

Threshold Pharmaceuticals

Pharma & biotech

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Pivotal STS Phase III continues as planned

The conclusion of the interim efficacy and safety analysis of Threshold's ongoing Phase III soft tissue sarcoma (STS) trial is for the study to continue as planned, in line with both our and management's expectations. Based on the current event rate, the number of events (n=434 deaths) required for the primary efficacy analysis are expected to be reached in H215. STS could be the first approved indication for TH-302.

Interim STS outcome as expected

A planned review of efficacy and safety, which included 256 events (deaths), by an independent committee (IDMC) has concluded that the Phase III STS trial should continue as planned, in line with both our and management's expectations. The IDMC had the option to terminate the trial early if TH-302 demonstrated a clear efficacy benefit, substantially higher than planned for in the primary analysis, or to terminate the trial for an unacceptable risk/benefit profile.

Trial continues; events for primary analysis in H215e

Threshold remains blinded to the data but based on the current event rate, the number of events (n=434 deaths) required for the primary analysis of overall survival are now expected in H215e (Threshold had previously expected these to be reached around mid-2015). Timelines for event-driven trials can be difficult to predict and there is little we can infer either way from this. The Phase III STS trial is investigating TH-302 with doxorubicin vs doxorubicin alone in 640 patients. The trial design has been agreed with the FDA under a special protocol assessment (SPA).

STS could be the first of many indications for TH-302

STS could represent the first approved indication for TH-302, if the data are positive. TH-302 is also being investigated in a Phase III pancreatic cancer trial, in addition to a number of other solid tumours and blood cancers in combination with chemotherapy and antiangiogenics, and as monotherapy in certain cancers. Early signals of clinical activity were observed in both a Phase I/II glioblastoma trial and a multiple myeloma study, presented at ASCO 2014. These could be eligible for accelerated development, given the unmet medical need.

Valuation: EV of around \$157m

End-June net cash of \$75.2m implies an EV of only c \$157m. TH-302 has potential across a broad range of tumours and Phase III trials in both STS and pancreatic cancer are ongoing, in addition to the \$525m deal with Merck KGaA.

Consensus estimates

Year end	Revenue (\$m)	PBT (\$m)	EPS (\$)	DPS (\$)	P/E (x)	Yield (%)
12/12	5.9	(71.1)	(1.31)	0.0	N/A	N/A
12/13	12.5	(28.2)	(0.49)	0.0	N/A	N/A
12/14e	15.5	(22.8)	(0.45)	0.0	N/A	N/A
12/15e	18.8	(32.1)	(0.52)	0.0	N/A	N/A

Source: Bloomberg

Price **\$3.91**
Market cap **\$232m**

Share price graph



Share details

Code THLD
Listing NASDAQ
Shares in issue 59.4m

Business description

Threshold Pharmaceuticals is a US oncology company focused on tumour hypoxia, a low-oxygen condition found in most solid tumours and some blood cancers. TH-302 is in Phase III for STS and pancreatic cancer, in addition to trials in multiple other cancers and is partnered with Merck KGaA.

Bull

- TH-302 has potential in a number of cancer indications, as both monotherapy in some cancers, and in combination with chemotherapy and antiangiogenics.
- Merck KGaA funds 70% of TH-302 development.
- Solid cash position of \$75.2m (end June).

Bear

- TH-302 could fail to show survival benefit in STS.
- Oncology is a highly competitive space.
- Single-product risk.

Analysts

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QUICKVIEW NOTES USE CONSENSUS EARNINGS ESTIMATES.

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