EDISON

Oxford BioMedica

Post FY16 results

CTL019 and product out-licensing to drive 2017

Pharma & biotech

We expect Oxford BioMedica's (OXB's) strategic vision to come to further fruition through 2017/18 with both the potential approval of Novartis's CTL019 in the US by year end and the possible spin-out/out-licensing of its priority development pipeline assets (OXB-102, OXB-202, and OXB-302). Full year 2016 results revealed robust growth in partnering revenues and 2017 will benefit from lower R&D expenses; we forecast a narrowing of EBITDA loss for the year. The net £17.5m equity fundraising and the Oberland debt facility has extended the current cash runway to 2019, aided by the reduction in near-term R&D; further funding and value may arise from additional manufacturing or IP licensing deals. Our revised valuation for OXB is £208.5m (6.75p/share).

Year end	Revenue (£m)	PBT* (£m)	EPS* (p)	DPS (p)	P/E (x)	Yield (%)
12/15	15.9	(16.6)	(0.49)	0.0	N/A	N/A
12/16	27.8	(20.0)	(0.59)	0.0	N/A	N/A
12/17e	39.0	(7.5)	(0.11)	0.0	N/A	N/A
12/18e	41.3	(2.8)	0.04	0.0	N/A	N/A

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

CTL019 next steps: Potential for US launch in 2017

The global registration trial (ELIANA) of CTL019 in paediatric r/r B-cell acute lymphoblastic leukaemia (B-ALL) demonstrated overwhelming efficacy; 82% of patients treated achieved a complete remission or complete remission with incomplete blood count recovery. FDA have accepted Novartis' Biologics License Application (BLA) and granted priority review for CTL019. We assume launch in 2017 (US) and Europe (2018) to directly benefit OXB, given its lentiviral technology remains vital to the manufacture of CTL019. We currently assume that a substantial portion of the $76m receivable from Novartis under the October 2014 contract has been delivered by mid-2017.

Priority assets: Spin-out to optimise returns

In order to balance risk and maximise reward OXB continues to focus on the priority assets in its portfolio, notably OXB-102 (Parkinson's disease), OXB-202 (corneal graft rejection) and OXB-302 (multiple solid cancer indications). The near-term goal is to crystallise value from the internally developed product pipeline either by out-licensing or by securing externally-funded spin-outs.

Valuation: Manufacturing and pipeline at £208.5m

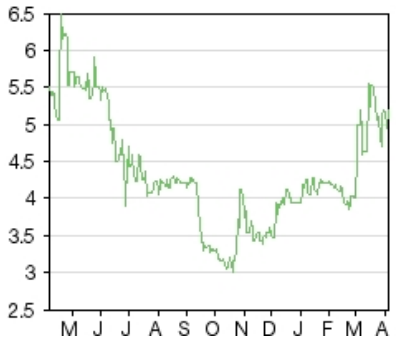
Our revised valuation of £208.5m (previously £173m) or 6.75p/share has mainly benefited from rolling forward our DCF. Our rNPV model consists of the clinical-stage pipeline, coupled with a DCF value for OXB's manufacturing and IP income net of corporate costs and 2016 net debt of £19.1m. In the near term, the valuation is underpinned by manufacturing deals; longer term, the upside potential is dependent on the performance of CTL019 and the revenues OXB receives from the use of its lentiviral vectors.

5 April 2017

Price	**5.20p**
Market cap	**£161m**

Net debt (£m) at end December 2016	19.1
Shares in issue	3,088m
Free float	83%
Code	OXB
Primary exchange	LSE
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	4.0	25.3	(4.9)
Rel (local)	4.5	22.4	(19.3)
52-week high/low		6.5p	3.0p

Business description

Oxford BioMedica has a leading position in gene-based therapy. The lenti-vector technology is wide ranging and underpins much of the development pipeline, notably OXB-102, OXB-202 and OXB-302. OXB's manufacturing expertise is gaining valuable commercial traction.

Next events

CTL019 Approval in B-ALL	Q417
CTL019 BLA in DLBCL	H2 17
Further partnership deals	2017/18
Licensing deals/spin-outs	2017/18

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Edison profile page

Balancing risk to optimise rewards

Oxford BioMedica is a leading player in gene- and cell-based medicines, with several programmes in the clinic, a proven delivery system and multiple GMP production facilities in place. OXB's commercial production of cell therapies is expected to continue to be a main source of revenue in the near term; prominently with Novartis, where OXB provides a key component (lentiviral vector) for its CD19 CAR-T (CTL019); the potential US regulatory approval for which could be by end-2017. OXB's expertise with the various aspects of developing and commercialising lentiviral products continues to be recognised, as highlighted by deals in 2016 with Orchard Therapeutics, Green Cross LabCell and Immune Design. OXB's commercial production of cell therapies is expected to continue to be a main source of revenue in the near term and should lead to further contracts.

