

RBC Capital Markets, LLC

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FY Dec	2012E	2013E	2014E	
Rpt EPS	(8.63)	(2.70)	(1.65)	
Revenue (MM)	0.0	1.3	50.6	
Rpt EPS	Q1	Q2	Q3	Q4
2012	(132.12)A	(260.25)A	(1.47)A	(1.23)E
2013	(1.17)E	(1.02)E	(0.43)E	(0.31)E
Revenue (MM)				
2012	0.0A	0.0A	0.0A	0.0E
2013	0.0E	0.0E	0.0E	1.3E

All values in USD unless otherwise noted.

COMPANY UPDATE | COMMENT

DECEMBER 12, 2012

Durata Therapeutics, Inc. (NASDAQ: DRTX)

First Phase III Meets Primary Endpoint; Second Phase III Expected In 1Q:13

Outperform
Speculative Risk

Price:	8.99	Price Target:	15.00
Shares O/S (MM):	18.4	Implied All-In Return:	67%
Dividend:	0.00	Market Cap (MM):	165
		Yield:	0.0%

Event

Dalbavancin was non-inferior to vancomycin in patients with abSSSI in DISCOVER 1

Investment Opinion

The first Phase III trial of dalbavancin met its SPA established primary endpoint of non-inferiority to vancomycin. Given that the ongoing second Phase III trial is larger, we believe the odds of success are high and an NDA filing is likely in 1H:13. Of note, dalbavancin appears as safe if not safer than vancomycin/linezolid, despite being a longer-acting antibiotic (two weekly doses). Several analysis are yet to be completed, which would provide details on secondary and other endpoints, needed for approval in the EU. We conservatively value US dalbavancin revenues at ~\$11/share and EU revenues at ~\$4/share using a very high discount rate of 17.5%. Further upside could come from a second positive Phase III expected in early 2013, which could lead us to reduce our discount rate. We are buyers of DRTX ahead of the second Phase III data expected in early 2013.

- **Primary endpoint met; dalbavancin non-inferior.** 83% of patients receiving dalbavancin vs. 81.8% on vancomycin/linezolid had resolution of fever and stoppage of lesion spread at 48-72 hours (primary endpoint). The non-inferiority margin of 10% was met (95% c.i., -4.9, +7.6). Another subset DRTX evaluated was at least a 20% reduction in lesion area without fever, which again favored the dalbavancin arm.
- **Safety appears clean.** Given that dalbavancin is a long-acting antibiotic (two doses, one week apart), there was an additional focus on safety. The rate of adverse events, treatment emergent adverse events with onset through day 28 or after day 28, SAEs, etc., were all lower with dalbavancin.
- **Secondary endpoints promising; analysis ongoing.** DRTX stated that it is satisfied with what it has seen regarding outcomes needed to support a filing, though further analyses are ongoing.
- **Filing to include all data but focus on DISCOVER 1 and 2, QT and VER001-9 studies.** We believe DRTX need only submit one Phase III study along with the completed QT and previously re-analyzed VER001-9 studies to reactivate its NDA; however, we expect the company to include DISCOVER 2 in its NDA submission.
- **DRTX retains all rights to dalbavancin** (patent/exclusivity protected through 2023) making it an attractive candidate for an opportunistic partnership or acquisition.

Priced as of prior trading day's market close, EST (unless otherwise noted).

For Required Conflicts Disclosures, see Page 7.

Details

SPA established primary endpoint met; dalbavancin non-inferior. 83% of patients receiving dalbavancin vs. 81.8% on vancomycin/linezolid had resolution of fever and stoppage of lesion spread at 48-72 hours (primary endpoint). The non-inferiority margin of 10% was met (95% c.i., -4.9, +7.6). Another subset DRTX evaluated was at least a 20% reduction in lesion area without fever, which again favored the dalbavancin arm. Recall that anti-biotic trials are run typically to demonstrate non-inferiority not superiority. Given DRTX's confidence in its ability to satisfy U.S. approval criteria, we believe secondary endpoints are at the very least supportive.

Safety appears clean with dalbavancin. Given that dalbavancin is a long-acting antibiotic (two doses, one week apart), there was an additional focus on safety. The rate of adverse events, treatment emergent adverse events with onset through day 28 or after day 28, serious adverse events, and drug related adverse events are all lower with dalbavancin than with vancomycin/linezolid.

