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# Threshold Pharmaceuticals

Pharma & biotech

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## STS interim analysis preview

**During September the planned interim analysis of the ongoing Phase III soft tissue sarcoma (STS) trial is expected to occur. An independent committee (IDMC) will review efficacy and safety to determine next steps. Of the three possible outcomes, Threshold believes the most likely is that the trial continues as planned with overall survival data then in H215e.**

### STS is one of the most advanced TH-302 indications

The Phase III STS trial is investigating TH-302 with doxorubicin versus doxorubicin alone in 640 patients; recruitment was completed in December 2013. The primary endpoint is overall survival (OS), and the trial is designed around an expected TH-302 survival benefit of four months (33% increase) and an expected 12-month OS on control arm. The trial design has been agreed with FDA under a Special Protocol Assessment (SPA), meaning the design of the trial is acceptable for approval.

### Interim analysis has three potential outcomes

An interim analysis when 235 events (deaths) have occurred is expected in September, when the IDMC will review both efficacy and safety data. There are three possible outcomes: (1) the trial continues as planned, with OS data then expected in H215; (2) the trial is stopped early for benefit if superiority of TH-302 is clearly established; this would need TH-302 to demonstrate around a 45% OS improvement (p=0.0023); and (3) the trial is stopped early, either for unacceptable safety, or if TH-302 is unlikely to show a benefit if the trial continues.

### Most likely outcome is trial continuation

We believe it is unlikely that the trial will be stopped for a lack of benefit based on a 21.5-month median OS in a previous Phase II open-label trial. Safety has also been under regular IDMC review during the Phase III trial. While it is possible that TH-302 could demonstrate an efficacy benefit sufficient to stop the trial early, this would require a clear demonstration of efficacy with a 45% OS improvement, substantially higher than planned for in the trial design. Threshold believes, and we agree, that the most common outcome is continuation of the trial as planned.

### Valuation: EV of around $210m

End-June net cash of $75.2m implies an EV of only c $210m. 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 a $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 | $4.80 |
| Market cap | $285m |

**Share price graph**


**Share details**

| | |
|---|---|
| Code | THLD |
| Listing | NASDAQ |
| Shares in issue | 59.3m |

**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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