EDISON

Oxford Biomedica

FY19 results

Further deals anticipated in 2020

Pharma & biotech

Oxford Biomedica's (OXB) FY19 results highlight strong operational momentum despite capacity constraints. OXB is investing for future growth and its 84,000 sq ft state-of-the-art bioprocessing facility OxBox is on track to produce commercial grade batches in Q220. Deals made include expansion of its commercial supply agreement with Novartis by five years and R&D partnerships with Santen and Microsoft, followed post period with the BMS/Juno licence and supply agreement. We expect further platform deals to be announced in 2020, as OXB exploits its position as the only FDA-approved, commercial-scale lentiviral vector (LVV) manufacturer in the US. In the long term, much value resides in OXB's ability to develop and monetise its own gene therapies, an out-licence deal is also on the cards and OXB plans to move several proprietary gene therapy assets into the clinic in the next 12 to 18 months.

Year end	Revenue (£m)	PBT* (£m)	EPS* (p)	DPS (p)	P/E (x)	Yield (%)
12/18	66.8	0.3	4.3	0.0	N/A	N/A
12/19	64.1	(16.8)	(16.4)	0.0	N/A	N/A
12/20e	76.5	(7.9)	(3.7)	0.0	N/A	N/A
12/21e	104.4	0.8	0.9	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

Partnerships diversify revenue streams

While total revenues declined 4% due to lower licence payments, these are by nature volatile from year to year. More importantly, operational revenues from bioprocessing and commercial development grew 17% to £47.3m. OXB has significantly diversified its revenue streams and expects to sign two further deals this year – discussions with multiple potential partners are ongoing. In FY19 OXB posted an operating loss of £14.5m as expenses increased to support the increased headcount and OxBox. We continue to expect ongoing growth in the top line, driven in the near term by Kymriah (Novartis), the progression of Sanofi/Bioverativ's haemophilia products to the clinic and the rapid advancement of its partnered products with Orchard and Axovant.

Debt removed, investment is key

Novo Holdings' equity investment (£53.5m) in May has enabled OXB to fully repay its costly debt facility, leading to a debt-free balance sheet, and boosted cash for developing its platform and own portfolio of assets. OXB is in a growth phase and ongoing investments are necessary to ensure future growth. We expect OXB to remain at break-even or positive net income in the near term. We also expect partnering deals to be announced that will strengthen OXB's balance sheet further.

Valuation: £709m (£9.22 per share)

Our revised valuation is £709m from £718m (£9.34/share). We have updated for FY19 results, removing the Orchard stake. We have made minor adjustments to OTL-101 and 201. Our sales forecasts are unchanged and our core drivers remain OXB's partnerships, which represent £5.98/share of our total value. We include OXB's reported cash and cash equivalents of £17.2m (at 30 April 2020).

18 May 2020

Price	**774p**
Market cap	**£600m**
	$:£0.82; €:£0.91; $:€0.91
Net cash (£m) at 30 April 2020	17.2
Shares in issue	76.9m
Free float	69%
Code	OXB
Primary exchange	LSE
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	12.3	17.8	12.2
Rel (local)	8.8	52.8	40.6
52-week high/low		774p	400p

Business description

Oxford Biomedica's (OXB) LentiVector® technology underpins the company's strategy. OXB generates significant revenue from partners that use its technology, notably Novartis, Juno Therapeutics (BMS), Bioverativ (Sanofi), Orchard Therapeutics, Axovant and Santen. OXB is implementing significant capacity upgrades to enable more partnering/out-licensing agreements.