Secondary endpoints appear promising; analysis ongoing. DRTX stated that it is satisfied with what it has seen regarding outcomes needed to support a filing, though further analyses are ongoing. 87% of clinically evaluable patients on dalbavancin were cured at day 14-15 vs. 91.4% on vancomycin/linezolid (absolute difference -4.4% vs. -2.8% investigator assessed). This is the primary endpoint for EU approval, which also has a 10% non-inferiority margin. 93.8% on dalbavancin were cured at day 28 vs. 96.1% on vancomycin/linezolid (absolute difference -2.3% vs. -3.1% investigator assessed). According to DRTX, several analyses from the dataset are planned. While we await further details on endpoints affecting EU approval, we note that the test of cure for recent EMA approved ceftaroline was lower than vancomycin plus aztreonam, the comparator (91.1% vs. 93.3%); however, it was higher for the MITT population (86.6% vs. 85.6%).

Phase III DISCOVER 1 Top-Line Efficacy

Endpoint	Patient Population	Dalbavancin		Vancomycin / linezolid		Difference	
						(95% Confidence Interval)	Absolute Difference
Primary (early response)	ITT	239 / 288	83.0%	233 / 285	81.8%	1.2% (-4.9, +7.6)	1.2%
>20% reduction in lesion area at 48-72 hrs	ITT	258 / 288	89.6%	259 / 285	90.9%	-1.3% (-6.1, +3.7)	-1.3%
Secondary Endpoints							
Clinical status at EOT (day 14-15)	CE*	214 / 246	87.0%	222 / 243	91.4%		-4.4%
	ITT	236 / 288	81.9%	247 / 285	86.7%		-4.7%
Investigator assessment at EOT (day 14-15)	CE	233 / 246	94.7%	237 / 243	97.5%		-2.8%
	ITT	260 / 288	90.3%	262 / 285	91.9%		-1.7%
Clinical status at SFU (day 28)	CE	212 / 226	93.8%	220 / 229	96.1%		-2.3%
	ITT	241 / 288	83.7%	251 / 285	88.1%		-4.4%
Investigator assessment at SFU (day 28)	CE	213 / 226	94.2%	223 / 229	97.4%		-3.1%
	ITT	248 / 288	86.1%	255 / 285	89.5%		-3.4%

*EMA primary endpoint.

Source: Company reports.

Phase III DISCOVER 1 Top-Line Safety

	Dalbavancin	Vancomycin / linezolid
N	284	284
Adverse events	39.8%	41.2%
Treatment emergent adverse events	34.9%	39.4%
TEAE with onset through D28 visit	33.8%	38.0%
TEAE with onset after D28 visit	4.2%	8.5%
Drug related TEAE	12.3%	18.3%
TESAE	1.8%	4.2%
Drug related SAE	0.0%	0.7%
TESAE leading to death	0.0%	1.8%
TEAE leading to discontinuation	1.8%	2.1%

	Unrelated	Related	Unrelated	Related
Patients with at least one TEAE through D28	21.5%	12.3%	19.7%	18.3%
TEAE at >= 2% in any arm				
Nausea	1.8%	2.5%	0.4%	4.2%
Diarrhea	0.7%	0.7%	0.7%	3.2%
Headache	1.8%	3.2%	2.5%	2.5%
Pruritis	0.0%	0.0%	0.7%	3.2%
Hypertension	2.5%	0.0%	2.5%	0.0%
Rash	0.7%	1.1%	0.4%	1.8%
Asthenia	0.4%	0.0%	1.8%	0.4%

Source: Company reports.

Filing to include all data but focus on DISCOVER 1 and 2, QT and VER001-9 studies. Technically DRTX need only submit one Phase III study along with the completed QT and previously re-analyzed VER001-9 studies to reactivate its NDA; however, we expect the company to include DISCOVER 2 in its NDA submission and see it as an insurance policy for fulfilling all FDA criteria. Recall that both DISCOVER 1 and 2 were conducted under an SPA and with buy-in from EU regulators. Efficacy and/or safety submissions will include data at 48-72 hours, day 14-15, day 28 and day 70.

