EDISON

Oxford Biomedica

Corporate update

Juno deal expands CAR-T revenue streams

Pharma & biotech

Following the 2017 commercial launch of partner Novartis's Kymriah (a CD19-targeting CAR-T that is approved for pALL and DLBCL), Oxford Biomedica (OXB) is the only FDA-approved lentiviral vector manufacturer worldwide. Validation of its capabilities continues with the recent licence and clinical supply agreement (LSA) with Juno Therapeutics (part of BMS group), a pioneer in cell and gene therapy research. The LSA 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. As these assets move towards approval, commercial manufacturing supply provides further upside. Our valuation of OXB increases to £718m.

Year end	Revenue (£m)	PBT* (£m)	EPS* (p)	DPS (p)	P/E (x)	Yield (%)
12/17	37.6	(13.1)	(16.7)	0.0	N/A	N/A
12/18	66.8	0.3	4.3	0.0	130.2	N/A
12/19e	65.4	(15.0)	(17.3)	0.0	N/A	N/A
12/20e	85.3	6.7	5.0	0.0	112.0	N/A

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

Juno tie up is a big deal

In the field of cell and gene therapy, Kite (Gilead), bluebird bio, Novartis, and Juno are pioneers. OXB has a long-standing collaboration with Novartis, on Kymriah and five additional programmes. With the Juno deal, OXB has added yet another major cell therapy player to its list of established customers. The deal covers four products (targets are undisclosed by OXB) and based on Juno's disclosed clinical pipeline, we assume the deal 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 plus an undisclosed royalty on net sales on products using its LentiVector platform.

OXB joins COVID-19 vaccine consortium

OXB has announced it 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 expected to start clinical phase testing shortly. This vaccine relies on adenoviral vector technology, but OXB can leverage on its LVV expertise to provide adenoviral vectors. OXB can provide the technical expertise for mass-scale production (via its OxBox manufacturing facility) if the initial vaccine development work proves positive.

Valuation: £718m (£9.33 per share)

Our valuation has increased to £718m (£9.33 per share) from £692m (£9.02 per share). We have included JCAR018 (pALL, NHL) as an illustrative example only under the Juno deal, we have removed OXB-202 (discontinued in corneal graft rejection) and OXB-201, reflecting OXB-203 in wet AMD (preclinical) instead. We reflect net cash of £16m at end December 2019.

8 April 2020

Price	**560p**
Market cap	**£431m**
	$:£0.82; €:£0.91; $:€0.91
Net cash (£m) at 31 December 2019	16
Shares in issue	76.9m
Free float	69%
Code	OXB
Primary exchange	LSE
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(4.6)	(16.4)	(24.4)
Rel (local)	9.4	12	(2.1)
52-week high/low		771p	400p

Business description

Oxford Biomedica's (OXB's) 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

Preliminary FY19 results	23 April
OTL-101 BLA/MAA rolling submission	H120

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Edison profile page

Juno deal strike two for OxBox investment

Over the last few years the global cell and gene therapy market has expanded rapidly as evidenced by the first approvals for both ex vivo (chimeric antigen receptor T-cells [CAR-Ts] Kymriah and Yescarta) and in vivo (Strimvelis for ADA-SCID and Luxturna for RPE65 inherited retinal disease) gene therapy products. OXB is a pioneer and global leader in the development and manufacture of commercial-scale lentiviral vectors (LVV), a critical component of cell and gene therapies. OXB's expertise in lentiviral development means it continues to remain extremely attractive to future and existing partners. By end 2020 OXB's commercial LVV production capacity will have increased via its investment in OxBox, an 84,000 sq ft state-of-the-art bioprocessing manufacturing facility. Extension of the Novartis (NOVN) commercial supply agreement (in December 2019) validated OXB's foresight to invest for growth as vector manufacturing capacity remains constrained globally. Under the recently announced LSA, Juno Therapeutics will have access to manufacturing capacity at OxBox on the four undisclosed active projects but will also be able to initiate additional projects in the future.

