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Gregory R. Wade, Ph.D. (415) 274-6863 David M. Nierengarten, Ph.D. (415) 274-6862 Christopher N. Marai, Ph.D. (415) 274-6861

Durata Therapeutics (DRTX - OUTPERFORM): DISCOVER 2 Phase III Meets FDA and EMA Required Primary Endpoints -- Data Points from a Recent Industry Check - Reiterate OUTPERFORM

Price: $7.97 **12-Month Price Target: $20**

- **Durata announced that the Phase III Discover 2 trial of dalbavancin for the treatment of abSSSI met the FDA and EMA required primary endpoints (Exhibit 1) of non-inferiority to vancomycin (with the option of switching to linezolid after initial 3-day vancomycin treatment).** The non-inferiority margin to meet in both studies was 10%, with the FDA endpoint defined as evidence of efficacy at 48-72 hours after therapy started, measured by absence of fever or cessation of lesion spreading (76.8% d vs. 78.3% vl CI -7.4%, 4.6%). The EMA required primary endpoints include "clinical status" and "investigators' assessment of clinical response". The "clinical status" endpoint measurements include a comparison of clinical efficacy of dalbavancin vs. comparator at end of treatment, based upon lesion size, local signs, temperature and receipt of other therapy at end of treatment visit (Day 14-15). The "investigator assessment of clinical response" includes a day 14-15 assessment of success (dalbavancin vs. comparator), defined as resolution or improvement of all signs and symptoms of infection without treatment-related discontinuation, death, or non-antibacterial intervention for abSSSI (Acute Bacterial Skin and Skin Structure Infections).
- **Safety and tolerability results continue to suggest to us that dalbavancin has a highly competitive profile to the comparator drugs (Exhibit 2 & 3).** Importantly, no late treatment emergent adverse events continue to support the idea that the prolonged pharmacokinetic profile for the drug isn't problematic.
- **We await further analysis into the DISCOVER 1 & 2 results focused on key populations and secondary endpoints.** Evidence of a difference in therapeutic benefit may arise from Kaplan Meier analyses of time to defervescence (cessation of fever), time to 20% reduction in lesion area, and these and other measures in immunosuppressed patients (diabetics and patients with elevated blood glucose at randomization). Additionally, we will also be focused on changes in renal parameters which are likely to be associated with exposure to vancomycin and may be more prominent in the 20% of patients in the DISCOVER program with diabetes.
- **A recent industry check we conducted confirms the importance of administration schedule on the use of IV antibiotics in the homecare setting and suggests there may be widespread inappropriate use of vancomycin.** Our check with the National Director of the Home Infusion Division of a large public company suggests the vast majority of vancomycin administered in the homecare setting occurs with a once daily schedule, one in which patients are put at both safety and efficacy risk. This observation highlights the potential for Durata, and other participants to engender change through education and grow the branded share of the marketplace.
- **Dalbavancin's unmatched profile makes Durata a potential takeout candidate, in our view.** We rarely call out names under coverage as potential takeout candidates. Investors would be, in our opinion, well-served to maintain significant exposure to Durata. With the second Phase III study in hand we have near certainty in terms of safety, tolerability and efficacy. The drug's US regulatory consideration is similarly well positioned with a complete review of the NDA already in hand and under the Gain Act visibility into at least 10 years of US market exclusivity is assured. Cubicin's approximately $500 million in outpatient use has established a foothold in this opportunity, which we roughly project from our recent check is just 25% of use on a days of therapy basis leaving 75% of share obtainable from vancomycin whose use in this setting appears to us to be inconsistent with the present guidelines for its appropriate administration schedule.
- **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 the attainment of our price target include; 1) commercial and launch risks, 3) regulatory risks and 4) risks to the IP estate of Durata and dalbavancin in the U.S. and ROW.

A recent industry check has yielded some interesting data points and confirms that administration schedule drives outpatient utilization of IV antibiotics. We recently spoke with the national director of a significant player in the home infusion marketplace. We reviewed patient demographics, commonly administered antibiotics, scheduling and the business environment.

