

# Belluscura

## Promising portable oxygen supplement device

Belluscura is focused on developing oxygen enrichment technologies. Its lead product, X-PLO<sub>2</sub>R, is pitched as the world's first modular portable oxygen concentrator (POC). It received FDA 510(k) clearance in March 2021 and came to the market in September 2021. Early uptake is encouraging, with the company signing five distribution agreements and exceeding its sales volume projections for the year. We expect recent reimbursement approval from the US Centers for Medicare & Medicaid Services (CMS) and expansion outside the US, to be the key growth catalysts for the company. Additional product launches (X-PLO<sub>2</sub>R CX and X-PLO<sub>2</sub>R DX) planned in the next 12 months should add further momentum.

### X-PLO<sub>2</sub>R: A 'lighter' alternative

X-PLO<sub>2</sub>R is a lightweight, pulse-based POC weighing less than 1.5kg (3.25lbs) designed to provide up to 95% pure oxygen 24/7. The company asserts that the device generates more oxygen by weight than any other FDA-cleared POC in its class, and is lighter and more convenient to carry than existing devices. The market response has been positive, with five distribution agreements already signed in North America and a sales volume for FY21 ahead of management estimates. Belluscura plans to launch two new products (X-PLO<sub>2</sub>R CX and X-PLO<sub>2</sub>R DX) in 2022 (higher capacity pulse-based POCs with continuous flow oxygen features; additional 510(k) approval not required) and apply for international regulatory clearances in 2022.

### US reimbursement approval will be a key catalyst

In a positive development, the company received reimbursement approval from the CMS in November 2021. According to management, Medicare reimbursement covers c 50% of the oxygen concentrator market in the US and we see this approval as a major endorsement of the company's X-PLO<sub>2</sub>R device and a key factor in advancing volume growth in the near term.

### Market opportunity remains attractive

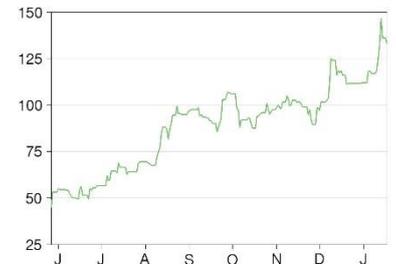
According to [Grand View Research](#), the North American oxygen concentrator market was valued at \$1.1bn in 2020 and is expected to grow at an annual rate of 10.7% from 2021 to 2028. An increasing number of chronic obstructive pulmonary disease (COPD) cases and the COVID-19 pandemic have been driving demand for respiratory products, particularly oxygen concentrators. Accounting for more than 50% of the market, POCs are expected to post the fastest growth rate in the forecast period, creating solid upside for the company. In this context, Belluscura benefits from a co-exclusive product licence and development agreement with Separation Design Group (SDG). However, we point out that if cumulative X-PLO<sub>2</sub>R sales do not reach \$20m within 48 months of launch, the company is required to make a one-off payment of \$3m (c 13% cash at end June 2021) to maintain this agreement.

## Medical devices

18 January 2022

**Price** **£1.33**  
**Market cap** **£152m**  
 US\$1.36/£

### Share price graph



### Share details

Code	BELL
Listing	AIM
Shares in issue	114m

### Business description

Founded in 2015 and incorporated in the UK, Belluscura is a portable oxygen concentrator manufacturer. Belluscura was listed on the AIM segment of the London Stock Exchange in May 2021. With operations mainly in the United States, it plans to apply for international regulatory clearance in 2022. The company received FDA 510(k) clearance for its X-PLO<sub>2</sub>R product in March 2021 and plans to launch two more products (X-PLO<sub>2</sub>R CX and X-PLO<sub>2</sub>R DX), which will be covered under the same 510(k) approval.

### Bull

- COVID-19 pandemic driving demand for oxygen concentrators.
- US CMS reimbursement approval.
- Well-funded following \$24.5m IPO.

### Bear

- Global supply chain issues.
- Competitive market.
- Difficulty and/or delays in gaining international regulatory clearances.

### Analysts

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