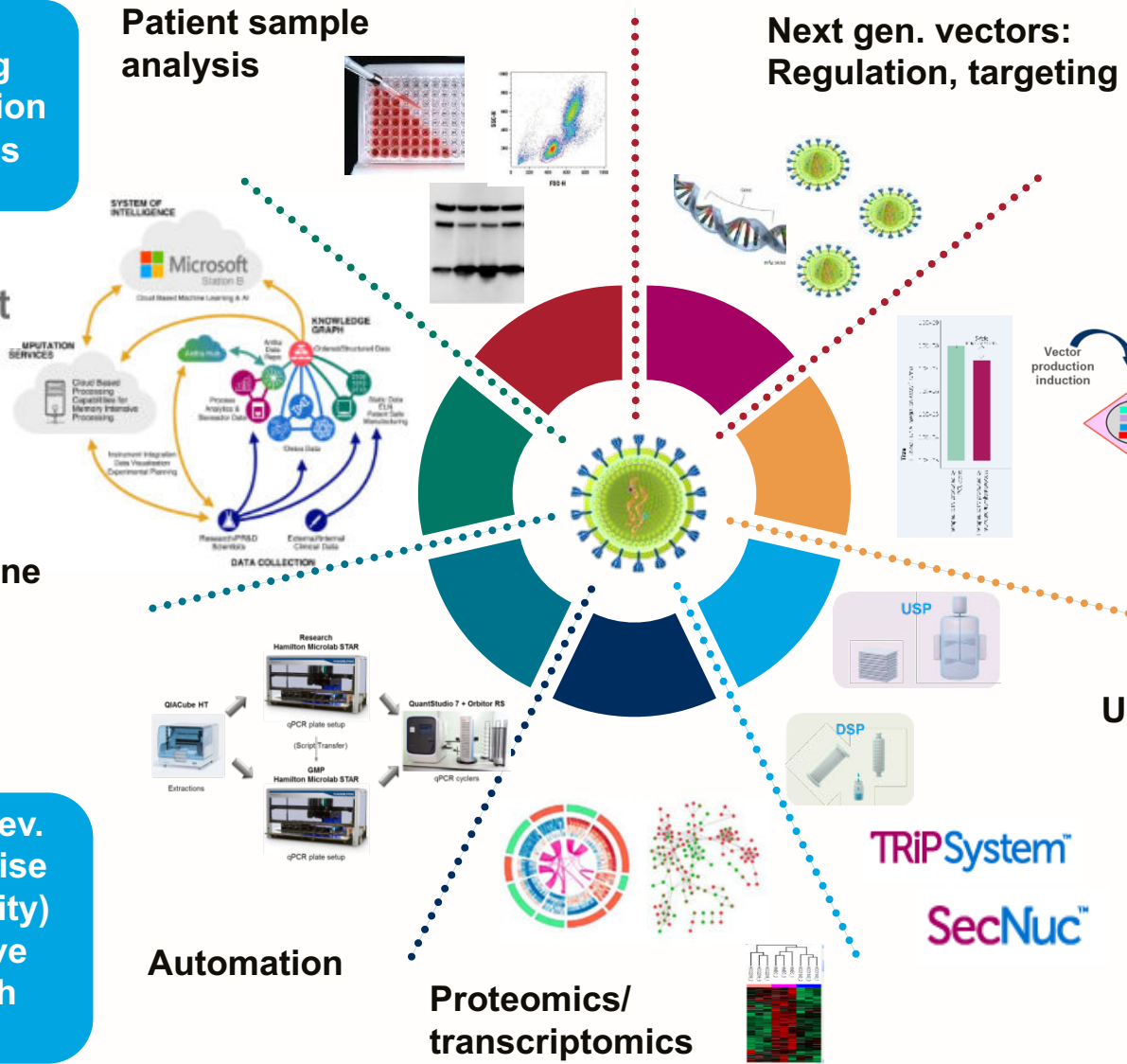
LentiStable™

Packaging and producer cell lines

USP and DSP

TRIPSystem™  
SecNuc™

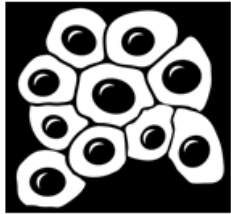
Large scale bioprocessing: Increase yield and improve purity



# Building industry leading know-how in multiple therapeutic areas

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Oxford Biomedica is involved at all stages of development for both proprietary and partners' lentiviral vector based products with a strong IP position