OXB has a broad gene therapy-based pipeline including five wholly owned in-house developed assets plus two fully out-licensed products and a number of IP-enabled and royalty-bearing products. Following a strategic review in 2016, OXB announced it is seeking to out-license or spin-out priority assets (OXB-102, OXB-202, and OXB-302) in order to capture the value of its Lentiviral-based product portfolio without the associated costs. The goal of each is to be advanced to at least proof of concept in humans via out-licensing or through the formation of externally-funded special purpose vehicles (SPVs). At the FY16 results, the company announced that OXB-102 (for Parkinson's disease) and OXB-202 (for corneal graft rejection) are both ready to start phase I/II studies following out-licensing/spin-out. Preclinical proof of concept data achieved on OXB-302 (for solid tumours) means it is ready for further development following out-licensing/spin-out. Management has stated that the process to spin-out or out-license the priority product development candidates is underway and the company is optimistic of success with this in 2017. Details of OXB's pipeline can be found in our note entitled Balancing risk to optimise reward.

Furthermore, 2016 saw significant resources directed towards upgrading and extending OXB's manufacturing and technical resources; as a result, lentiviral vector production capacity has increased substantially. This expansion allows for the continued delivery of vectors to Novartis, with additional production utilised for OXB assets and the potential for further collaborative deals with new and existing partners. We forecast manufacturing income streams through to 2029. In the main, these are based on the Novartis contract being extended (assuming CTL019 is approved). The partnership with Novartis is focused around CTL019 (OXB is the sole supplier of the lentiviral vector for the CTL019 clinical study) and an undisclosed CAR-T programme is set to provide up to $76m of performance-based milestones under the October 2014 contract; we assume that a substantial portion this is delivered by mid-2017. Regulatory approval for CTL019 could see production rates of the lentiviral vector used in CTL019 increase, which we believe could add significantly to OXB's revenue stream via royalty payments.

Novartis's CTL019 at the fore in 2017

Positive results from the ELIANA trial have prompted Novartis to publically confirm its timelines for filing CTL019 in paediatric B-ALL; the FDA has accepted the BLA filing and has granted priority review, and Novartis will file with the EMA later in 2017. A priority review means FDA aims to make an approval decision on an application within six months (vs 10months under a standard review). The positive data for CTL019 mean we retain our expectations for a US launch in 2017, from which OXB will generate revenues (milestones, manufacturing and royalties) from the production of its lentiviral vectors, which are a key component of CTL019. Additionally, three-month interim data from the pivotal JULIET Phase II trial in 3rd line r/r diffuse large B-cell lymphoma (DLBCL) patients is expected shortly with primary analysis expected by the summer. Positive data in this larger

indication would enable Novartis to file it for approval in both the US and EU in Q417. Approval would generate additional significant manufacturing and royalty revenues for OXB as demand from Novartis for its lentiviruses would increase accordingly. While we expect competition in this indication from Kite Pharmaceuticals who could launch six to 12 months ahead of Novartis, we believe Novartis still has an opportunity to capture significant market share on the back of positive data from the JULIET trial. Key to this will be the long-term duration of the complete or partial responses from the competing CAR-T products; any marked difference in either product could enable Novartis or Kite to capture significant market share.

CTL019 is an investigational chimeric antigen receptor T-cell (CAR-T) therapy, which Novartis is testing across multiple Phase II trials. OXB's lentiviral technology is utilised to enable the chimeric antigen receptor expression on the T-cell. T-cells are isolated from the patient and are then modified ex vivo with lentiviral vector. The lentiviral vector encodes for the anti-CD19 chimeric antigen receptor. These chimeric antigen modified t-cells (CAR-T) are then expanded before infusion back into the patient.

Changes in the regulatory landscape both in Europe with the launch of PRIME (March 2016) and in the US with the introduction of 'breakthrough therapy designation' in 2012 allow for innovative therapeutics that demonstrate major therapeutic benefit to reach the market faster than under standard regulatory approval pathways. Recently in June, the EMA granted PRIME designation to CTL019 for the treatment of paediatric patients with ALL.