Next events

ChAdOx1 nCov-19 Phase I initial data	Q320
AXO-Lenti-PD six-month efficacy data	Q420
New partnership and licensing deals	2020

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Multiple partners enhance revenue streams

OXB is the only FDA-approved, commercial-scale, GMP-approved LVV manufacturer in the US. Progression during 2019 and post period has validated OXB's position as a leader in its field, as well as its decision to invest heavily in the OxBox bioprocessing facility and, more recently, the Windrush Innovation Centre. We continue to expect ongoing growth in the top line, driven in the near term by Kymriah (Novartis), the commercial development fees related to Juno and the additional other assets covered under the Novartis deal, the progression of Sanofi's (previously Bioverativ) haemophilia products to the clinic (via development milestone payments) and the rapid advancement of OXB's partnered products with Orchard (notably OTL-201) and Axovant (six-month efficacy data expected in Q420). Additionally, early-stage collaborations with Santen and Boehringer Ingelheim/UK Cystic Fibrosis Gene Therapy Consortium will continue to contribute a growing share of the top line as OXB undertakes development work. OXB expects to sign two further deals this year, which would represent upside to our financial forecasts and valuation.

Kymriah uplift in growth trajectory in Q419

Kymriah (a CD19-targeting CAR-T that is approved for pALL and DLBCL) sales were initially below market expectations (due to a deepening competitive landscape and Novartis patient cell processing issues). However, sales continue to demonstrate strong quarter-on-quarter growth towards end 2019 (Q120: $93m, Q419: $96m, Q319: $79m and Q219: $58m). We note that Q120 sales were flat on Q419 related to the impact of COVID-19 on commercial flights used in the Kymriah supply chain (Novartis has circumvented this by alternative flight routes). Kymriah is now approved for reimbursement in over 20 countries (for at least one indication) including the US, Canada, Japan, Australia and several counties in Europe, with more than 130 qualified centres able to offer the treatment, and we expect OXB to benefit from increasing royalty and manufacturing revenue. In April 2020, the FDA granted regenerative medicine advanced therapy (RMAT) designation to Kymriah for relapsed or refractory follicular lymphoma, Novartis expects to file for this indication in 2021. Kymriah consensus sales are estimated at more than $1.2bn by 2025 (source: GlobalData Pharma/OXB presentations).

Novartis committed to CAR-T as programmes expand

Following the 2017 commercial launch of partner Novartis's Kymriah, OXB has successfully expanded its commercial supply agreement with Novartis by five years. OXB is now working on six different LVVs for use in Novartis's CAR-T products. Although OXB has not disclosed the targets, we assume (based on Novartis's recent R&D day) they are focused on CD19, BCMA, CD22, IL3RA and EGFRvIII. We note that the $75m minimum revenue announced in the expanded commercial partnership is for vector batches only. As a result, OXB will benefit separately from development revenue for these new assets, which could provide substantial upside to our current assumptions. OXB will dedicate some of its new 84,000 sq ft manufacturing facility (OxBox) to Novartis, while also ensuring that at least two of its GMP facilities are capable of commercial supply, essentially ensuring a dual-sourced supply if the need arises.

BMS/Juno another major gene therapy player added to the list

The post-period licence and clinical supply agreement (LSA) with Juno Therapeutics (part of the BMS group) grants Juno a non-exclusive licence to OXB's LentiVector platform for its application in a number of novel CAR-T and TCR-T programmes. This is a significant deal, albeit early stage, in terms of multiple programmes and further diversifies OXB's revenue streams. The deal covers four products (targets are undisclosed by OXB) and, based on Juno's disclosed clinical pipeline, we

assume it covers early clinical-stage assets as well as preclinical ones. Deal terms include a $10m upfront payment from Juno, up to $86m in potential development and regulatory milestones (spread across four assets and multiple indications), up to $131m in potential sales-related milestones and an undisclosed royalty on net sales of products using its LentiVector platform. As these assets move towards approval, commercial manufacturing supply provides further upside. In the near term the key revenues will be from commercial development which will move to batch revenues.

Santen minimal risk with upside opportunity

In June 2019, OXB signed an R&D collaboration, in addition to an option and licence agreement with Santen Pharmaceutical, a publicly listed, leading Japanese ophthalmic pharmaceutical company. The agreement covers the development of gene therapy vectors for an undisclosed rare inherited retinal disorder. Under the terms of the initial agreement, OXB will provide preclinical proof of concept with its lentiviral vector platform. OXB is entitled to an undisclosed milestone payment on Santen exercising the option to the LentiVector platform, as well as development milestones and up to a 10% royalty on net sales. Santen has worldwide commercial rights to the programme, while OXB retains an option to co-fund and participate in the development and commercialisation in the US and Europe. The structure of this deal is interesting as it is of minimal risk at this early stage but provides the opportunity to share in the upside if this gene therapy has commercial viability in the US/EU.