More details expected in 1Q:13 including results from second Phase III trial. DRTX will report Phase III data from DISCOVER 2, the larger of the two pivotal studies, in 1Q:13. Furthermore, using the EU ceftaroline approval as a guide, we expect several analyses from DISCOVER 1 to be reported including cure for both evaluable and MITT populations, efficacy based on patient co-morbidities, infection sizes, microbiological responses, cure rates by baseline pathogens, including patients with MRSA and MSSA, among others.

DISCOVER 1 & 2	
# of patients	~568 in DISCOVER 1 and ~740 in DISCOVER 2
Design	Randomized, double blind, double dummy
Treatment arms	Dalbavancin - 1g on day 1 and 500mg on day 8 Vancomycin 1g or 15mg/kg BID for 10-14 days; switch to oral Zyvox allowed at day 3
Inclusion	- abSSSI (severe disease) - Involving deeper soft tissue or requiring surgical intervention - Systemic manifestations of infection: fever or elevated white blood cell count - Discharge, local warmth, tenderness, or swelling - Appropriate for a minimum of 3 days of IV therapy
Exclusion	Antibiotics within 14 days prior Gram-negative bacteremia Burns, diabetic ulcers, infected device, venous catheter infection
Statistics	Non-inferiority with a margin of 10%
Primary outcome	Clinical response at 48-72 hours based on lesion size
Secondary outcomes	At day 14-15: Clinical status at end of treatment visit; per-patient microbiological efficacy; efficacy by individual pathogens; pathogen eradication rates; investigator's assessment of clinical response At day 70: Safety and tolerability
Locations	80-90 sites (DISCOVER 1) 120-150 sites (DISCOVER 2)

Source: Company reports and www.clinicaltrials.gov

Valuation Scenarios: Base, Upside and Downside Case

- **Base case: \$15/share.** We arrive at a \$15 price target using the average of two methodologies. Our sum-of-the parts analysis for dalbavancin arrives at a value of \$15/share, including approximately \$4/share for the value of EU royalties. We assume that dalbavancin is protected through 2023 with patents and/or exclusivity. We use a P/E multiple of 12x our 2017 fully taxed GAAP EPS estimate of \$2.82 and a discount rate of 17.5% for five years to arrive at a value of \$15/share.
- **Upside case: \$20/share.** We assume peak dalbavancin market share will be 7-8% up from 5-6% assumed in our base case scenario.
- **Downside case: \$11/share.** We assume dalbavancin data may not meet EMA requirements for approval and remove the ~\$4 per share in value coming from EU royalties in our base case model.

Upcoming Events

Timing	Expected News Flow	Program
YE:12	Initiate bone penetration study	Dalbavancin
4Q:12	First Phase III trial in abSSSI	Competitor: MDCO Oritavancin
YE:12	Phase III data from first study in abSSSI	Dalbavancin
Early 2013	Phase III data from second study in abSSSI	Dalbavancin
Early 2013	Second Phase III trial in abSSSI	Competitor: TSRX Tedizolid
1H:13	File NDA	Dalbavancin
Mid 2013	Second Phase III trial in abSSSI	Competitor: MDCO Oritavancin
3Q:13	File MAA	Dalbavancin
2013	Initiate lung penetration study	Dalbavancin
2013	Potential initiation of Phase III pediatric osteomyelitis study	Dalbavancin
1H:14	Potential approval for abSSSI in the US	Dalbavancin
2H:14	Potential approval for abSSSI in the EU	Dalbavancin

Source: Company reports and RBC Capital Markets estimates.

Products and Pipeline

Product	Stage	Indication	Partner
Dalbavancin	Phase III	abSSSI	Proprietary
		Osteomyelitis	
		Diabetic foot infection	

Source: Company reports.

Valuation

We arrive at a \$15 price target using the average of two methodologies:

1) Dalbavancin DCF. Our sum-of-the parts analysis for dalbavancin arrives at a value of \$14/share, including approximately \$4/share for the value of EU royalties. We assume that dalbavancin is protected through 2023 with patents and/or exclusivity.

2) P/E Multiple. We use a P/E multiple of 12x our 2017 fully taxed GAAP EPS estimate of \$2.82 and a discount rate of 17.5% for five years to arrive at a value of \$15/share.

