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## Durata Therapeutics (DRTX - OUTPERFORM): QIDP Designation Adds 5 Years of Exclusivity, Priority Review and Fast-Track Status to Dalbavancin

Price: \$7.65

12-Month Price Target: \$20

- **Durata announced that dalbavancin received QIDP (Qualified Infectious Disease Product) designation from FDA, which provides an additional 5 years of exclusivity along with priority review and fast-track status.** We had anticipated that dalbavancin would be a QIDP; this confirmation importantly maintains at least 10 years of exclusivity for dalbavancin in the USA.
- **Our estimates are for exclusivity through 2028 in the US, as we expect full Hatch-Waxman patent term extension.** The QIDP designation lowers downside risk of patent challenge or expiry to 10 years post-approval, or 2024, assuming a 2014 approval. Even in the worst case scenario of no patent extension and dalbavancin lose of exclusivity in 2024, our valuation method would yield a price target of \$16.
- **Key upcoming catalysts include release of top-line Phase III results for dalbavancin in the DISCOVER 1 and 2 trials in the abSSSI setting, estimated to occur YE:12/Q1:13, and subsequent filing for regulatory approvals in both the US and EU. Three prior Phase III studies have already demonstrated dalbavancin's non-inferiority to comparators, and we view positive results in the pivotal Phase III trials to be likely, given the previously-generated data.** DRTX is a uniquely de-risked pre-commercial biotechnology company in our view.

YE:12 Results of 960 patient first Phase III study of oritavancin (SOLO-1) in the abSSSI setting

YE:12 Top-line Phase III results for dalbavancin (DISCOVER 1) in the abSSSI setting

Q1:13 Top-line Phase III results for dalbavancin (DISCOVER 2) in the abSSSI setting

H2:12 Potential completion of enrolment in the second Phase III study of oritavancin (SOLO-2) in the abSSSI setting

H2:12 Potential re-partnering transaction for THRX of Vibativ (telavancin)

Mid:13 Potential EU MAA filing for dalbavancin in the abSSSI setting

Mid:13 Potential US NDA filing for oritavancin in the abSSSI setting with an anticipated 6 month review cycle

H1:13 Potential NDA filing with FDA for dalbavancin

- **Reiterate OUTPERFORM rating and \$20 price target.** Our \$20 share price target is derived from the net present value (25% discount rate) of our estimate of profits and losses for DRTX through our projection of the end of dalbavancin's exclusivity period in the U.S. and EU in 2027 and 2023, respectively, with no terminal value and cash per share in 12 months.
- Risks to our price target include; 1) dalbavancin to demonstrate non-inferiority ongoing Phase III abSSSI clinical trials, 2) commercial and launch risks, 3) regulatory risks and 4) risks to the IP estate of Durata and dalbavancin in the U.S. and ROW.

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Company	Disclosure
Durata Therapeutics	1,3,4,5,7

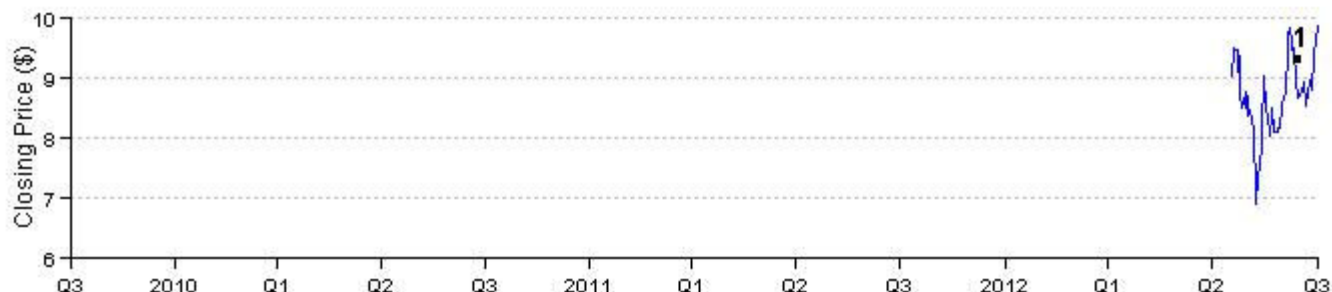
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DRTX

1) 09/10/12  
OUTPERFORM \$20


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