AXO-Lenti-PD hitting development milestones

Partner Axovant has accelerated AXO-Lenti-PD into the clinic, with a Phase I/II dose-escalation study (SUNRISE-PD) in advanced PD patients ongoing. Following positive early data in the lowest dose cohort (n=2), a second dose cohort is enrolling (OXB received a $15m milestone payment on dosing of the first patient). In January 2020, Axovant reported 12-month post-dosing data, which demonstrated an average 22-point change from baseline (represents a 37% improvement) in motor function as assessed by the UPDRS Part III 'OFF' score. These data are encouraging (although restricted to two patients) as they expand from the 17-point change from baseline (29% improvement) seen at six months on the same scale. Six-month data from the first and second cohort are expected in Q420. Furthermore, Axovant expects to start the sham-controlled portion of the study by year end. OXB is eligible for remaining milestones of up to c $800m ($40m left for development) and 7–10% tiered royalties on any sales.

Debt removed, investing for future growth in OxBox

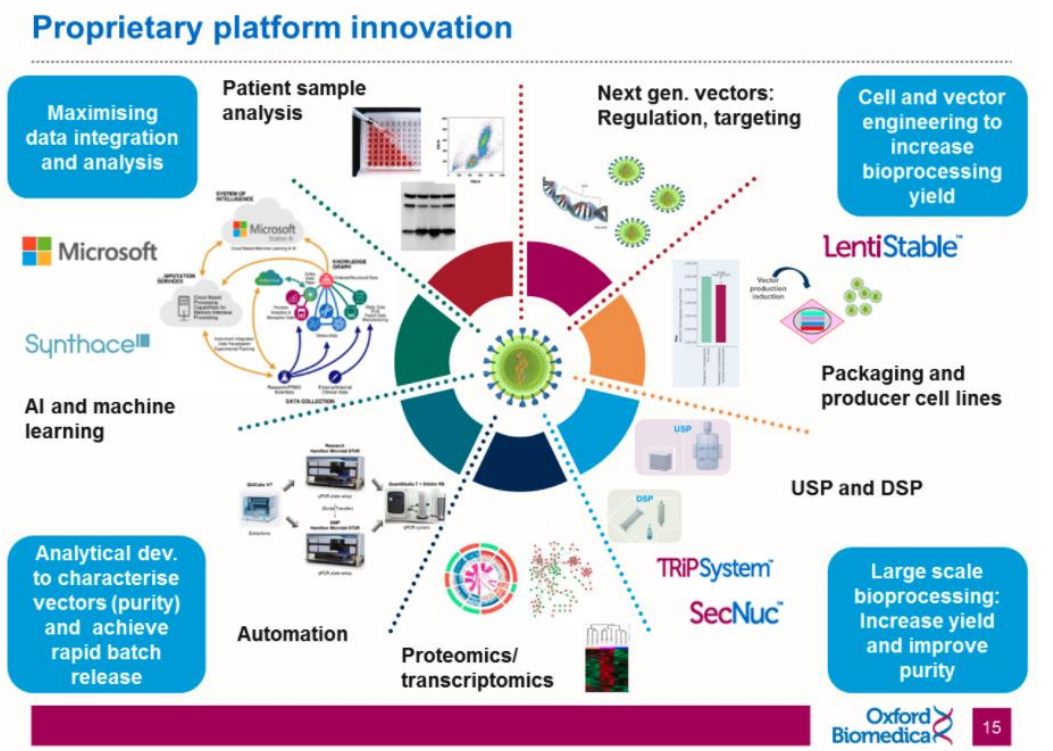
Novo Holdings' equity investment in May of £53.5m (for 10.1% of the outstanding share capital) has enabled OXB to fully repay the £43.6m debt facility with Oaktree Capital Management. At end April 2020, OXB reported cash and cash equivalents of £17.2m, we believe the balance sheet will be strengthened further by signing deals (clinical supply agreements or out-licensing of its pipeline candidates). We expect OXB to operate close to break-even during 2020 as it continues to invest in capacity (finalising OxBox and the Windrush Innovation Centre – the latter will focus on innovation and technological advances to support both the product pipeline and LentiVector platform). At 31 December 2019, the employee count had risen to 554 from 432 at the end of 2018.