Novartis presented overwhelmingly positive clinical trial data from its global registration trial (ELIANA) of CTL019 in relapsed/refractory (r/r) paediatric and young adults with B-cell acute lymphoblastic leukaemia (B-ALL) at the 58th American Society of Hematology (ASH) annual meeting December 2016. In one of the largest CAR-T trials to date, 41 out of 50 (82%) treated patients achieved a complete remission or complete remission with incomplete blood count recovery. While a key concern for CAR-Ts in general has been duration of response, Novartis reported an impressive estimated relapse-free rate of 60% six months after the administration of treatment. Additionally, following the suspension of development of Juno's CD19 CAR-T (JCAR015) after the death of a further two patients (in addition to a previous three) due to neurotoxicity, it is positive to see that Novartis in the same indication (r/r B-ALL but in adult patients) reported no grade 4 or above neurotoxic events. In line with most CAR-Ts to date, 48% of patient's experienced grade 3 or 4 cytokine release syndrome. Novartis reported no patient deaths relating to treatment.

The partnership with Novartis focused around CTL019 and an undisclosed CAR-T programme provided up to $76m of performance-based milestones ($14m of the $90m deal signed in 2014 was received upfront) the substantial proportion of which will be received by mid-2017. OXB's lentiviral vector is a key component of CTL019 and a regulatory approval in the first indication (paediatric r/r B-ALL) for it could see a dramatic uplift in lentiviral vectors needed. We believe this could add significantly to OXB's revenue stream as an increase in demand from Novartis feeds through. Novartis is at present dependent on OXB for vector supply, which is a critical part of the CTL019 manufacturing process. Additionally, we expect royalties from the sale of CTL019 to become substantial as sales progress. We estimate that Novartis will launch CTL019 for DLBCL and paediatric ALL in 2017, with combined royalties expected in 2017 of £978k and peak combined royalties in 2023 of £12.4m. We assume Novartis can capture 20% of the refractory DLBCL market and 30% of the refractory paediatric ALL market with an average £150k price. We point out that our pricing assumptions may be conservative due to the substantial costs required in delivering these personalised medicines. We believe increased competition from Kite in DLBCL will impact market share dynamics; however, it is lagging behind Novartis on plans to launch in paediatric ALL. We assume OXB receives royalty on sales of 1% on both indications.

Pipeline update

An internal review in April 2016 led to the prioritisation of three internally developed pipeline assets: OXB-102 (Parkinson's disease – Phase I/II), OXB-202 (corneal graft rejection – Phase I/II) and OXB-302 (cancer, multiple types – preclinical), which could deliver the best potential economic returns. The goal for each is to be advanced to at least proof of concept in humans via out-licensing or through the formation of externally-funded SPVs. OXB will look to obtain value through upfront payments, equity stakes or developmental milestones and from royalty on sales.

Product candidates that fall outside the priority programme (OXB-201 for wet age related macular degeneration and OXB-301 for multiple cancers) will only be progressed once suitable opportunities, like partnering, enable reduced investment from OXB.

The group will continue to invest in earlier-stage gene and cell therapy concepts (eg in ocular, CNS and respiratory indication) with the aim of identifying new candidates for further development via out-licensing or spin-outs.

We note that SAR422459 (licensed to Sanofi) for Stargardt disease has progressed into Phase II development.

Valuation

Our sum-of-the-parts valuation consists of an rNPV model of the R&D pipeline, coupled with a simple DCF valuation of the projected manufacturing revenues and our forecast licence income and IP royalties and milestones (Exhibit 1). Our revised valuation of £208.5m (previously £173m) or 6.75p/share has mainly benefited from rolling forward our DCF. Our valuation is based on a number of assumptions, which are highlighted in the table below. We have applied a top-down analysis of the Parkinson's disease and corneal graft rejection markets, which form the basis of our sales projections for clinical stage, priority assets OXB-102 and OXB-202, respectively.

Exhibit 1: OXB sum-of-the-parts valuation

Product(s)	Indication	Partner	Status	Probability of success (%)	Estimated launch year	Estimated maximum royalty or margin (%)	Estimated peak sales ($m)	NPV (£m)	rNPV (£m)	rNPV/ share (p)
OXB-102	Parkinson's disease		Phase I/II	20%	2024	15%	$1,048.1	133.9	26.8	0.87
OXB-202	Corneal graft rejection		Phase I/II	20%	2026	15%	$381.3	37.6	7.5	0.24
OXB-201	Wet AMD		Phase I/II	20%	2026	15%	$337.5	49.9	10.0	0.32
OXB-301	Cancer (multiple)		Phase I/II	20%	2024	15%	$360.0	31.7	6.3	0.21
SAR422459 (StarGen)	Stargardt disease	Sanofi	Phase II	25%	2021	7%	$337.5	33.0	8.2	0.27
SAR421869 (UshStat)	Usher syndrome type 1B	Sanofi	Phase I/II	20%	2023	7%	$45.0	4.2	0.8	0.03
Manufacturing (including CTL-019)		Various		100%		40% operating margin	$81.9	123.9	123.9	4.01
Licence income & IP milestones		Various		100%		100% operating margin		44.0	44.0	1.42
Less net debt at December 2016								-19.1	-19.1	-0.62
Total								**439.2**	**208.5**	**6.75**

Source: Edison Investment Research. Note: *Sanofi has fully licensed these products – we estimate a 7% royalty rate on forecast product sales. rNPV = risk-adjusted NPV.

