Threshold Pharmaceuticals - QuickView



12 November 2012

Investment summary: Landscape change

The twin outcome of competing Phase III studies – one positive and one negative – in pancreatic cancer gives Threshold and partner Merck KGaA more clarity on the landscape in this indication, as the pivotal Phase III trial with TH-302 gets underway. The combination of Friday's positive result for Celgene's Abraxane (nab-paclitaxel) and today's negative outcome for Clavis/Clovis's CP-4126/CO-101 allows Threshold and Merck KGaA to plan for a shift in the standard of care. Threshold still faces near-term uncertainty in soft tissue sarcoma but with a clearer competitive landscape in pancreatic cancer, its shares are now looking much more attractive.

Clearer path for pancreatic cancer future

Merck KGaA's 600-patient Phase III trial of gemcitabine ± TH-302 in first-line pancreatic cancer is due to read-out in 2015. This will be two years into potential approvals of Abraxane and/or AB Science's masitinib (which has been filed in the EU for an unspecified subset of poor prognosis pancreatic patients). However, although multiple commercial risks in this indication remain, the landscape is getting clearer and probably the most important question could be addressed by a hypothetical Phase II study of gemcitabine/Abraxane in combination with TH-302.

But Abraxane benefits pancreatic cancer

No survival data has yet been reported for Abraxane (this will be presented in January) and it possible that a very high efficacy bar will be set by this new combination. Threshold's 214-patient Phase IIb showed a 63%, two-month increase (p=0.005) in PFS over gemcitabine alone, but did not show – nor was it powered to do so – a statistical significant improvements in OS.

Exploring the soft tissue sarcoma universe

Threshold also faces near-term uncertainty in soft tissue sarcoma with the read-out from Ziopharm's PICASSO study of doxorubicin± palifosfamide due in the next few weeks. If positive, this study could also set a new standard. Threshold's 450-patient Phase III trial of doxorubicin ± TH-302 is due to render results in mid-2014.

Valuation: EV of \$175m

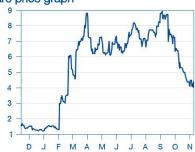
Threshold's shares have fallen heavily in recent months because of the uncertainty around competitors, but these are starting to clarify. The apparently clear result for Abraxane in pancreatic cancer probably represents the best-case scenario from a commercial perspective.

Consensus estimates

| Year end 12/11 | Revenue (US\$m) 0.06 | PBT (US\$m) (25.7) | EPS (US\$) (0.56) | DPS (US\$) N/A | P/E (x) N/A | Yield (%) N/A |
|----------------------|----------------------------|--------------------------|-------------------------|----------------------|-------------------|---------------------|
| 12/12e | 8.1 | (104.3) | (2.43) | N/A | N/A | N/A |
| 12/13e | 13.4 | (14.6) | (0.39) | N/A | N/A | N/A |

Price \$4.38 Market cap \$241m





Share details

| Code | THLD |
|-----------------|------------------|
| Listing | NASDAQ |
| Sector | Pharma & biotech |
| Shares in issue | 55.1m |

Business

Threshold is a US biotech company focused on oncology drugs targeting tumour hypoxia, the low oxygen condition found in most solid tumours and some blood cancers. TH-302 is in Phase III trials for soft tissue sarcoma and pancreatic cancer and in Phase I/II trials for leukaemia, multiple myeloma, glioblastoma, and renal cell and hepatocellular carcinomas. TH-302 has been partnered with Merck KGaA.

Bull

- TH-302 has blockbuster potential.
- Merck KGaA funds 70% of development costs.
- \$66m of cash at 30 September 2012.

Bear

- Pancreatic cancer treatment landscape will change before 2015.
- Combination studies will have to examine gem/Abraxane/TH-302.
- Single product risk.

Analysts

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