- Patients generally fall into one of four categories; the chronically ill (cystic fibrosis, etc.), immunosuppressed cancer patients (pediatric and adult), healthy people with serious infections (generally men aged 20-50 with a poorly cared for skin injury or post orthopedic surgical infections) and the elderly.
- Reimbursement under Medicare isn't typically sufficient to cover the price of this service.
- This provider typically has between 5 and 40 thousand patients on service on any given day.
- This is a highly fragmented marketplace with 2 participants having approximately 30% market share with the remainder taken up by very small participants.
- Demand is greatest in urban centers primarily due to physician awareness (and potentially administrative processes to minimize hospital census).
- The business is growing at about 10% per annum however recently, pressures related to antibiotic stewardship have seen Cubicin demand grow at a slightly lower rate than vancomycin.
- The business consists of several distinct revenue streams – cost plus on the drug (favors more expensive therapeutics), equipment rental (pumps and other), skilled services (nursing time to administer therapy – low margin) and skilled on-call professional services (patients receiving therapy have 24/7 access to skilled care – very profitable – favors therapeutics with infrequent administration schedule).
- On a days of therapy basis, vancomycin enjoys a 3:1 utilization rate over Cubicin
- Vancomycin is primarily administered on a once daily basis with only about 10% of patients receiving the drug on a more frequent schedule through the use of pumps

Widespread prescription of once daily vancomycin in the homecare setting is a surprising finding. As an industry contact in clinical research commented to us when we discussed this [my paraphrase] "you get it at both ends with that schedule, on safety you hit the kidneys, and then on efficacy, if kidney function was close to normal, you can be sure that trough MIC is falling below the guidelines. This is going to lead to increasing rates of reduced susceptibility to vancomycin".

Upcoming Milestones

H1:13	Completion of enrolment of MDCO's SOLO-2 oritavancin Phase III abSSSI study
H2:13	Top line data from the second Phase III study of oritavancin (SOLO-2) in the abSSSI setting
YE: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
2013	Potential re-partnering transaction for THRX of Vibativ (telavancin)
2014	MDCO launch of oritavancin in the US

INVESTMENT SUMMARY

Durata's dalbavancin is an intravenous antibiotic in development for the treatment of serious Gram + bacterial infections and if approved, would primarily compete with vancomycin (generic), Cubist's CUBICIN (daptomycin), Forest's Teflaro, and potentially, the Medicines Company's oritavancin. The Company's Phase III clinical studies have been successful and we expect FDA and EMA filings for approval in mid:13 and YE:13, respectively. Dalbavancin's primary potential competitive advantage lies with its infrequent, once weekly administration that should simplify delivery of IV antibiotic therapy in the outpatient setting facilitating care outside of the expensive inpatient settings found in hospitals and skilled nursing facilities. FDA and EMA (European Medicines Agency) NDA (new drug application) and MAA (marketing authorization application) filings are expected in mid:13 and by YE:13 respectively. Uniquely, the drug has been reviewed by FDA with the only outstanding issue remaining the conduct of at least one new Phase III skin clinical study with current, standard efficacy endpoints and non-inferiority margins.

Exhibit 1: Top-line Data from the DISCOVER 1 and 2 Trials

DISCOVER PROGRAM
Efficacy Analysis: Primary Endpoint

Primary Endpoint (Early Response)	Dalbavancin	Vancomycin/ linezolid	Difference (95% Confidence Interval)
DISCOVER 2	285/371 (76.8%)	288/368 (78.3%)	-1.5% (-7.4, 4.6)
DISCOVER 1	240/288 (83.3%)	233/285 (81.8%)	1.5% (-4.6, 7.9)

Sensitivity analysis (>20% reduction in lesion area at 48-72 hours)	Dalbavancin	Vancomycin/ linezolid	Difference (95% Confidence Interval)
DISCOVER 2	325/371 (87.6%)	316/368 (85.9%)	1.7% (-3.2, 6.7)
DISCOVER 1	259/288 (89.9%)	259/285 (90.9%)	-1.0% (-5.7, 4.0)

Source: Company reports

- **Key takeaway – the lower bounds of the 95% confidence interval are >-10 and therefore, both studies have achieved non-inferiority.**

Exhibit 2: Safety data from Discover 2

DISCOVER 2
Safety Assessment

Patients who experienced at least one of:	Dalbavancin (N=368)	Vancomycin/ linezolid (N=367)
Adverse event	122 (33.2%)	144 (39.2%)
Treatment emergent adverse event (TEAE)	115 (31.3%)	135 (36.8%)
TEAE with onset through the SFU (D28) visit	108 (29.3%)	125 (34.1%)
TEAE with onset after the SFU (D28) visit	14 (3.8%)	21 (5.7%)
Drug Related TEAE	45 (12.2%)	37 (10.1%)
Treatment emergent serious adverse events (SAE)	12 (3.3%)	14 (3.8%)
Drug related treatment emergent SAE	2 (0.5%)	2 (0.5%)
Treatment emergent SAE leading to death	1 (0.3%)	2 (0.5%)
TEAE leading to premature discontinuation (d/c) from drug	9 (2.4%)	7 (1.9%)

Source: Company reports

- **Key takeaway – treatment emergent adverse events after day 28 do not show evidence of late safety signal, consistent with previous findings and further evidence that the prolonged half-life of the drug isn't problematic.**