Innovation at the heart of its platform and pipeline

OXB continues to innovate within its platform capabilities and its proprietary gene therapy R&D pipeline. It has made advances in technology in its platform, as it drives the industrialisation of vectors towards better yield and lower cost of production, OXB's successful transition to Process B bioreactor vector production for Kymriah (a tenfold yield and tenfold efficiency over Process A) in

H119 demonstrated its expertise in vector manufacturing. Moving to Process B bioreactor vector production also enabled deals such as Bioverativ (Sanofi), given the large number of vectors needed for the treatment of conditions such as haemophilia (liver). To move further along the efficiency pathways, the group has continued to focus on developing, refining and enhancing its technology through advances such as its next-generation Transgene Repression in Vector Production (TRiP) manufacturing system and LentiStable cell lines that provide improved vector yields and scalable, cost-effective manufacturing. Additionally, in an effort to ensure it remains at the cutting edge, in March 2019 OXB announced a collaboration with Microsoft Research to utilise its machine learning technology to develop insights into OXB's processes. The aim of the partnership is to improve the yield and quality of OXB's next-generation gene therapy vectors. The partnership will initially run for two years, but can be extended by either party. Exhibit 1 highlights the ongoing in-house innovation initiatives to generate new intellectual property that can be licensable and utilised in in-house programmes to ultimately drive increasing value.

Exhibit 1: OXB innovation wheel



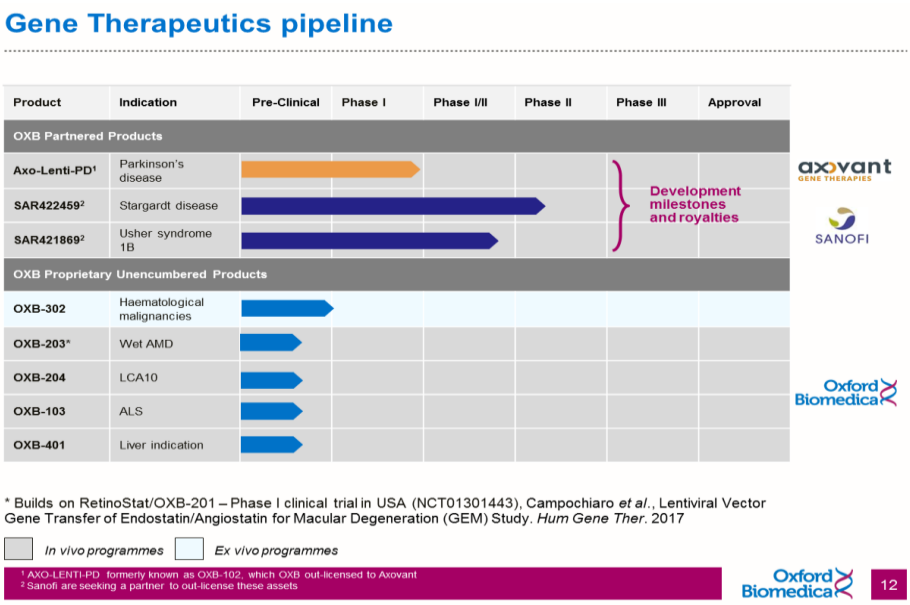
Source: OXB corporate presentation

Preclinical candidates poised to move to clinic in 12–18 months

OXB has completed a review of its internal pipeline; work on OXB-201 (wet age-related macular degeneration (AMD)) and OXB-202 (corneal graft rejection) have been discontinued. OXB-203 takes over from its predecessor OXB-201 for wet AMD.