Juno Therapeutics: A pioneer in CAR-T and TCR-T research

US-based Juno Therapeutics is one of the main pioneers in CAR-T development (alongside NOVN, and Kite/GILD. Juno has been developing a broad pipeline of CAR-T and T-cell receptor T-cell (TCR-T) programmes in oncology and other indications spanning preclinical, clinical trials and a biologics license application (BLA) filing for its most advanced asset (JCAR017). Recognising its unique and broad pipeline in cell and gene therapy, Celgene acquired Juno in 2018 for $9bn. The hunter became the hunted in 2019 as Bristol-Myers Squibb (BMS) acquired Celgene for $74bn. Juno is now nestled within the BMS group, and the rationale for the BMS-Celgene acquisition was to leverage on differing competencies in the immuno-oncology space (potential for combination approaches with check point inhibitors, eg Opdivo, with CAR-T cell therapies). We highlight that prior to the OXB-Juno deal announcement, OXB will have been active on development and validation work for Juno's potential programmes and OXB will have received process development revenue). As such, the Juno/Celgene/BMS acquisition may have delayed deal timings.

Multiple value streams to the Juno deal which could grow further

Under the terms of the recently announced deal, OXB will receive an upfront payment of $10m in cash. OXB is eligible for up to $86m upon achievement of certain development and regulatory milestones spread across four undisclosed assets (we assume that these are focused on CAR-T or TCR-T assets in preclinical and clinical development and may include one of the CD22, WT1, L1CAM and MUC16 programmes) over multiple potential indications (discussed below). In addition, OXB is eligible to receive up to $131m in sales-related milestones plus an undisclosed royalty on the net sales of products sold by Juno utilising OXB's LentiVector platform. OXB is working on four assets covering multiple indications (see below), this is a non-exclusive deal, thus OXB can supply LVV for these targets to others; in context, the licence with NOVN gives exclusivity to CD19.

We expect multiple revenue streams from the deal to include bioprocessing (the sale of vector batches) revenues and development milestones in addition to payments from process development and scale-up projects. If Juno's pipeline progresses towards regulatory approvals and launch, then we expect this mix to alter as the royalty stream builds. This is an initial deal with Juno and as these assets progress towards commercial viability, we would expect additional deals to cover commercial manufacturing supply. However, our caveat remains that much of Juno's pipeline is at the proof-of-concept stage. In terms of deals we illustrate how the original NOVN deal signed in October 2014 was a process and manufacturing deal (for CTL019) consisting of $90m over three

years ($14m upfront including a $4.3m equity subscription, $76m in milestones over three years and undisclosed royalties). In June 2017 as CTL019 (Kymriah) moved towards commercialisation NOVN signed a new commercial supply agreement for CTL019 which included $10m upfront and in excess of $90m in additional revenue over the next three years. Kymriah received FDA approval for paediatric acute lymphoblastic leukaemia (pALL) in August 2017 and diffuse large B-cell lymphoma (DLBCL) in May 2018. OXB is the only supplier to NOVN and, as its technology and manufacturing process was involved in the regulatory application of Kymriah, we believe it is extremely unlikely that NOVN will switch. If OXB's LVV technology forms the basis of regulatory filings for Juno's assets this will likely apply to Juno.

Juno deal: Four assets spanning multiple indications

The OXB-Juno deal covers four CAR-T and TCR-T candidates. The targets are undisclosed by OXB. Currently approved CAR-T therapies, Kymriah (NOVN) and Yescarta (Kite/GILD), target the CD19 antigen and are focused on the lymphoid haematological segment, mainly ALL and DLBCL. We note that under a previous agreement, OXB granted exclusivity for CD19-related manufacturing to NOVN; Juno's pipeline contains three CD19-targeting CAR-T assets (JCAR017, JCAR014 and JCARH125) that we assume are not included in the LSA with OXB.

CAR-Ts are individual treatments that are personalised to a patient (autologous) by the removal and isolation of their T-cells (leukapheresis) and the modification of these cells to express the relevant chimeric antigen receptors (CARs). This is followed by incubation with a viral vector (such as OXB's LVV), expansion of these cells and then reinfusion into the patient. The combination of a cancer-recognising element with the cell-killing ability of T-cells makes for an effective therapeutic combination. OXB's lentiviral technology is used to insert genetic material into a patient's isolated T-cells, which enables the cell to make and present cancer-targeting receptors (CARs). However, while many companies have adequate R&D facilities, OXB is one of a few globally that can manufacture LVVs on the commercial scale needed for use in these therapies.

The holy grail in CAR-T therapy is targeting solid cancers, an elusive area but a potentially huge market for a successful CAR-T. To be effective with low side effects requires the identification of a cell surface protein that is overexpressed in malignant tumours and not healthy cells. This is a very rare set of attributes that have only been validated for haematological cancers with CD19, and more recently CD22, though not yet for solid tumours. TCR-T therapies target peptide fragments expressed on the cell's surface that can be from proteins expressed either inside the cell or on the cell's surface. This potentially allows TCR-Ts to successfully target a broader range of tumours, including solid cancers.