Upside to our forecasts could come from adjustments to our conservative 17.5% discount rate, a lower than forecast tax rate, especially in the outer years, competitor setbacks, and a higher than forecast penetration.

Price Target Impediment

Our price target is dependent primarily on the clinical, regulatory and commercial success of Dalbavancin for acute bacterial skin and skin structure infections (abSSSI). Any setbacks in clinical development, delay in launch, increased competition or other limitations to the market potential of Dalbavancin could negatively impact our valuation. Upside could come from pricing, compliance, better than anticipated market penetration, new partnerships, clinical success of programs that are not included in our valuation, setbacks for potential competitors, and/or a takeout.

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.

Durata Therapeutics (Nasdaq: DRTX)

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Annual and Quarterly Income Statement

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(\$ in millions, except per share)

	2011A	1Q12A	2Q12A	3Q12A	4Q12E	2012E	1Q13E	2Q13E	3Q13E	4Q13E	2013E	2014E	2015E	2016E	2017E	2018E	2019E
Fiscal Year Ends December																	
Dalbavancin sales (US) (probability adj.)	-	-	-	-	-	-	-	-	-	-	-	45.6	109.6	166.3	277.1	381.6	454.0
Dalbavancin (royalties) (probability adj.)	-	-	-	-	-	-	-	-	-	-	-	-	11.0	16.6	27.7	38.2	45.4
Contracts, licensing fees, and milestones	-	-	-	-	-	-	-	-	-	1.3	1.3	5.0	5.0	5.0	5.0	3.8	-
Total Revenues	-	-	-	-	-	-	-	-	-	1.3	1.3	50.6	125.6	188.0	309.8	423.5	499.4
Cost of goods sold	-	-	-	-	-	-	-	-	-	-	-	6.8	15.3	20.0	33.3	45.8	54.5
Research & development	30.1	6.8	16.5	19.0	19.8	62.0	18.0	15.0	7.0	5.0	45.0	29.0	33.0	38.0	43.0	47.0	54.9
SG&A	4.3	1.2	2.4	2.6	2.8	9.0	3.7	3.9	4.1	4.3	16.0	58.0	73.0	88.0	103.0	110.0	115.0
Contingent consideration	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Operating Expenses	35.6	8.3	19.2	21.8	22.8	72.0	21.9	19.1	11.3	9.5	61.8	94.6	122.1	146.8	180.1	203.6	225.2
Operating Income (Loss)	(35.6)	(8.3)	(19.2)	(21.8)	(22.8)	(72.0)	(21.9)	(19.1)	(11.3)	(8.3)	(60.6)	(44.0)	3.4	41.2	129.7	219.9	274.3
Interest income	0.0	0.0	0.0	0.0	0.1	0.1	0.2	0.2	0.2	0.3	0.8	2.2	0.4	0.5	0.6	1.0	2.0
Interest expense	-	-	-	-	-	-	-	-	-	-	-	(1.3)	(2.5)	(2.5)	(2.5)	(2.5)	(1.3)
Total Other Income (expense)	0.0	0.0	0.0	0.0	0.1	0.1	0.2	0.2	0.2	0.3	0.8	1.0	(2.1)	(2.0)	(1.9)	(1.5)	0.8
Income before Tax	(35.5)	(8.3)	(19.2)	(21.8)	(22.7)	(71.9)	(21.8)	(19.0)	(11.1)	(8.0)	(59.8)	(43.1)	1.3	39.2	127.8	218.4	275.0
Provision for taxes	(2.5)	-	-	-	-	-	-	-	-	-	-	-	0.5	13.7	44.7	76.4	96.3
Net Income (Loss)	(33.0)	(8.3)	(19.2)	(21.8)	(22.7)	(71.9)	(21.8)	(19.0)	(11.1)	(8.0)	(59.8)	(43.1)	0.9	25.5	83.1	142.0	178.8
EPS - Basic (GAAP)	(\$27.22)	(\$132.12)	(\$260.25)	(\$1.47)	(\$1.23)	(\$8.63)	(\$1.17)	(\$1.02)	(\$0.43)	(\$0.31)	(\$2.70)	(\$1.65)	\$0.03	\$0.93	\$2.97	\$4.98	\$6.14
EPS - Diluted* (GAAP)	(\$27.22)	(\$132.12)	(\$260.25)	(\$1.47)	(\$1.23)	(\$7.16)	(\$1.17)	(\$1.02)	(\$0.43)	(\$0.31)	(\$2.70)	(\$1.65)	\$0.03	\$0.88	\$2.82	\$4.73	\$5.84
Shares Outstanding - Basic (MM)	1.2	0.1	0.1	14.8	18.4	8.3	18.5	18.6	25.7	25.8	22.2	26.2	26.9	27.4	28.0	28.5	29.1
Shares Outstanding - Diluted (MM)	-	-	-	20.3	19.9	10.0	20.0	20.1	27.2	27.3	23.7	27.7	28.4	28.9	29.5	30.0	30.6