OXB-302 (CAR-T 5T4) remains the priority candidate in preparation to enter clinical-stage testing in the next 12 to 18 months. Furthermore, preclinical work on OXB-204 (LCA10) and OXB-103 (ALS) are continuing and a new preclinical programme, OXB-401 (liver indication), has been initiated. Management is targeting the spin-out/out-licence of one in-house product candidate during 2020. The out-licence agreement achieved with Axovant for Axo-Lenti-PD demonstrates the scale of economic terms reached previously, although we note the unmet need and large patient population in PD as the driver for the large deal terms.

Exhibit 2: OXB proprietary gene therapy pipeline

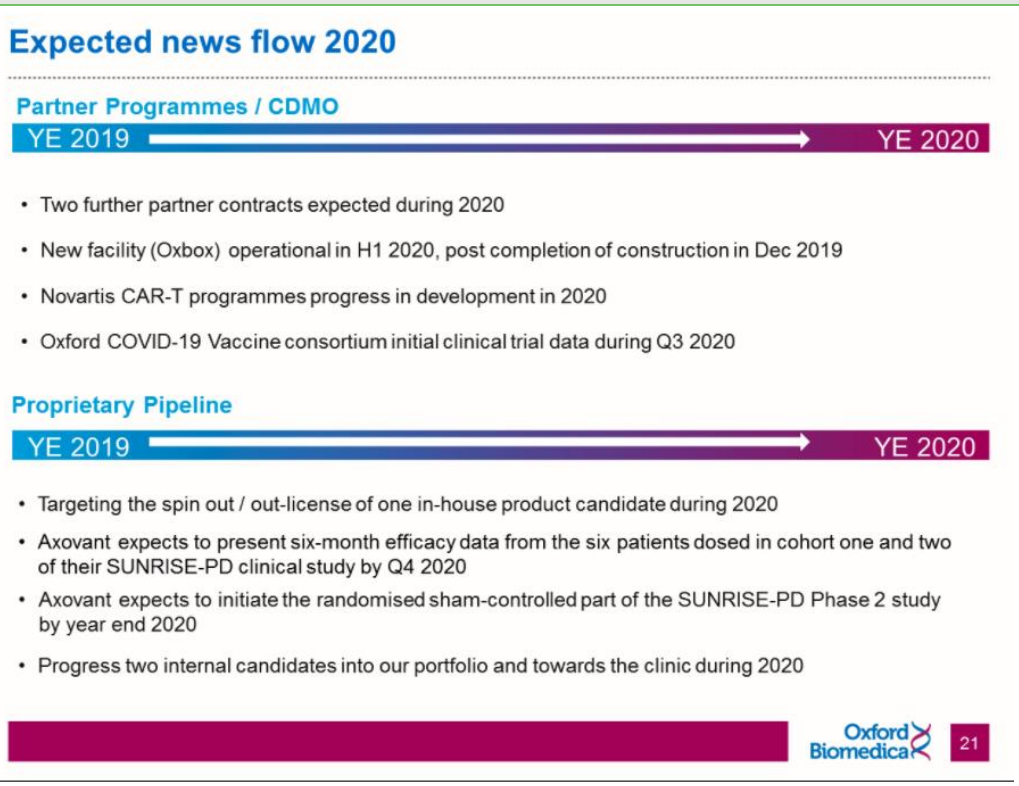


Source: OXB corporate presentation

2020 outlook

OXB has highlighted expected newsflow for the year (Exhibit 3). Management expects two further partner contracts during 2020 and discussions with multiple potential partners are ongoing. OxBox will begin manufacturing the first commercial vector batches by end H120. Fill and finish will also be provided in-house for the first time in this new facility, providing customers with an end-to-end offering. In May 2020 OXB received MHRA approval for the first two manufacturing suites at OxBox and this will enable it to start commercial production of batches for partner programmes within the coming weeks. Furthermore, OXB is targeting the out-licence/spin-out of one of its proprietary gene therapy candidates, in addition to progressing two of its internal candidates from preclinical into the clinic (see above).