Further challenges posed to CAR-T therapies by solid cancers include finding, infiltrating and surviving the tumour microenvironment. Many solid cancers have seen minimal progress in patient survival rates for decades, with old and ineffective therapies still being used extensively.

Juno's pipeline covers several antigens and a range of haematological and solid cancers. The assets covered are undisclosed under the terms of the deal, and are likely to be a mixture of preclinical and early clinical-stage assets. For illustrative purposes we discuss JCAR018 in detail and include it in our valuation to contextualise the impact. Exhibit 1 highlights the clinical-stage assets presented on the Juno website; preclinical assets are not listed. We have not included CD19-targeting therapies given the exclusivity to CD19 that OXB has under its deal terms with Novartis.

JCAR018 (CAR-T) Phase I in pALL & NHL

CD22, much like antigen target CD19, is widely expressed on B lymphocytes and is expressed by the majority of B-cell malignancies including ALL, chronic lymphocytic leukaemia (CLL) and non-Hodgkin lymphoma (NHL). CD19 expression still remains more common in these cancers, however

we note that 60–90% of B-cell malignancies express CD22 and when expressed, CD22 is expressed throughout a tumour. Importantly, like CD19, CD22 is not known to be expressed on any other healthy tissue, or more specifically, hematopoietic stem cells.

In the relapse and refractory setting, the uptake of CD19-targeting therapies has led to the emergence of CD19-negative cancer cells, with significantly reduced levels of CD19 expression, in some patients. These cells retain CD22 expression and therefore a CD22-targeting CAR-T could be an important potential treatment. There is also an opportunity for combination therapies that target both CD19/CD20 to provide enhanced efficacy and duration of response.

JCAR018 is being evaluated in a Phase I study in paediatric and young adult patients with relapse/refractory ALL (NCT02315612). In August 2019, JCAR018 was granted breakthrough therapy designation by the FDA for this indication based on preliminary data from the study. The five-year survival rate for paediatrics with ALL has greatly increased over recent years, with only 15% of patients relapsing after treatment. This is largely due to advances in the treatment armament which include CD19 CAR-T's (Kymriah and Yescarta), Blincyto (CD19 BiTE) and Besponsa (CD22 antibody). Future treatment modalities are likely to use combination therapies; several clinical studies are currently investigating various combinations.

JCAR018 is also being evaluated in relapse/refractory NHL in the same study (NCT02315612). First-line treatment is with R-CHOP, a combination of Rituxan (CD20 antibody) and four chemotherapy drugs (CHOP) that have been the standard of care for more than 25 years. However, treatment in the relapse/refractory setting has been revolutionised by the approval of the CD19 CAR-T therapies, Kymriah and Yescarta, although resistance is an issue for a fraction of patients; If approved, JCAR018 could offer a potential treatment for these CD19-resistant patients (18% of initial non-responders and 38% that relapse within a year of CD19 treatment).

Exhibit 1: Juno assets

Asset	Modality	Target	Indication	Clinical trial	Notes
JCAR018	CAR-T	CD22	pALL	Phase I (NCT02315612)	CD22 expressing relapsed and refractory patients under 30
			NHL	Phase I (NCT02315612)	CD22 expressing relapsed and refractory patients under 30
JTCR016	TCR-T	WT1	AML	Phase I/II (NCT01640301)	Relapsed patients after treatment with donor stem cell transplant
			NSCLC (mesothelioma)	Phase I/II (NCT02408016)	Patients with stage III–IV malignancies
JCAR023	CAR-T	L1CAM	Neuroblastoma	Phase I (NCT02311621)	Refractory and relapsed patients after conventional chemotherapy under 26
JCAR020	CAR-T	MUC16	Ovarian (solid tumours)	Phase I (NCT02498912)	Relapsed and refractory patients that have progressed after chemotherapy
JCAR024	CAR-T	ROR1	NSCLC/breast	Phase I (NCT02706392)	ROR1+ stage IV NSCLC or metastatic triple negative breast cancer patients
Undisclosed	CAR-T	LeY	Lung	Phase I (NA)	Originally developed by the Peter MacCallum Cancer Centre

Source: Company website, Edison Investment Research

Trading update: Strong H219

OXB provided an unaudited trading update on its FY19 numbers and post period end review on 18 March 2020 and expects to announce preliminary results on 23 April. Financial highlights are as follows.

