Cleveland BioLabs – QuickView

15 January 2013

Investment summary: First line of (bio)defence

Cleveland BioLabs' biodefence franchise is fundamental to its near-term investment case and 2013 should see significant progress in the development of Entolimod (CBLB502) as the first available treatment for acute radiation syndrome (ARS). A potential development funding contract from BARDA in H113 is a major stock catalyst and financing event. Pivotal studies in animals and humans are planned for 2013 and a BLA submission is targeted for Q414. Entolimod, a TLR5 agonist, also holds potential as an anti-cancer agent, with a Phase I study to complete in Q413.

Animal efficacy rules OK

The FDA created the Animal Efficacy Rule in 2002 to encourage and enable the development of new products when human efficacy studies are not ethical or feasible. To date, four products have been approved under this pathway, two gaining approval in 2012 (raxibacumab for inhalational anthrax and levofloxacin for plague), confirming the viability of this regulatory process for Entolimod.

Efficacy in animals, safety in humans

A pivotal study of Entolimod in 179 non-human primates (single im admin 25 hours after total body irradiation) demonstrated efficacy at the highest-anticipated radiation level requested by the FDA (60-day survival rate of 75% for Entolimod vs 28% placebo), a dose response and validation of biomarkers (G-CSF and IL-6). Human safety trials have been completed in 150 healthy volunteers and Cleveland is planning further pivotal animal efficacy and human safety studies through 2013. A pre-emergency use authorisation (EUA) submission is also targeted for Q313; most countermeasures stockpiled by the US government are procured through an EUA.

Longer-term oncology play

Entolimod's TLR5 agonist activity delivers protective qualities (via healing cytokines/ anti-apoptotic factors) but also mobilises an innate immune response, particularly against TLR5+ tumours (eg liver, breast, colon, lung). Cleveland is conducting a Phase I study of Entolimod in 48-patients with unresectable solid tumours, with results due in H114. Two further oncology candidates (CBL0137 and CBL0102) are also undergoing Phase I studies through a Russian subsidiary, Incuron.

Valuation: Undemanding $35m EV

With $35m cash after a $13.8m public offering in October 2012, Cleveland's EV of $35m is undemanding with potential upside from a BARDA contract in H113. The stock may also offer an attractive entry point with a view to Cleveland's future in oncology. We intend to initiate full coverage of Cleveland BioLabs in due course.

Consensus estimates

Year End	Revenue ($m)	PBT ($m)	EPS ($)	DPS ($)	P/E (x)	Yield (%)
12/10	15.3	(26.7)	(1.01)	0.0	N/A	N/A
12/11	8.8	(5.2)	(0.12)	0.0	N/A	N/A
12/12e	1.9	(33.8)	(0.92)	0.0	N/A	N/A
12/13e	2.0	(36.6)	(0.76)	0.0	N/A	N/A

Price	$1.56
Market cap	$70m

Share price graph

Share details

Code	CBLI
Listing	NASDAQ
Sector	Pharma & biotech
Shares in issue	44.5m

Business

Cleveland BioLabs is a clinical-stage US biotechnology company focused on oncology and the mitigation of radiation injury. Cleveland's lead compound, Entolimod (CBLB502), is being developed as both a radiation countermeasure (pivotal studies) and a cancer treatment (Phase I study in advanced solid tumours).

Bull

- Entolimod to become first approved and stockpiled product for ARS.
- Entolimod's anti-cancer potential adds to an emerging cancer portfolio.
- US government contracts provide major non-dilutive finance.

Bear

- Failure to win BARDA contract adds near-term fresh financing pressure.
- US government contracts hard to predict/fickle, adds uncertainty.
- Early-stage cancer pipeline yet to provide proof-of-concept data

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QUICKVIEW NOTES USE CONSENSUS EARNINGS ESTIMATES.

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