Exhibit 1: Key 2020 inflection points



Source: OXB corporate presentation

COVID-19 impact

OXB has stated that 'so far, the Group has not experienced any and does not currently expect to experience significant supply issues or any changes in customer demand'. It has 19 programmes in development, 12 of which are in commercial development at the vector construct stage and as such will not be affected by clinical trial delays. The second Novartis and Axovant products could potentially be affected by clinical trial delays. However, OXB said it has seen no change in demand from customers. It has been granted key worker status, which has allowed it to continue servicing its customers during the UK lockdown period.

Additionally, OXB has joined a consortium led by the Jenner institute within the University of Oxford to develop, scale up and manufacture a potential vaccination for COVID-19 known as ChAdOx1 nCov-19, which is currently recruiting in Phase I. This vaccine relies on adenoviral vector technology, but OXB can leverage its LVV expertise to provide adenoviral vectors. It can provide the technical expertise for mass-scale production (via its OxBox manufacturing facility) if the initial vaccine development work proves positive. AstraZeneca has also joined the consortium and will contribute to the global development and distribution of a successful vaccine. Initial trial data are expected in Q320.

Financials

OXB reported FY19 total revenues of £64.1m (-4% y-o-y from £66.8m). Licence fees, milestone and royalty (LMR) revenue were reported at £16.8m in FY19, as FY18 (£26.3m) benefited from large upfront payment contributions on signing the Axovant and Sanofi (Bioverativ) partnerships. LMR revenue in FY19 comprised an £11.5m ($15m) milestone from Axovant and, although undisclosed, we assume the majority of the remainder is £5.3m in royalties for Kymriah.

Bioprocessing/commercial development revenues, which are historically more predictable, grew to £47.3m (+17%, £40.5m in FY18), driven by growth in Novartis's bioprocessing volumes (notably for Kymriah) and from increased commercial development services and greater volume of development activity provided to new customers (UK Cystic Fibrosis Gene Therapy Consortium, Axovant and Santen). Novartis-related revenues now represent approximately 50% of group revenues, highlighting the diversification of customer base and revenue streams.

R&D and bioprocessing costs increased to £22.6m (FY18: £18.0m) and £7.4m (FY18: £1.2m) respectively in FY19. For R&D, this was a result of increased investments in commercial and technical projects, while the increase in bioprocessing costs is a result of headcount, facility costs and related spend on OxBox. Costs were also affected by downtime at the Yarnton bioprocessing facility (switch from Process A to B), where associated downtime costs were accounted for in bioprocessing costs rather than as COGS (as no goods were produced in the downtime). We currently include forecast bioprocessing costs in our R&D line. COGS were reported at £35.7m in FY19 (£33.3m FY18 restated) and this line now reflects reallocation of costs, which were previously consolidated with research, development and bioprocessing costs. Administrative costs rose to £11.9.m (vs £7.4m in FY18), reflecting the significant increase in employees to support expansion of the business.

Finance costs decreased to £6.5m (FY18: £9.0m), mainly due to a lower interest charge of £5.4m (FY18: £6.2m) as the Oaktree Capital Management loan was repaid at the end of June 2019. R&D tax credits increased to £4.8m (FY18: £2.5m), reflecting an increase in R&D expenditure, both in terms of headcount and materials. Capital expenditure in FY19 was £25.8m (vs £10.1m in FY18), driven mainly by the ongoing build and fit of OxBox that completed in December and expansion of the business as a whole. We expect this to drop significantly in FY20.

Gross and net cash was £16.2m at 31 December 2019 (£17.2m at 30 April 2020). We forecast £76.5m in total revenues and a £8.0m operating loss in FY20, but note that multiple sensitivities remain around this figure, including cost sensitivities in R&D, facilities and personnel, in addition to revenue sensitivities with regard to Kymriah sales growth, the extent of bioprocessing revenue, milestone payments and the execution of any new deals.

