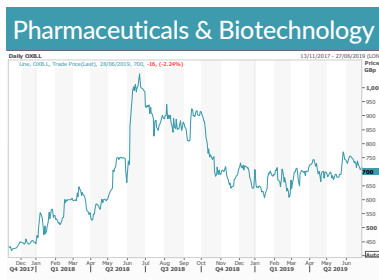




1 July 2019



Source: Refinitiv

Market data

EPIC/TKR	OXB
Price (p)	716
12m High (p)	1,029
12m Low (p)	581
Shares (m)	76.7
Mkt Cap (£m)	549.4
EV (£m)	503.9
Free Float	59.3%
Market	LSE

Description

OXB is a UK-based biopharmaceutical company specialising in cell and gene therapies developed using the LentiVector platform, technology for creation of gene-delivery vehicles based on viruses. In addition to vector development and manufacture, OXB has a pipeline of therapeutic candidates and undertakes innovative pre-clinical R&D in gene-medicine.

Company information

CEO	John Dawson
CFO	Stuart Paynter
Chairman	Lorenzo Tallarigo
	+44 1865 783 000
	www.oxfordbiomedica.co.uk

Key shareholders

Directors	0.3%
Vulpes	15.2%
M&G	15.1%
Novo Holdings A/S	10.1%
Canaccord Genuity	5.2%
Hargreaves Lansdown	4.7%
Oaktree	3.5%
Aviva	3.5%

Diary

Sep'19 est.	Interim results
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OXFORD BIOMEDICA**Eying up long-term value**

Oxford BioMedica (OXB) is a specialist, advanced therapy, viral-vector biopharma company. It offers vector manufacturing and development services, while developing proprietary drug candidates, with its LentiVector® platform. 2018 saw significant growth in gross income, the majority through licensing deals. A new R&D collaboration deal with Santen, coupled with the recent equity financing and debt repayment, demonstrate OXB's deal-making ability and its strategy to secure future, long-term potential. Near term, this R&D arrangement will provide modest additional profit, adding confidence to OXB's new net cash status in 2019.

- **Strategy:** OXB has four strategic objectives: i) delivery of vector development services that embed its technology within partners' commercial products; ii) bioprocessing and commercial manufacture of vector; iii) out-licensing of proprietary candidates; and iv) investment in R&D and the LentiVector platform.
- **New R&D deal:** Santen Pharmaceutical Co. (Santen) and OXB have agreed to collaborate in developing a gene therapy for an inherited retinal disease. The financial details have not been disclosed, although the potential royalty is high at up to 10%. Commercial development income will increase in the short term.
- **Equity investment:** OXB recently signed an agreement with Novo Holdings A/S for an equity investment of £53.5m, at £6.90/share, representing 10.1% of OXB's enlarged share capital. This greatly strengthens the balance sheet, with OXB repaying in full its debt facility with Oaktree Capital on 28 June 2019.
- **Risks:** OXB's mid-term sales model is dependent on successful progress of partners' clinical trials and commercialisation of LentiVector-enabled products. OXB is investing heavily in infrastructure for manufacturing capacity and in personnel, which could potentially affect the bottom line depending on deal flow.
- **Investment summary:** OXB is an exciting company with market-leading technology. It has been extensively validated through large deals with leading (bio)pharmaceutical partners and through grants from the UK government. On expectations of further milestones in 2019, OXB is now profitable, net cash positive and cashflow positive at the operating level.

Financial summary and valuation

Year-end Dec (£m)	2016	2017	2018	2019E	2020E	2021E
Gross revenue	30.78	39.36	67.84	83.47	104.60	123.04
EBITDA	-6.78	-2.63	13.54	14.63	18.53	30.40
Underlying EBIT	-10.45	-7.00	9.18	9.84	13.27	25.16
Reported EBIT	-11.32	-7.97	7.93	8.50	11.82	23.62
Underlying PBT	-15.34	-16.38	4.57	7.67	13.66	25.71
Statutory PBT	-20.31	-11.76	5.01	5.93	12.21	24.16
Underlying EPS (p)	-21.00	-21.99	10.88	13.68	24.35	43.08
Statutory EPS (p)	-29.95	-14.56	11.57	11.27	22.17	40.75
Net (debt)/cash	-19.05	-22.54	-8.91	34.80	43.82	64.93
Capital increase	17.50	0.39	19.81	52.43	0.10	0.10
P/E (x)	-	-	65.80	52.36	29.40	16.62
EV/sales (x)	-	-	-	9.31	6.40	5.61

Source: Hardman & Co Life Sciences Research

Long-term value in retinal disease

R&D collaboration with Santen Pharmaceutical Co

The market has been awaiting a deal in accordance with OXB's stated objective to close one out-licensing deal, three platform technology deals, and to start two feasibility studies, in 2019 (source: 2018 Annual Report). Five days prior to the interim period-end, an R&D collaboration with licence option has been secured with the specialist Japanese ophthalmology company, Santen Pharmaceutical Co. Ltd ('Santen'; TYO:4536; market cap ¥704.9bn/£5bn). This arrangement falls into both the 'platform technology' and 'the feasibility study' categories, implying that management is aiming for another three deals in 2019.