DISCOVER 2
Adverse Events

	Dalbavancin (N=368)		Vancomycin/linezolid (N=367)	
	Unrelated	Related	Unrelated	Related
Patients with at least one TEAE [1]	63 (17.1%)		88 (24.0%)	
		45 (12.2%)		37 (10.1%)
TEAE[1] at ≥2% in any arm				
Nausea	6 (1.6%)	9 (2.4%)	8 (2.2%)	7 (1.9%)
Headache	8 (2.2%)	3 (0.8%)	6 (1.6%)	3 (0.8%)
Pruritus	2 (0.5%)	3 (0.8%)	1 (0.3%)	6 (1.6%)
Diarrhea	1 (0.3%)	3 (0.8%)	1 (0.3%)	7 (1.9%)
Vomiting	6 (1.6%)	2 (0.5%)	2 (0.5%)	2 (0.5%)

[1]Through Day 28

Source: Company reports

- **Key takeaway – related and un-related observations are largely balanced – we believe that the apparent differences in diarrhea and pruritis favoring dalbavancin are real and expect that physicians' adjudication of vomiting as mostly un-related in the dalbavancin arm is accurate, likely based upon the absence of a temporal relationship with administration.**

Analyst Certification
I, Gregory R. Wade, Ph.D., David M. Nierengarten, Ph.D., Christopher N. Marai, Ph.D., certify that the views expressed in this report accurately reflect my personal opinion and that I have not and will not, directly or indirectly, receive compensation or other payments in connection with my specific recommendations or views contained in this report.

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

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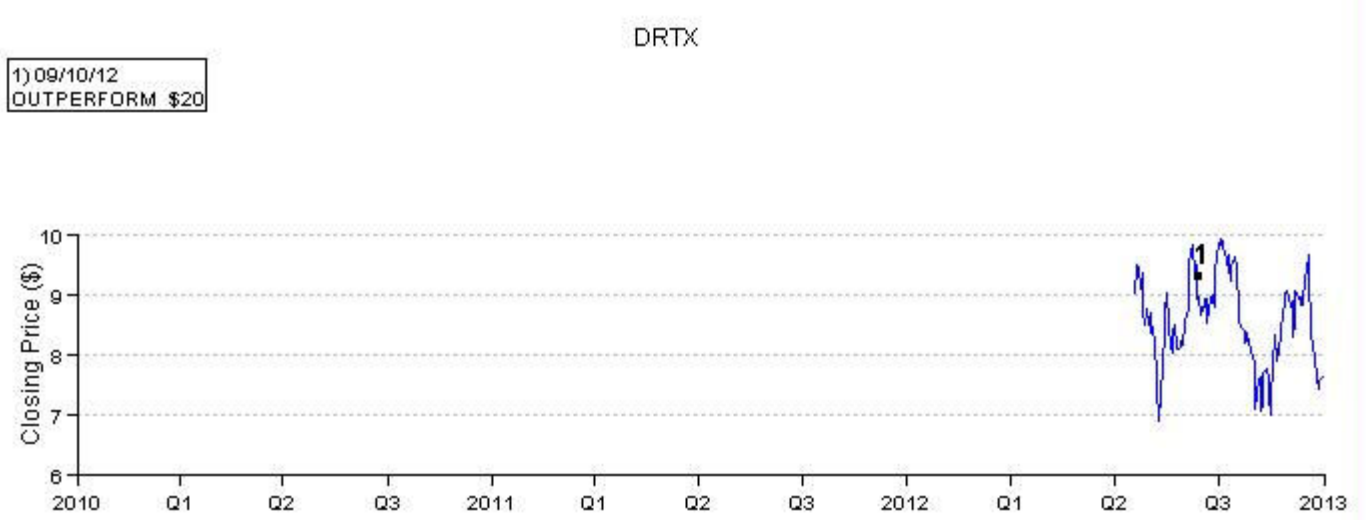

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EQUITY RESEARCH DEPARTMENT

(213) 688-4529

DIRECTOR OF RESEARCH
Mark D. Benson (213) 688-4435

MANAGER, RESEARCH OPERATIONS
Ellen Kang (213) 688-4529

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Rommel T. Dionisio (212) 938-9934
Kurt M. Frederick, CFA CPA (415) 274-6822

Footwear, Apparel and Accessories
Corinna Freedman (212) 668-9876

Healthy Lifestyles
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John Garrett, CFA (213) 688-4523

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Christopher N. Marai, Ph.D. (415) 274-6861

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Ryan Jue, CFA (415) 263-6669

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David M. Nierengarten, Ph.D. (415) 274-6862
Christopher N. Marai, Ph.D. (415) 274-6861

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CORPORATE HEADQUARTERS
1000 Wilshire Blvd., Los Angeles, CA 90017-2465
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