Our DCF model for the manufacturing income streams forecasts the lentiviral production revenues (OXB solution) through to 2029. We separately model milestone and licence income to reflect the value of Novartis CTL019 (potential incoming royalty stream from CTL019 should the Novartis contract be extended; assuming CTL019 is approved) and other deals eg Immune Design and Green Cross LabCell. These are summed and discounted at 10%, in line with other revenue

generating units under Edison coverage. We estimate that Novartis will launch CTL019 for DLBCL and paediatric ALL late 2017 to mid-2018, with combined royalties expected in 2017 of £978k and peak combined royalties in 2023 of £12.4m. We assume OXB will be due a 1% royalty on sales for both indications. Further information on our valuation methodology can be found in our recently published outlook note.

Financials

OXB reported FY16 gross income (the aggregate of revenues and other operating income) of £30.8m, an increase of 64% from £18.8m in FY15, driven by higher bioprocessing and process development income (£24.0m in FY16 vs £12.4m in FY15). This was due mainly to process development activities for Novartis (CTL019), but with a smaller contribution from new partnerships (Immune Design and Orchard Therapeutics). OXB has been manufacturing CTL019 at the new clean room facility at Yarnton from the start of the year in addition to ongoing manufacturing at Harrow House. R&D collaboration revenues (licenses, milestone, and grant income) increased slightly to £6.8m FY16 (£6.4m in FY15) related to higher process development fees and milestones from Novartis and the receipt of the upfront payment related to the Immune Design deal announced in March 2016. From 2017 we expect US approval and launch of CTL019 to aid gross income growth as OXB benefits from growth in bioprocessing and process development income in addition to receiving royalties on CTL019 sales. FY18 gross income should benefit from CTL019 launch in Europe. We forecast gross income of £40.0m in FY17 and £42.3m in FY18, compromised of £39.0m in revenues in 2017 and £41.3m in 2018. We forecast other operating income in both years to be flat at £1m. Gross income growth will also be aided by the new partnership agreements signed in 2016 (Immune Design, Orchard Therapeutics, and Green Cross LabCell).

R&D and bioprocessing costs increased to £24.3m FY16 (£20.3m in FY15); however, from 2017 we forecast a significant reduction reflecting the near-term strategy to out-license or spin-out the product portfolio (£21.5m in 2017 and £18.5m in 2018). We forecast profitability at the EBITDA level in 2017 of £1.2m and £5.8m in 2018 driven by the increase in bioprocessing and partner income, improvement in gross margin and the reduction of R&D expenses. Given the high levels of depreciation associated with the recent two-year manufacturing expansion programme (completed in 2016) and finance costs relating to the Oberland Capital loan weighing on PBT, we forecast a normalised loss before tax of £7.5m and £2.8m in FY17 and FY18, respectively.

Finance costs increased significantly in FY16 to £9.0m related to the Oberland loan facility ($25m drawn down in May, $15m in September 2015). From FY17 onwards, we expect cash burn to reduce significantly reflecting the reduction in capital requirements associated with plant expansion and R&D. The significant reduction in cash burn coupled with the move towards profitability in FY18 means the 2016 equity raise of £17.5m net should ensure sufficient cash to FY19.

Note that in May 2015 Oxford BioMedica secured a $50m loan facility from Oberland Capital as non-dilutive funding to progress its manufacturing expansion. The loan has to be repaid by 1 May 2022, but may be paid at any time (an undisclosed fee is payable upon any repayment). Interest is payable quarterly at an annual rate of 9.5% plus the greater of 1% or three-month Libor. A further 0.35% of net revenues is payable for eight years starting on 1 April 2017 for each $5m drawn down over $30m (this may be closed at any time but an undisclosed exit fee is payable). An initial $25m was drawn down immediately to fund the production expansion required for the Novartis contract and a further $15m was drawn down in September 2015. The remainder is available in tranches of a minimum of $5m prior to 31 December 2016. Due to the restrictive nature of the Oberland facility it can only be utilised for manufacturing expansion. The group is required under the Oberland facility to maintain cash and cash equivalents of not less than $10m while the Oberland loan is outstanding. The loan facility is secured on the group's assets.