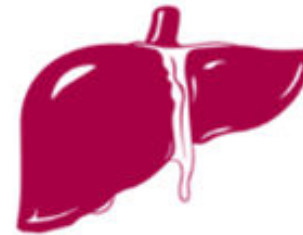
Gene modified  
cell therapies



Ocular  
diseases



CNS  
disorders



Liver  
diseases



Respiratory  
disease

- Large-scale, high-quality vector production to address indications requiring high vector volumes with large patient populations such as for liver and lung diseases
- Efficient and targeted genetic modification of specific cell types enabled by ability to utilise multiple vector surface proteins
- Incorporate latest platform technologies into our own innovative products





# Financials, Outlook and Newsflow

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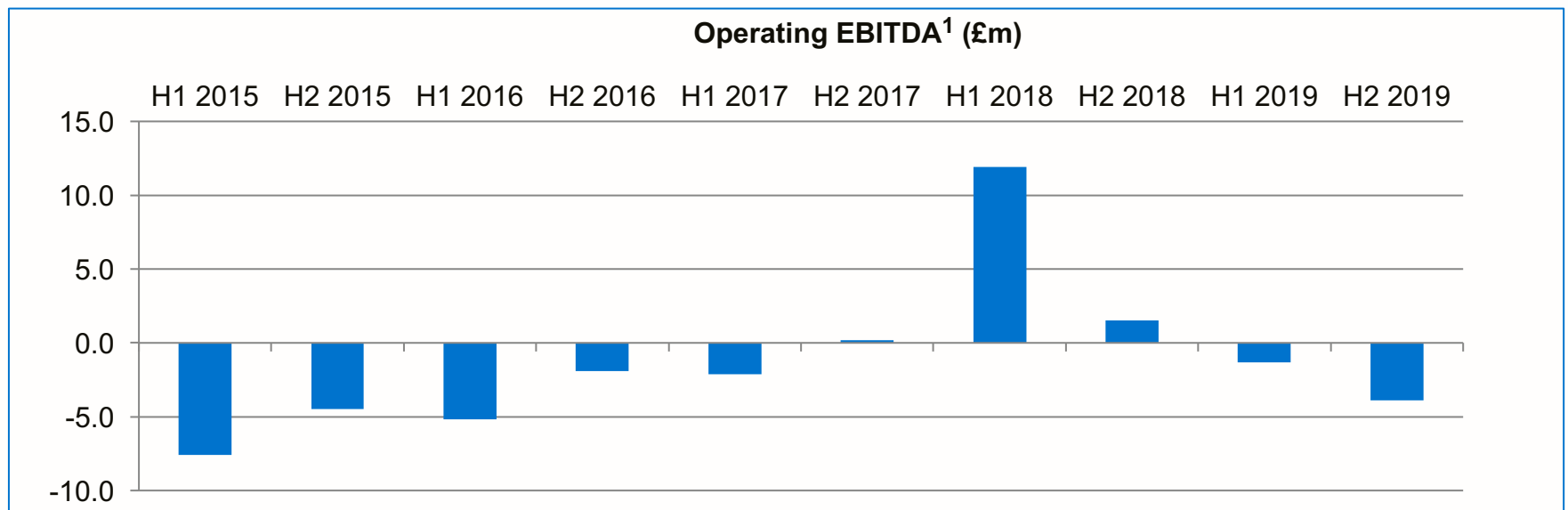
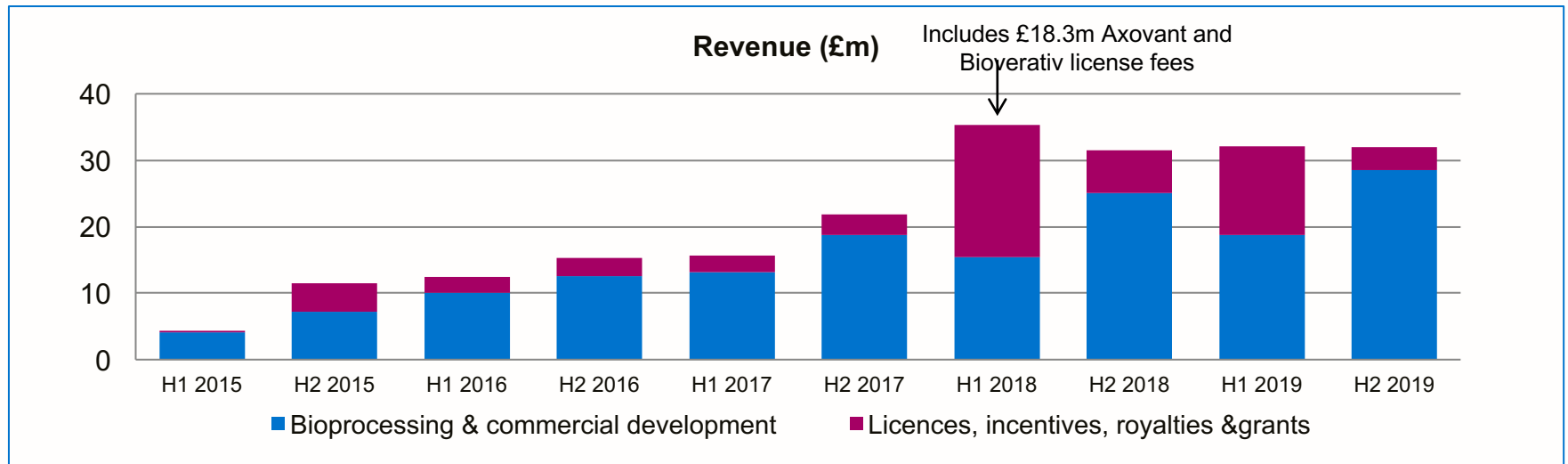
# 2019 Financial Highlights

