

# BioLargo

## Clyra gets 510(k) clearance

BioLargo announced on 23 September 2019 that it received 510(k) marketing clearance for the Clyra Wound Irrigation Solution developed by the Clyra Medical subsidiary. The product uses antimicrobial technology based on the delivery of iodine using chemistry similar to the other products developed by BioLargo. The product is designed for cleansing, irrigation and debridement of skin lesions (partial and full thickness) and burns (1st and 2nd degree). With this clearance, the company is free to market and distribute the product, with the ultimate goal of Clyra operating as an independent wound-care company.

### Bringing new technology to an established practice

Iodine has a long history in medicine and is an indispensable element of modern practice in the povidone iodine formulation (eg Betadine). However, despite its widespread use, povidone iodine is not without side effects and can cause irritation to mucous membranes and exposed tissue, and is therefore limited to topical use. The Clyra Wound Irrigation Solution instead generates small quantities of reactive iodine in situ that are too low to cause the irritation associated with other formulations (or even risk of staining), but sufficient to provide antiseptic benefit.

### Product can be sold nationwide now

The 510(k) clearance means that Clyra is free to sell the product throughout the US or license it to another party for distribution. Products cleared through the 510(k) pathway must show substantial equivalence to an already approved product and not raise any additional safety or effectiveness concerns. We find it encouraging that the FDA upon examination of the data did not foresee any of these concerns with this product, but the details of the medical claims are forthcoming. We expect it to be an attractive product addressing some of the limitations of traditional iodine.

### What's next: An independent wound-care company

BioLargo has repeatedly stated its intent to spin off Clyra as an independent wound-care company, and 510(k) clearance is the first step in that process. There is little operational overlap between Clyra and the other aspects of the business, so this strategy makes sense. Moreover, the company has sought to independently finance Clyra, as the majority (59%) is owned by outside shareholders. Clyra has sought to establish a pipeline outside of the current product and in 2018 purchased the intellectual property of the SkinDisc technology, a regenerative product for wound healing. Finally, it has proposed a series of follow-on indications for the wound-care solution, including dental and orthopedic applications.

#### Historical financials

Year end	Revenue (\$m)	PBT (\$m)	EPS (\$)	DPS (\$)	P/E (x)	Yield (%)
12/15	0.1	(5.1)	(0.06)	0.0	N/A	N/A
12/16	0.3	(8.1)	(0.09)	0.0	N/A	N/A
12/17	0.5	(9.5)	(0.10)	0.0	N/A	N/A
12/18	1.4	(10.7)	(0.09)	0.0	N/A	N/A

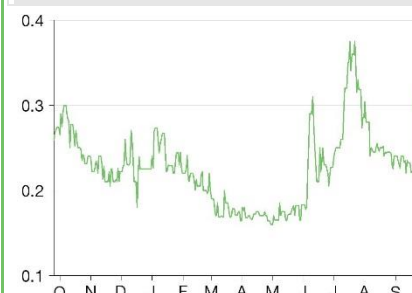
Source: BioLargo reports

#### Healthcare & industrial services

26 September 2019

**Price** \$0.30  
**Market cap** \$47m

#### Share price graph



#### Share details

Code	BLGO
Listing	OTCQB
Shares in issue	157.4m
Net debt (\$m) at 30 June 2019	3.31

#### Business description

BioLargo has a number of subsidiaries and products focused on using iodine chemistry. CupriDyne is a product that is currently on the market for industrial odor control. The firm is also developing the AOS as a low-cost water purification device. The Clyra Medical subsidiary is a wound care company with an iodine-based irrigation solution and SkinDisc, a cell therapy for wounds. Finally, the company has a full service environmental engineering team.

#### Bull

- Diversified portfolio of products.
- Unique technology with broad applications.
- CupriDyne is gaining market share.

#### Bear

- Additional capital needed.
- Sales ramp has been slow.
- Regulatory and development risk for Clyra and AOS.

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