



FIRST GLANCE | COMMENT

NOVEMBER 5, 2012

Durata Therapeutics, Inc. (NASDAQ: DRTX; 7.12)

Dalbavancin Eligible for Quicker Review and Longer Exclusivity

Outperform Speculative Risk

Impact

Modest positive – DRTX announced that dalbavancin qualifies as a qualified infectious disease product.

First Impression

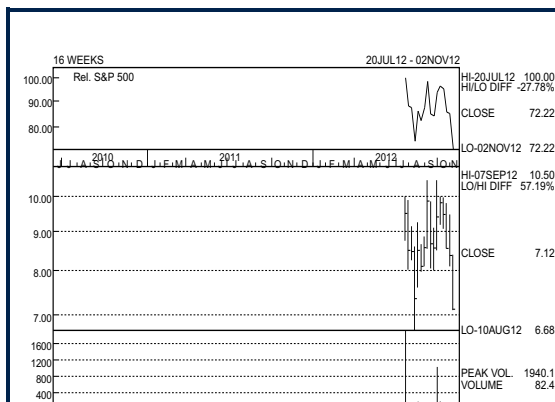
Dalbavancin being designated a qualified infectious disease product (QIDP) by the FDA holds several positives including a faster review time and longer exclusivity. We had anticipated dalbavancin being granted QIDP status and continue to believe risk/reward remains favorable ahead of pivotal Phase III readouts for dalbavancin for abSSSI by YE:12 and early 2013. Durata has all rights to dalbavancin making it a potentially attractive candidate for partnership or acquisition.

Benefits of being a QIDP:

- **Exclusivity:** Dalbavancin will have 5 years of market exclusivity on top of the 5 year Hatch Waxman new chemical entity for a total of 10 years of protection. This applies with or without patents being in place. Dalbavancin has patent and/or exclusivity protection in the US and EU through 2023.
- **Priority review:** The review cycle would be 8 months, not the 12-month standard review period (both have been extended by two months from 6 and 10 months, respectively, previously under the current PDUFA). We expect a filing in 1H:13 followed by approval in 1Q:14.
- **Fast track:** We expect frequent and timely communication by the FDA, which could help the clinical and review cycle.

Timeline to data and NDA unchanged. We continue to expect results from the first Phase III study by YE:12 and from the second study in early 2013. DRTX has previously maintained the guidance of filing an NDA in 1H:13, which would be followed by an MAA in the EU. We currently forecast U.S. approval in 1Q:14 and EU approval in 2H:14.

Enrollment completed in both Phase III studies. DRTX announced in late October that enrollment in DISCOVER 2 had completed. Enrollment in DISCOVER 1 was completed in early September.



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All values in USD unless otherwise noted.

Company Description

Durata Therapeutics is focused on the development and commercialization of novel therapeutics for patients with infectious diseases and acute illnesses. Enrollment in two global Phase III clinical trials with Dalbavancin, DRTX's primary value driver, for the treatment of acute bacterial skin and skin structure infections (abSSSI) is ongoing and results are expected in YE:12 from the first study and early 2012 from the second study. Dalbavancin is an intravenous antibiotic product candidate designed for once-weekly dosing, which differentiates from currently marketed antibiotics and increase the convenience of treating patients in the out-patient and in-patient settings, while lowering the overall cost of care to the healthcare system. Assuming a positive outcome, Durata will submit an NDA to the FDA in 1H:13 and an MAA to the EMA in 2H:13. Currently, the company plans to commercialize Dalbavancin directly in the US and EU with a targeted hospital sales force.

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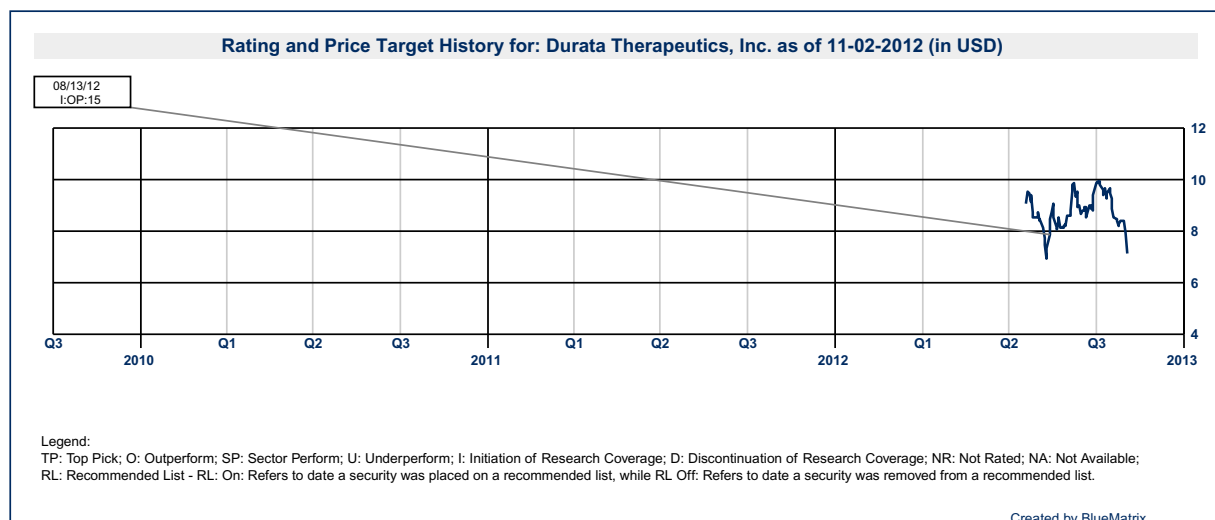
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