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- Bioprocessing and commercial development revenues increased by 17% to £47.3 million (2018: £40.4 million) despite the capacity constraints within the business.
- Licences, milestones & royalties revenues decreased by 36% to £16.8 million (2018: £26.4 million) with the £11.5 million (\$15 million) Axovant milestone and strongly growing royalties unable to compensate for the sizable licence income received on signing the Sanofi (Bioverativ) and Axovant agreements in 2018.
- Total revenues decreased by 4% to £64.1 million (2018: Revenue of £66.8 million)
- Operating expenses increased by 57% from £26.6 million to £41.8 million.
- Operating EBITDA<sup>1</sup> loss incurred of £5.2 million (2018: £13.4 million profit)
- Operating loss incurred of £14.5 million (2018: £13.9 million profit)
- Capital expenditure £25.8 million (2018: £10.1 million) reflecting the continued capital expenditure on the planned new Oxbox bioprocessing facility
- Cash of £16.2 million (31 December 2018: £32.2 million)
- Cash outflow before financing activities of £22.9 million (2018: £2.8 million inflow)
- £53.5 million of equity raised from new Investor Novo Holdings which was used to fully repay the £43.6 million (\$55 million) Oaktree loan facility

<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

# COVID-19

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## Assessment of COVID-19 potential impact

The Group has conducted an assessment of the potential risks to the business and takes comfort from:

- The day to day changes in working practices put in place to protect our employees seem to be effective, with work continuing on in as near to normal way as possible
- Revenues are based on long term contracts with financially sound and resilient companies
- The Group has a stronger and more diversified customer base than it has had previously
- The Group has key worker status allowing continued provision of services to our customers

While the Group is yet to experience any significant impact from the virus, there may be an impact on revenue, supply chain and operating facilities if the situation continues or worsens and the Group continues to constantly monitor the ongoing situation

## Oxford COVID-19 Vaccine Consortium

- Joined a Consortium led by the Jenner Institute, Oxford University, to rapidly develop, scale-up and manufacture a potential vaccine candidate for COVID-19
- AstraZeneca subsequently entered into an agreement with Oxford University for the global development and distribution of the vaccine on 30<sup>th</sup> April.
- Potential impact on the Group is currently uncertain, should clinical trials be successful the Group will provide access to its large scale GMP manufacturing facilities including Oxbox to support the manufacturing scale up for Oxford University and AstraZeneca

# Expected news flow 2020

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## Partner Programmes / CDMO

YE 2019



YE 2020

- Two further partner contracts expected during 2020
- New facility (Oxbox) operational in H1 2020, post completion of construction in Dec 2019
- Novartis CAR-T programmes progress in development in 2020
- Oxford COVID-19 Vaccine consortium initial clinical trial data during Q3 2020