- Strong H219 vs H119 as expected in terms of growth in underlying bioprocessing and commercial development business revenues. FY19 double-digit revenue growth across both despite capacity constraints. A decline of c 36% is expected in reported FY19 revenues from milestones, licenses and royalties despite the £11.5m ($15m) milestone payment from Axovant and the strongly growing royalty stream. FY18 benefited from the upfront payments related to

the Axovant and Bioverativ signings. Thus OXB expects FY19 total revenues of c £65m, representing a small decline y-o-y.

- OXB expects an operating EBITDA loss in the single-digit range in H219; we note the H119 EBITDA loss was £1.4m. We have adjusted our FY19 forecasts to assume a £2.4m EBITDA loss. We forecast profitability in 2020 at the EBITDA, operating and net income levels.
- OXB reported cash and cash equivalents of £16m at 31 December 2019. Operating cash outflow for FY19 was c £7m reflecting the continued capex on the new OxBox bioprocessing facility.
- Strengthening of the balance sheet – Novo Holdings' equity investment (£53.5m) in May has enabled OXB to fully repay its costly revolving debt facility ($55m Oaktree loan), leading to a much-improved debt-free balance sheet.
- We await the FY19 audited results; however, we have reduced our forecast revenue for FY19 by £10m to £65m and EBITDA loss to £2.4m. Our cash flow forecasts for FY19 reflect £7m cash from operations (CFO) and a net cash position of £16m at year end.
- Pipeline update: 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. 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-license of one in-house product candidate during 2020.

We have highlighted the main operational highlights achieved in FY19 in our note published in February 2020 OxBox investment to aid future growth.

We also note that long-standing chairman of the group, Dr Lorenzo Tallarigo, has announced his retirement from the OXB board. A replacement is yet to be announced.

COVID-19: Potential impact

We note that BMS has suspended many of its clinical trials. This comes as no surprise as global hospital capacity is overrun with COVID-19 patients, many of whom are in a critical condition and the majority of resources are directed towards the pandemic. While we anticipate a delay in clinical trials in the short term, we expect OXB to continue to manufacture and supply the viral vectors required for products in clinical trials for all its partners. OXB has stated 'so far, the Group has not experienced any and does not currently expect to experience significant supply issues or any changes in customer demand.' OXB has 18 programmes in development, of which 14 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 has said it has seen no change in demand from customers.

Following the Novo Holdings equity investment, OXB has a strong balance sheet to fund its operations. Furthermore, as it is approaching profitability we believe OXB is in a strong position to weather this global pandemic and related economic downturn.

Valuation

We value OXB at £718m (£9.33 per share) vs £692m (£9.02 per share) previously. The uplift stems largely from our inclusion of the Juno deal netting off the impact of the removal of OXB-202 from our valuation. Additionally, we roll our model forward and update for exchange rates and net cash of £16m at 31 December 2019. For the Juno partnership we have modelled the opportunity for JCAR018 only for illustrative purposes, given the assets are undisclosed. At present we do not

have sufficient visibility on the assets, indications and Juno's timeline for progression, but we will revisit our assumptions as we gain more visibility as time progresses. We have applied a low (20%) probability of success for JCAR018 for pALL and NHL. We have also removed OXB-201, replacing it with OXB-203 in wet AMD (preclinical) instead. The impact here is longer timelines for development given it is a preclinical asset.

In all partnerships except Sanofi, we value the royalty, milestone and bioprocessing (manufacturing) revenues; with Sanofi we only value potential future royalties and milestones. We forecast that all internal assets are out-licensed post Phase II data. We value all partnerships to 2040 and, due to an expanding and evolving long-term revenue stream, we include a terminal value (10% discount rate, 1% growth) for OXB, which contributes £2.40/share to our valuation. We forecast that OXB will receive bioprocessing manufacturing revenue from partners throughout the collaborations and not just on commercial launch. We assume our standard 12.5% discount rate for assets, with a 10.0% discount rate for manufacturing revenues. We note that pricing of gene therapies remains a key sensitivity and, as the market evolves and these dynamics change, we assume pricing of $475,000 for rare diseases and $300,000–350,000 for more common indications.