Exhibit 2: Financial summary

£'000s	2015	2016	2017e	2018e	2019e
Year end 31 December	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue	15,909	27,776	39,000	41,250	45,840
Cost of Sales	(5,839)	(11,835)	(15,240)	(15,240)	(16,709)
Gross Profit	10,070	15,941	23,760	26,010	29,131
R&D	(20,274)	(24,299)	(21,500)	(18,500)	(17,000)
Other operating income	2,862	3,002	1,000	1,000	1,000
EBITDA	(12,456)	(7,638)	1,230	5,831	10,101
Depreciation	(1,264)	(3,340)	(3,719)	(3,365)	(3,056)
Operating profit (before GW and except)	(13,720)	(10,978)	(2,489)	2,467	7,045
Amortisation	(363)	(335)	(268)	(214)	(171)
Exceptionals	0	0	0	0	0
Operating profit	(14,083)	(11,313)	(2,757)	2,253	6,874
Net Interest	(2,899)	(8,994)	(5,011)	(5,231)	(5,461)
Other	0	0	0	0	0
Profit Before Tax (norm)	(16,619)	(19,972)	(7,500)	(2,764)	1,584
Profit Before Tax (reported)	(16,982)	(20,307)	(7,767)	(2,978)	1,413
Tax	3,963	3,666	4,000	4,000	4,000
Profit After Tax (norm)	(12,656)	(16,306)	(3,500)	1,236	5,584
Profit After Tax (reported)	(13,019)	(16,641)	(3,767)	1,022	5,413
Average Number of Shares Outstanding (m)	2,574	2,778	3,087	3,087	3,087
EPS - normalised (p)	(0.49)	(0.59)	(0.11)	0.04	0.18
EPS - reported (p)	(0.51)	(0.60)	(0.12)	0.03	0.18
Dividend per share (p)	0.00	0.00	0.00	0.00	0.00
Gross Margin (%)	63.3%	57.4%	60.9%	63.1%	63.5%
EBITDA Margin (%)	(78.3%)	(27.5%)	3.2%	14.1%	22.0%
Operating Margin (before GW and except) (%)	(86.2%)	(39.5%)	(6.4%)	6.0%	15.4%
BALANCE SHEET					
Fixed Assets	26,139	29,501	26,514	23,936	21,709
Intangible Assets	0	657	657	657	657
Intangible Assets	1,743	1,330	1,062	849	678
Tangible Assets	24,396	27,514	24,795	22,430	20,374
Current Assets	25,712	27,441	32,604	36,734	45,778
Stocks	2,706	2,202	2,836	2,836	3,109
Debtors	10,930	6,904	8,877	9,432	10,563
Cash	9,355	15,335	17,558	21,133	28,772
Other	2,721	3,000	3,334	3,334	3,334
Current Liabilities	(13,169)	(9,316)	(13,751)	(12,708)	(12,469)
Creditors	(9,286)	(6,003)	(10,438)	(9,395)	(9,156)
Provisions	(838)	0	0	0	0
Deferred income	(3,045)	(3,313)	(3,313)	(3,313)	(3,313)
Long Term Liabilities	(27,788)	(35,011)	(36,519)	(38,092)	(39,735)
Long term borrowings	(27,255)	(34,389)	(35,897)	(37,470)	(39,113)
Other long term liabilities	(533)	(622)	(622)	(622)	(622)
Net Assets	10,894	12,615	8,848	9,870	15,283
CASH FLOW					
Operating Cash Flow	(14,871)	(5,979)	3,060	4,233	8,457
Net Interest	(1,494)	(3,258)	(3,518)	(3,672)	(3,833)
Tax	3,247	4,131	3,666	4,000	4,000
Capex	(16,716)	(6,458)	(1,000)	(1,000)	(1,000)
Acquisitions/disposals	0	0	0	0	0
Financing	144	17,497	0	0	0
Dividends	0	0	0	0	0
Other	38	47	15	15	15
Net Cash Flow	(29,652)	5,980	2,223	3,575	7,639
Opening net debt/(cash)	(13,195)	17,900	19,054	18,339	16,337
HP finance leases initiated	0	0	0	0	0
Other	(1,443)	(7,134)	(1,508)	(1,574)	(1,643)
Closing net debt/(cash)	17,900	19,054	18,339	16,337	10,341

Source: Edison Investment Research, Oxford Biomedica

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