Valuation: £709m (£9.22 per share)

Our revised valuation is £709m from £718m (£9.34/share). We have updated for FY19 results, removing the Orchard stake. We have made minor adjustments to OTL-101 and 201, we have delayed OTL-101 launch to 2022 as Orchard have deprioritised this asset in favour of advancing OTL-201 into the clinic, we reflect a higher probability of success as it moves from preclinical to clinical stage development (OTL-201 – progressed to Phase I with first patient dosed on 27 April. Interim data expected in 2021). Our valuation is based on a risk-adjusted NPV of partnered products with Novartis (Kymriah and undisclosed second CAR-T: £2.05/share), Orchard Therapeutics (OTL-101 and OTL-201), Bioverativ/Sanofi (Factor VIII and Factor IX), Sanofi (SAR422459 and SAR421869), AXO-Lenti-PD (PD: £2.30/share), Juno (23p/share), OXB-203 (wet AMD), and OXB-302 (cancer). We include net cash (22p/share) and a terminal value (£2.50/share).

For extensive details of our valuation, please see our outlook note, In a cell and gene therapy sweet spot.

Exhibit 4: Valuation summary

Product/partner/indication/status	Estimated launch year	Peak royalties (£m)	Peak manufacturing revenue (£m)	Probability of success	NPV (£m)	rNPV (£m)	rNPV per share (p/share)
Kymriah/Novartis/r/r pALL/approved in US and EU	Launched	4	2	100%	40	40	52.05
Kymriah/ Novartis/DLBCL/approved in US and EU	Launched	24	13	100%	96	96	124.86
2nd CAR-T/Novartis/Cancers/Phase I/II	2022	27	33	20%	111	22	28.52
OTL-101/ Orchard/ADA-SCID/Phase II/III	2022	0	1	70%	6	5	5.88
OTL-201/Orchard/Sanf A synd/Phase I	2025	13	11	10%	37	6	8.03
Factor VIII/Bioverativ/Haemophilia A/preclinical	2025	499	119	5%	949	52	67.51
Factor IX/Bioverativ/Haemophilia B/preclinical	2025	125	30	5%	252	18	22.77
SAR422459/Sanofi/Stargardt/Phase II	2025	36	N/A	25%	65	18	22.86
SAR421869/Sanofi/Usher/Phase I/II	2026	29	N/A	20%	46	10	12.96
Axo-Lenti-PD/Axovant/Parkinson's/Phase I/II	2022	83	17	30%	501	177	230.48
OXB-302/NA/cancer/preclinical	2025	64	64	5%	106	5	6.33
OXB-203/NA/wet AMD/preclinical	2027	134	15	20%	171	34	44.74
Juno collaboration	2025 onwards			20%	66	17	22.51
Total pipeline and partnership value						**499**	**649.51**
Terminal value						**192**	**250.11**
Net cash at 30 April 2020						**17**	**22.37**
Total						**709**	**922.00**