## Proprietary Pipeline

YE 2019



YE 2020

- Targeting the spin out / out-license of one in-house product candidate during 2020
- Axovant expects to present six-month efficacy data from the six patients dosed in cohort one and two of their SUNRISE-PD clinical study by Q4 2020
- Axovant expects to initiate the randomised sham-controlled part of the SUNRISE-PD Phase 2 study by year end 2020
- Progress two 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 Oxbox coming on stream
- CDMO partnering discussions / feasibility studies ongoing – Group aims to increase number of partners and programmes and to complete two further CDMO deals
- Plans to attract third party funding for proprietary products – targeting one deal this year
- Capex anticipated to be lower, with first phase of Oxbox construction now complete
- Group expects an increase in operating expenses due to increases in employee scale
- Despite the COVID-19 crisis, 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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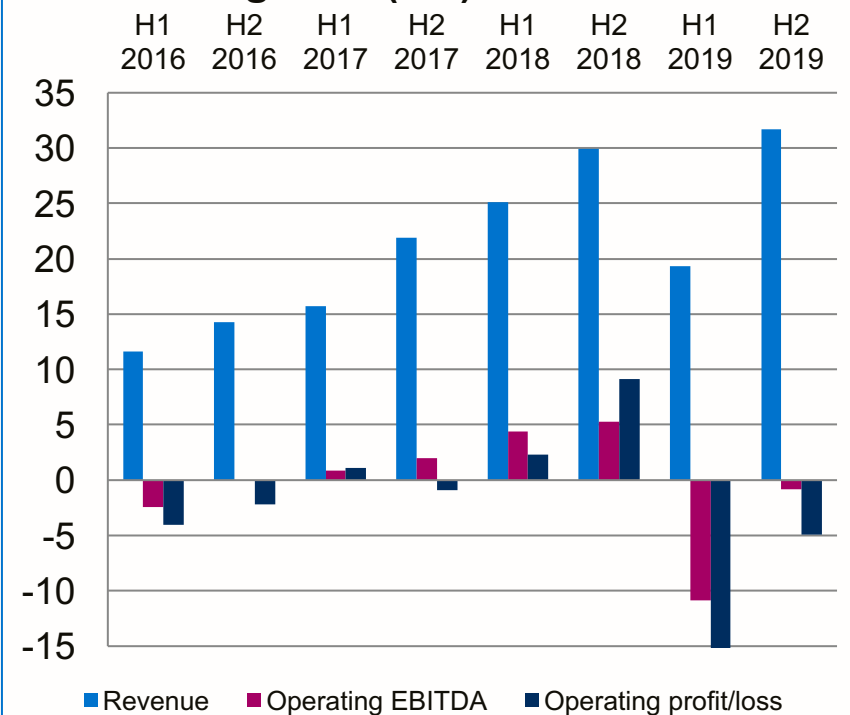
# Appendix

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# Segmental analysis

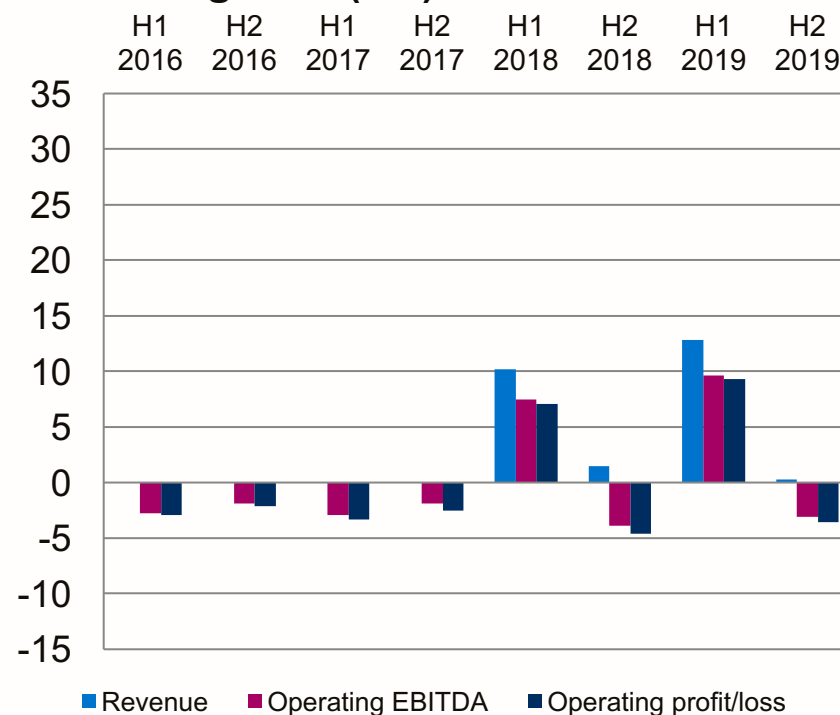
## Platform segment (£m)



### Platform segment

- Includes revenue received from commercial partnerships and costs of investing in LentiVector® technology
- Revenues lower as increase in commercial development unable to offset licence income received in 2018
- Operating results lower due to increased headcount and additional material and subcontracted cost spend