Exhibit 2: 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	2020	0	1	70%	7	5	6.25
OTL-201/Orchard/Sanf A synd/pre-clinical	2025	13	11	5%	37	6	7.72
OXB Orchard stake	N/A	N/A	N/A	N/A	10	10	12.76
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						**509**	**662.34**
Terminal value						**192**	**250.10**
Net cash						**16**	**20.81**
Total						**718**	**933.25**

Source: Edison Investment Research

Exhibit 3: Financial summary

Accounts: IFRS, year end 31 December (£000s)	2016	2017	2018	2019e	2020e
Income statement					
Total revenues	27,776	37,590	66,778	65,447	85,296
Cost of sales	(11,835)	(18,442)	(22,763)	(24,312)	(31,448)
Gross profit	15,941	19,148	44,015	41,134	53,847
Administrative expenses	(5,957)	(7,276)	(7,433)	(10,035)	(13,547)
R&D and bioprocessing costs	(24,299)	(21,611)	(29,714)	(39,925)	(47,000)
Other income/(expense)	3,002	1,774	1,064	0	0
Exceptionals and adjustments	0	2,297	5,983	(1,411)	0
Operating profit/(loss)	(11,313)	(5,668)	13,915	(10,236)	(6,700)
Finance income/(expense)	(8,994)	(6,093)	(8,901)	(6,197)	31
Reported PBT	(20,307)	(11,761)	5,014	(16,433)	(6,668)
Income tax expense (includes exceptionals)	3,666	2,744	2,527	2,653	2,786
Reported net income	(16,641)	(9,017)	7,541	(13,780)	(3,882)
Basic average number of shares (m)	56	62	65	72	77
Basic EPS (p)	(29.9)	(14.6)	11.6	(19.3)	(5.0)
Adjusted EBITDA	(6,773)	(2,645)	13,535	(1,861)	1,255
Adjusted EBIT	(10,448)	(7,020)	9,178	(8,825)	(6,700)
Adjusted PBT	(19,442)	(13,113)	277	(15,022)	(6,668)
Adjusted EPS (p)	(28.4)	(16.7)	4.3	(17.3)	(5.0)
Balance sheet					
Property, plant and equipment	27,514	25,370	31,791	51,119	58,422
Intangible assets	1,330	97	117	113	109
Other non-current assets	657	2,954	10,966	0	0
Total non-current assets	29,501	28,421	42,874	51,232	58,532
Cash and equivalents	15,335	14,329	32,244	16,588	6,280
Inventories	2,202	3,332	4,251	4,330	5,600
Trade and other receivables	6,904	17,088	30,585	22,951	25,706
Other current assets	3,000	2,232	2,446	13,619	13,752
Total current assets	27,441	36,981	69,526	57,488	51,338
Non-current loans and borrowings	34,389	36,864	41,153	0	0
Contract liabilities and deferred income	0	0	6,434	6,434	6,434
Other non-current liabilities	622	630	1,566	9,735	9,735
Total non-current liabilities	35,011	37,494	49,153	16,169	16,169
Trade and other payables	6,003	8,690	11,422	12,199	17,232
Contract liabilities and deferred income	3,313	13,072	17,084	17,084	17,084
Total current liabilities	9,316	21,762	28,506	29,283	34,316
Equity attributable to company	12,615	6,146	34,741	63,267	59,385
Cash flow statement					
Operating profit/(loss)	(11,313)	(5,668)	13,915	(10,236)	(6,700)
Depreciation and amortisation	3,675	4,375	4,357	6,964	7,955
Share based payments	865	945	1,246	0	0
Other adjustments	(579)	(1,326)	(8,012)	0	0
Movements in working capital	1,423	141	(2,292)	8,333	1,007
Income taxes paid	4,081	4,512	3,654	2,446	2,653
Cash from operations (CFO)	(1,848)	2,979	12,868	7,507	4,916
Capex	(6,458)	(1,969)	(10,148)	(26,288)	(15,255)
Other investing activities	47	38	52	83	31
Cash used in investing activities (CFIA)	(6,411)	(1,931)	(10,096)	(26,205)	(15,224)
Net proceeds from issue of shares	17,497	385	19,808	50,475	0
Movements in debt	0	8,361	0	(41,153)	0
Interest paid	(3,258)	(10,800)	(4,665)	(6,280)	0
Other financing activities	0	0	0	0	0
Cash from financing activities (CFF)	14,239	(2,054)	15,143	3,042	0
Increase/(decrease) in cash and equivalents	5,980	(1,006)	17,915	(15,656)	(10,308)
Currency translation differences and other	0	0	0	0	0
Cash and equivalents at beginning of period	9,355	15,335	14,329	32,244	16,588
Cash and equivalents at end of period	15,335	14,329	32,244	16,588	6,280
Net (debt) cash	(19,054)	(22,535)	(8,909)	16,588	6,280

Source: Oxford Biomedica, Edison Investment Research

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