Source: Edison Investment Research

Exhibit 5: Financial summary

Accounts: IFRS, Yr end: December, GBP: Thousands	2016	2017	2018	2019	2020e	2021e
Income statement						
Total revenues	27,776	37,590	66,778	64,060	76,536	104,446
Cost of sales	(11,835)	(18,442)	(33,261)	(35,723)	(41,445)	(53,271)
Gross profit	15,941	19,148	33,517	28,337	35,091	51,175
Administrative expenses	(5,957)	(7,276)	(7,433)	(11,881)	(12,237)	(13,461)
R&D and bioprocessing costs	(24,299)	(21,611)	(19,216)	(29,924)	(30,822)	(36,872)
Other income/(expense)	3,002	1,774	1,064	884	0	0
Exceptionals and adjustments	0	2,297	5,983	(1,883)	0	0
Operating profit/(loss)	(11,313)	(5,668)	13,915	(14,467)	(7,968)	842
Finance income/(expense)	(8,994)	(6,093)	(8,901)	(6,422)	26	16
Reported PBT	(20,307)	(11,761)	5,014	(20,889)	(7,942)	858
Income tax expense (includes exceptionals)	3,666	2,744	2,527	4,823	5,064	(163)
Reported net income	(16,641)	(9,017)	7,541	(16,066)	(2,878)	695
Basic average number of shares, m	56	62	65	73	77	77
Basic EPS (p)	(29.9)	(14.6)	11.6	(22.1)	(3.7)	0.9
Adjusted EBITDA	(6,773)	(2,645)	13,535	(4,550)	(329)	8,911
Adjusted EBIT	(10,448)	(7,020)	9,178	(10,337)	(7,968)	842
Adjusted PBT	(19,442)	(13,113)	277	(16,759)	(7,942)	858
Adjusted EPS	(28.4)	(16.7)	4.3	(16.4)	(3.7)	0.9
Balance sheet						
Property, plant and equipment	27,514	25,370	31,791	61,932	69,262	73,172
Intangible assets	1,330	97	117	95	95	95
Other non-current assets	657	2,954	10,966	0	0	0
Total non-current assets	29,501	28,421	46,874	65,991	73,583	77,493
Cash and equivalents	15,335	14,329	32,244	16,243	5,252	3,299
Inventories	2,202	3,332	4,251	2,579	7,381	5,838
Trade and other receivables	6,904	17,088	26,585	30,045	26,211	35,769
Other current assets	3,000	2,232	2,446	8,070	7,783	2,719
Total current assets	27,441	36,981	65,526	56,937	46,626	47,625
Non-current loans and borrowings	34,389	36,864	41,153	0	0	0
Contract liabilities and deferred income	0	0	6,434	5,005	5,005	5,005
Other non-current liabilities	622	630	1,566	13,352	13,614	13,777
Total non-current liabilities	35,011	37,494	49,153	18,357	18,619	18,782
Trade and other payables	6,003	8,690	11,422	14,297	14,193	18,244
Contract liabilities and deferred income	3,313	13,072	17,084	13,156	13,156	13,156
Total current liabilities	9,316	21,762	28,506	28,941	28,837	32,888
Equity attributable to company	12,615	6,146	34,741	75,630	72,752	73,448
Cashflow statement						
Operating profit/(loss)	(11,313)	(5,668)	13,915	(14,467)	(7,968)	842
Depreciation and amortisation	3,675	4,375	4,357	5,787	7,639	8,069
Share based payments	865	945	1,246	2,247	0	0
Other adjustments	(579)	(1,326)	(8,012)	1,886	0	0
Movements in working capital	1,423	141	(2,292)	(2,089)	(1,071)	(3,966)
Income taxes paid	4,081	4,512	3,654	3,128	5,351	5,064
Cash from operations (CFO)	(1,848)	2,979	12,868	(3,508)	3,951	10,010
Capex	(6,458)	(1,969)	(10,148)	(25,774)	(14,969)	(11,979)
Other investing activities	47	38	52	104	26	16
Cash used in investing activities (CFIA)	(6,411)	(1,931)	(10,096)	(19,398)	(14,943)	(11,963)
Net proceeds from issue of shares	17,497	385	19,808	53,363	0	0
Movements in debt	0	8,361	0	(43,589)	0	0
Interest paid	(3,258)	(10,800)	(4,665)	(2,513)	0	0
Other financing activities	0	0	0	0	0	0
Cash from financing activities (CFF)	14,239	(2,054)	15,143	6,905	0	0
Increase/(decrease) in cash and equivalents	5,980	(1,006)	17,915	(16,001)	(10,992)	(1,953)
Currency translation differences and other	0	0	0	0	0	0
Cash and equivalents at beginning of period	9,355	15,335	14,329	32,244	16,243	5,252
Cash and equivalents at end of period	15,335	14,329	32,244	16,243	5,252	3,299
Net (debt) cash	(19,054)	(22,535)	(8,909)	16,243	5,252	3,299

Source: Oxford Biomedica, Edison Investment Research

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