## 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
- Revenues were higher aided by the £11.5 million (\$15 million) Axovant milestone received in 2019

Operating EBITDA = Earnings Before Interest, Taxation, Depreciation, Amortisation, Revaluation of investments and Share-based payments

# Consolidated statement of comprehensive income

	Group	
	2019 Total £'000	2018 Total £'000
<b>Continuing operations</b>		
Revenue	64,060	66,778
Cost of sales	(35,723)	(33,261)
<b>Gross profit</b>	<b>28,337</b>	<b>33,517</b>
Research, development costs	(22,546)	(17,973)
Bioprocessing costs	(7,378)	(1,243)
Administrative expenses	(11,881)	(7,433)
Other operating income	884	1,604
Revaluation of investments	-	5,983
Change in fair value of asset held at fair value through profit & loss	(1,883)	-
<b>Operating profit/(loss)</b>	<b>(14,467)</b>	<b>13,915</b>
Finance income	104	71
Finance costs	(6,526)	(8,972)
<b>Profit/(loss) before tax</b>	<b>(20,889)</b>	<b>5,014</b>
Taxation	4,823	2,527
<b>Profit/(loss) and total comprehensive income/(expense) for the year</b>	<b>(16,066)</b>	<b>7,541</b>
<b>Basic earnings/(loss) per ordinary share</b>	<b>(22.10p)</b>	<b>11.57p</b>
<b>Diluted earnings/(loss) per ordinary share</b>	<b>(20.10p)</b>	<b>(10.89p)</b>

# Balance Sheet

	Group	
	2019	2018
	£'000	£'000
<b>Assets</b>		
<b>Non-current assets</b>		
Intangible assets	95	117
Property, plant and equipment	61,932	31,791
Investments at fair value through profit and loss	-	10,966
Trade and other receivables	3,605	4,000
Deffered tax assets	359	-
	<b>65,991</b>	<b>46,874</b>
<b>Current assets</b>		
Inventories	2,579	4,251
Assets at fair value through profit & loss	2,719	-
Trade and other receivables	30,045	26,585
Current tax assets	5,351	2,446
Cash and cash equivalents	16,243	32,244
	<b>56,937</b>	<b>65,526</b>
<b>Current liabilities</b>		
Trade and other payables	14,297	11,422
Contract liabilities	13,156	17,084
Deferred income	1,006	-
Lease Liabilities	482	-
Provisions	-	-
	<b>28,941</b>	<b>28,506</b>
<b>Net current assets</b>	<b>27,996</b>	<b>37,020</b>
<b>Non-current liabilities</b>		
Loans	-	41,153
Provisions	5,086	1,287
Contract liabilities	1,695	1,401
Deferred income	3,310	5,033
Lease liabilities	7,907	-
Deferred tax liability	359	279
	<b>18,357</b>	<b>49,153</b>
<b>Net assets</b>	<b>75,630</b>	<b>34,741</b>
<b>Equity attributable to owners of the parent</b>		
Ordinary share capital	38,416	33,034
Share premium account	222,618	172,074
Other reserves	2,291	3,509
Accumulated losses	(187,695)	(173,876)
<b>Total equity</b>	<b>75,630</b>	<b>34,741</b>

# Statement of cash flows

	Group	
	2019	2018
	£'000	£'000
<b>Cash flows from operating activities</b>		
Cash generated from/(used in) operations	(6,636)	9,214
Tax credit received	3,128	3,654
Net cash generated from/(used in) operating activities	(3,508)	12,868
<b>Cash flows from investing activities</b>		
Purchases of property, plant and equipment	(25,774)	-
Purchases of intangible assets	-	(10,103)
Proceeds on disposal of property, plant and equipment	2	(45)
Proceeds on disposal of investment assets	6,270	-
Interest received	104	52
Net cash used in investing activities	(19,398)	(10,096)
<b>Cash flows from financing activities</b>		
Proceeds from issue of ordinary share capital	54,132	21,184
Costs of share issues	(769)	(1,376)
Proceeds from the exercise of warrants	1,345	-
Loan to subsidiary	-	-
Interest paid	(2,513)	(4,665)
Redemption fee	(866)	-
Payment of lease liabilities	(835)	-
Loans repaid	(43,589)	-
Net cash generated from/(used in) financing activities	6,905	15,143
<b>Net increase/(decrease) in cash and cash equivalents</b>	(16,001)	17,915
Cash and cash equivalents at 1 January	32,244	14,329
<b>Cash and cash equivalents at 31 December</b>	16,243	32,244