Dalbavancin - Revenues	2011A	1Q12A	2Q12A	3Q12A	4Q12E	2012E	1Q13E	2Q13E	3Q13E	4Q13E	2013E	2014E	2015E	2016E	2017E	2018E	2019E
Dalbavancin - US							-	-	-	-	-	45.6	109.6	166.3	277.1	381.6	454.0
Dalbavancin - EU							-	-	-	-	-	-	54.8	83.2	138.5	190.8	227.0
Dalbavancin Royalties - EU							-	-	-	-	-	-	11.0	16.6	27.7	38.2	45.4

Margin Analysis	2011A	1Q12A	2Q12A	3Q12A	4Q12E	2012E	1Q13E	2Q13E	3Q13E	4Q13E	2013E	2014E	2015E	2016E	2017E	2018E	2019E
Gross margin											85.0%	85.0%	86.0%	88.0%	88.0%	88.0%	88.0%
Cost of goods											15%	15%	14%	12%	12%	12%	12%
Research & development											3600%	57%	26%	20%	14%	11%	11%
Sales, general & administrative											1280%	115%	58%	47%	33%	26%	23%
Operating margin													3%	22%	42%	52%	55%
Tax rate											0%	35%	35%	35%	35%	35%	35%
Net margin													1%	14%	27%	34%	36%

Source: Company reports and RBC Capital Markets estimates.

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Conflicts Disclosures

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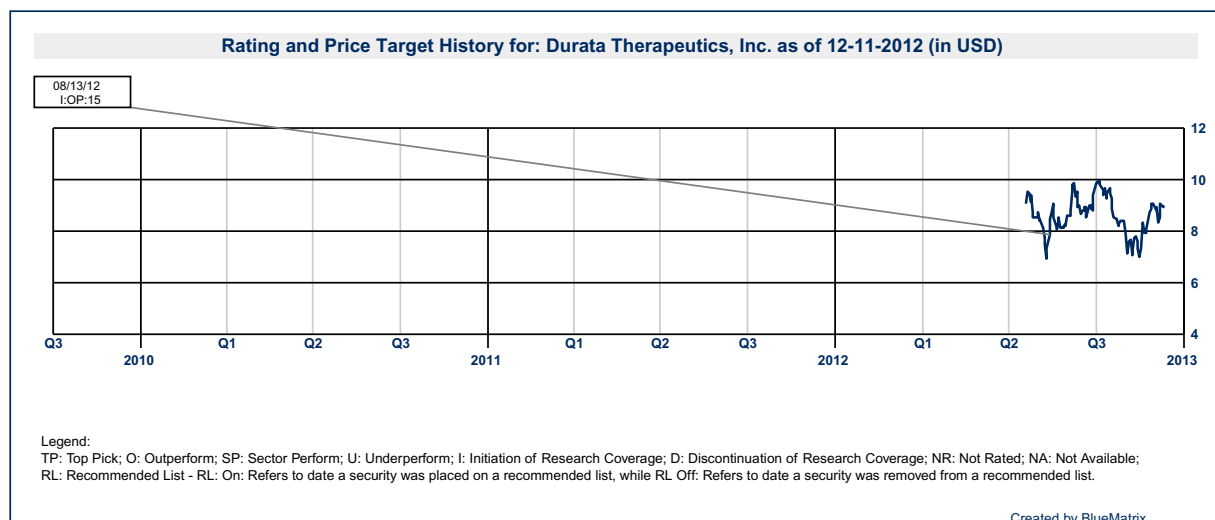
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