KaloBios Pharmaceuticals

Pharma & biotech

23 July 2013

Investment summary: Seeking a good life

Complete enrolment in a Phase II study of KB003 (anti-GM-CSF MAb) for severe asthma sets KaloBios on course for its first clinical proof-of-concept data in Q114 for its recombinant antibody technology. Conversely, recruitment into a Phase II trial of KB001-A (anti-PcrV MAb fragment) for *Pseudomonas* infections in cystic fibrosis (CF) patients has been slower than expected, delaying results by six months until Q414. Nevertheless, 2014 is shaping to be a pivotal year for KaloBios, and with a modest $75m EV, the current share price could prove to be an attractive entry point.

Severe asthma study on track...

KaloBios has completed enrolment, ahead of schedule, into a 160-patient Phase II study of KB003 in patients with asthma inadequately controlled by corticosteroids. Randomised 1:1, patients will receive 400mg IV antibody or saline (+ current medications) on weeks 0, 2, 4, 8, 12, 16, 20, with change in FEV_1 at week 24 the primary end point. Phase I/II data suggest that patients with airway reversibility (≥12% change in FEV_1 after beta agonist) respond better to anti-GM-CSF, and targeting GM-CSF has potential for both allergic and non-allergic severe asthma.

...while CF study slower than expected

Recruitment into the 180-patient Phase II study of KB001-A has been slower than planned, partly due to other CF trials underway in the US. Top-line data, previously targeted for Q214, should now be available in Q414. Randomised 1:1, patients will receive 10 mg/kg IV antibody or saline on weeks 0, 2, 4, 8, 12, with time-to-need for antibiotic (ABX) treatment by week 16 the primary end point. KB001-A has anti-inflammatory and anti-infective properties by blocking the ability of Pseudomonas aeruginosa to secrete toxins that kill immune cells and reducing cytokine release. Sanofi is developing KB001-A for ventilator-associated pneumonia and has global opt-in rights to the antibody post-Phase II (18% royalties ex-US/50% US profits).

Blood cancer target adds third pipeline option

KB004 (anti-EphA3 MAb) has potential in haematologic malignancies. A 40-patient dose-escalation Phase I study is ongoing (sixth dose level, 190mg, being tested), with expansion into a Phase II study in AML/MDS planned for Q313.

Valuation: $75m EV could prove attractive

With $77m in cash at end-Q113 ($62m net IPO – 8.75m shares at $8 – funds in February 2013), and $10m debt (from $15m MidCap Financial venture finance facility), KaloBios' $75m EV seems modest given the significant pipeline potential.

Consensus estimates

Year End	Revenue ($m)	PBT ($m)	EPS ($)	DPS ($)	P/E (x)	Yield (%)
12/12	6.1	(23.5)	(11.2)	0.0	N/A	N/A
12/13e	0.1	(41.4)	(1.83)	0.0	N/A	N/A
12/14e	11.3	(35.5)	(1.26)	0.0	N/A	N/A

Source: Bloomberg

Price	$5.87
Market cap	$142m

Share price graph

Share details

Code	KBIO
Listing	NASDAQ
Sector	Pharma & biotech
Shares in issue	24.2m

Business description

KaloBios is a US biotechnology company developing monoclonal antibodies for severe respiratory diseases and cancer. KB003 (anti-GM-CSF MAb), KB001-A (anti-PcrV MAb fragment) and KB004 (anti-EphA3 MAb) are undergoing Phase I and II clinical studies.

Bull

- Maturing pipeline from novel antibody technology.
- Potential first-in-class candidates for novel targets.
- Strong balance sheet with additional funds available from MidCap and Sanofi.

Bear

- Pipeline candidates yet to achieve clinical proof-of-concept.
- Targeting competitive markets and established products.
- Financing required in 12-18 months; delay to CF study puts strain on existing cash reserve.

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