BioInvent International

BI-505 first clinical data

Edison investment research

The one into two at 10

Pharma & biotech

January 2013 brought a clear safety and dose signal in the BI-505 Phase I for relapsed and refractory multiple myeloma (MM). In preclinical studies, BI-505 showed a tumour cell killing effect possibly by making myeloma cells susceptible to apoptosis. The Phase I was dose escalating with a safety end point. Interestingly but anecdotally, seven of 29 patients (24%) on extended dosing showed stable disease. BI-505 will progress to a small Phase IIa during 2013. BioInvent intends to partner BI-505 either with Phase II efficacy data or sooner if a lucrative Phase I deal can be achieved.

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/10	83	(124)	(2.1)	0.0	N/A	N/A
12/11	125	(67)	(1.0)	0.0	N/A	N/A
12/12e	45	(148)	(1.9)	0.0	N/A	N/A
12/13e	45	(29)	(0.4)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding intangible amortisation and exceptional items.

The one: BI-505 is crucial to current value

BI-505 is the remaining clinical programme from the January 2012 portfolio. Hence, gaining maximum value is important for investors. A deal by GenMab in August 2012 with J&J on a Phase I MM antibody, daratumumab, shows possible value. GenMab, a larger company, gained $55m upfront and $88m in equity with milestones and a 10%+ royalty. However, such Phase I deals are infrequent and BioInvent investors need to be prepared to fund BI-505 to add value by generating Phase II efficacy data.

Into two at 10: BI-505 progression to Phase II

BI-505 blocks the function of the cell surface adhesion molecule ICAM-1 (CD54). In the cancer literature, myeloid cells show cell-adhesion mediated drug resistance if attached to other cells. In BioInvent's patent EP 2468775 (priority December 2006), ICAM blocking is claimed to cause apoptosis (cell suicide). The 35-patient dose escalation study in relapsed and refractory MM tested 11 dose stages of 0.0004mg/kg to 20mg/kg. BI-505 at 10mg/kg saturated the ICAM sites on bone marrow myeloma cells; this dose will be used for Phase II. Stable disease (based on M protein biomarker levels) was seen in 24% of the 29 patients who received extended dosing over 0.06mg/kg (level 6). The likelihood of success remains at 30%.

Valuation: Cash conservation to rebuild the portfolio

BioInvent had Q3 ytd cash of SEK153m with revenues of SEK 34m. Estimating year-end 2012 cash is difficult due to the actual H212 restructuring costs; SEK25-40m seems a probable range. The company needs to invest in BI-505, bring forward two other candidates into Phase I and support n-CoDeR. Operating cash costs in 2013 should be SEK75m. The small Phase IIa BI-505 study due to start sometime in 2013 will be inexpensive; a broader Phase IIb may eventually follow. Collaborations may generate milestones in 2013 if partners designate clinical candidates. This could give funding into 2014 before any BI-505 deal value, if partnered in 2013.

4 February 2013

Price	SEK3.55
Market cap	SEK262m
Shares in issue	73.93m
Code	BINV
Primary exchange	OMX Stockholm

Share price performance

%	1m	3m	12m
Abs	1.2	31.5	(82.9)
Rel (local)	(4.8)	18.8	(84.4)
52-week high/low	SEK20.4	SEK1.8	

Business description

BioInvent is a human therapeutic antibody company based in Lund in southern Sweden. It has an innovative cancer antibody, BI-505 for multiple myeloma entering Phase II, plus the n-CoDeR antibody library and various research collaborations that generate some income.

Next events

FY12 results	21 February 2013

Analysts

Dr John Savin MBA +44(0)20 3077 5735

Robin Davison +44(0)20 3077 5737

healthcare@edisoninvestmentresearch.co.uk

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Exhibit 1: Financial summary

SEKm	2010	2011	2012e	2013e
31-December	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	83	125	45	45
Cost of Sales	0	0	0	0
Gross Profit	83	125	45	45
EBITDA	(135)	(66)	(147)	(24)
Operating Profit (before amort and except)	(125)	(72)	(153)	(30)
Intangible Amortisation	3	0	0	0
Restructuring and provisions	(1)	0	(48)	0
Other	0	0	9	0
Operating Profit	(124)	(72)	(192)	(30)
Net Interest	1	5	5	1
Profit Before Tax (norm)	(124)	(67)	(148)	(29)
Profit Before Tax (FRS 3)	(123)	(67)	(187)	(29)
Tax	0	0	0	0
Profit After Tax (norm)	(126)	(67)	(139)	(29)
Profit After Tax (FRS 3)	(123)	(67)	(187)	(29)
Average Number of Shares Outstanding (m)	60.5	67.2	72.2	73.9
EPS - normalised (ore)	(2.08)	(1.00)	(1.92)	(0.39)
EPS - normalised fully diluted (ore)	(2.08)	(1.00)	(1.92)	(0.39)
EPS - (IFRS) (ore)	(2.04)	(1.00)	(2.59)	(0.39)
Dividend per share (c)	0.0	0.0	0.0	0.0
Gross Margin (%)	100.0	100.0	100.0	100.0
EBITDA Margin (%)	N/A	N/A	N/A	N/A
Operating Margin (before GW and except) (%)	N/A	N/A	N/A	N/A
BALANCE SHEET				
Fixed Assets	14	12	10	9
Intangible Assets	3	0	0	0
Tangible Assets	10	11	10	8
Investments	1	1	1	1
Current Assets	124	193	47	23
Stocks	1	0	0	0
Debtors	12	19	16	16
Cash	106	174	31	7
Other	5	0	0	0
Current Liabilities	(64)	(68)	(20)	(20)
Creditors	(64)	(68)	(20)	(20)
Short term borrowings	0	0	0	0
Long Term Liabilities	0	0	0	0
Long term borrowings	0	0	0	0
Other long term liabilities	0	0	0	0
Net Assets	74	137	37	12
CASH FLOW				
Operating Cash Flow	(118)	(60)	(241)	(20)
Net Interest	1	5	5	1
Tax	0	0	0	0
Capex	(5)	(5)	(5)	(5)
Acquisitions/disposals	0	0	0	0
Financing	144	128	97	0
Dividends	0	0	0	0
Net Cash Flow	22	68	(143)	(24)
Opening net debt/(cash)	(84)	(106)	(174)	(31)
HP finance leases initiated	0	0	0	0
Other	0	0	0	0
Closing net debt/(cash)	(106)	(174)	(31)	(7)

Source: Edison Investment research, BioInvent International