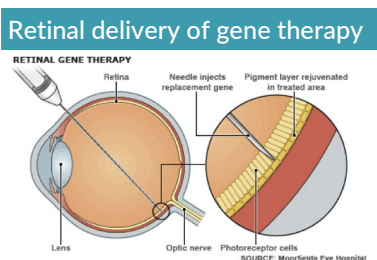
- ▶ **Programme:** An R&D partnership towards development of gene-therapy products for the treatment of an inherited retinal disease.
- ▶ **Lentiviral vectors:** OXB will undertake research and development work to develop vectors for the programme.
- ▶ **Santen option:** Santen has the option of a licence to OXB's LentiVector platform, on which OXB would receive an undisclosed milestone payment.
- ▶ **Milestones:** OXB is entitled to receive further development milestones if Santen exercises its option.
- ▶ **Royalty:** In the long term, OXB would receive royalty payments of up to 10% on net sales of any commercialised products if Santen exercises its option.
- ▶ **Commercial rights:** Santen has the worldwide rights to the programme.
- ▶ **OXB option:** OXB has an option to co-fund and participate in development and commercialisation in the US and Europe.

Positive and with expansion potential

The partnership will be focused on one inherited retinal disease. Its initial aim is research towards generating pre-clinical proof-of-concept data supporting progression towards development of a therapeutic vector. If successful, OXB would then undertake product development and manufacturing work. The arrangement is very positive, lending OXB the following:

- ▶ **Validation:** An R&D partnership with a well-known, global pharmaceuticals company, which specialises in retinal disorders.
- ▶ **Long-term potential:** The potential to secure long-term value, with the option to participate in commercialising a therapeutic product in the US and Europe while sharing the clinical risk.
- ▶ **Geographical reach:** OXB's first programme to involve a partner in Asia, the global operations of which could increase potential sales volumes (necessary for a rare disease treatment).
- ▶ **Expansion potential:** Given that Santen is the market leader in ophthalmic pharmaceuticals in Japan, the expertise and relationship is in place to expand into additional retinal disorders caused by mutations in different genes in the future.

Due to the specific advantages of lentiviral vectors in certain applications, OXB's particular therapeutic areas of interest include retinal and CNS disorders. As such, this programme has also some synergy with its other programmes, with OXB having four proprietary therapeutic candidates for retinal diseases, in addition to its two assets that are out-licensed to Sanofi. (Note: there has not been any update on Sanofi's



Source: Moorfields Eye Hospital & Al-Saikhan F¹

¹ Fahad I. Al-Saikhan, Pharm. D, The gene therapy revolution in ophthalmology (2013)27(2) Saudi Journal of Ophthalmology

position with respect to these assets, with the latest news being that Sanofi would be seeking a partner for progression.) OXB has demonstrable experience in pre-clinical and clinical development of viral vectors that target retinal cells, as well as in manufacturing retinal vector batches for clinical trials.

Value impact

High risk, high long-term value

It is clear from the information provided that the value created by the partnership is subject to the full spectrum of clinical and commercial risk, due to its very early stage, but that this value could potentially be high. The magnitude is difficult to estimate without knowing the financial terms of the deal or which disease is being targeted, and due to the speed of innovation in the area. The time needed to realise this value is also difficult to estimate, although gene therapies for rare diseases can progress faster than the average biopharmaceutical (if they are awarded breakthrough designation, for example). Some precedent in the area has been set by inherited retinal gene therapies such as Luxturna® (Novartis), the first approved *in vivo* gene therapy, which has overcome many of their commonly touted commercial hurdles (delivery, being one).

Given that much of the clinical and commercial risk will be borne by Santen, this feels like a very positive arrangement with mutual benefits for both parties. In terms of the initial research work, OXB is guaranteed to make a margin, being set to lose only the milestone if Santen does not exercise its option. In the highly unlikely event that Santen does not exercise its option, OXB will not have lost any realised investment. Moreover, if commercialisation is successfully achieved, the company will not only receive a relatively high royalty (up to 10%) on net sales, but will also have the opportunity to participate in development and commercialisation of a therapeutic product in the main markets for these kinds of therapies, the US and Europe.

Near-term value

No speculation is being made on the financials of the deal; however, given that OXB's commercial development work for partners is usually carried out at 50%-55% margin, this arrangement should contribute to gross profits in the near term. In our opinion, there is unlikely to have been any upfront payment received, or it is likely to have been relatively small; OXB is more likely to be rewarded when the option is exercised after a successful first research stage.

Mutually beneficial

Santen will be able to leverage OXB's experience in gene therapies for retinal applications and the capabilities of the LentiVector platform, which has particular advantages in being able to deliver bigger replacement genes than other viral vectors and in localised delivery of replacement genes to non-dividing cells such as those of the retina. Importantly, OXB is invaluable as a partner in being able to offer commercial quality vector manufacture.

Conclusion

Overall, while very early stage, this R&D collaboration and option and licence agreement is positive news from OXB. In addition to the advantages described, there could be potential for the programme to be expanded into new indications in the future and for OXB to be involved in the commercialisation of a therapy in the US and Europe, which would be its first, without having to bear the full load of clinical risk. Retinal diseases will perhaps become one of the more competitive gene-therapy markets, with many currently in development. Nevertheless, having the expertise of a specialist ophthalmology company with global sales is a real advantage and should help drive market share if development is successful and approval is secured.

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