

#### 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(2	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

FEBRUARY 25, 2013

**Durata Therapeutics, Inc.** (NASDAQ: DRTX)
Two Positive Phase IIIs For Dalbavancin; Fully Owned
Asset

# Outperform Speculative Risk

Price:	7.54	Price Target:	15.00
		Implied All-In Return:	99%
Shares O/S (MM):	18.4	Market Cap (MM):	139
Dividend:	0.00	Yield:	0.0%

#### **Event**

DRTX reported positive Phase III data from 2<sup>nd</sup> pivotal DISCOVER 2 study

# **Investment Opinion**

The second Phase III trial of dalbavancin also met its SPA established primary endpoint of non-inferiority to vancomycin. Efficacy and safety both appear clean. Of note, the Phase III program was conducted under an SPA and with EMA guidance which reduces regulatory risk and makes dalbavancin more approvable in the US and EU. DRTX owns all rights to dalbavancin, a long-acting antibiotic, which we believe will find a role in the competitive, severe, gram positive infection landscape. The next steps are more detailed data presentation, NDA and MAA filings, and details on commercialization plans either alone or in conjunction with a commercial partner. We value US dalbavancin revenues at ~\$11-12/share and EU revenues at ~\$3-4/share using a very high discount rate of 17.5%.

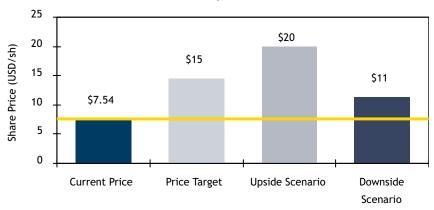
- Primary and secondary endpoints met; dalbavancin non-inferior to vancomysin / linezolid. 77% of patients receiving dalbavancin vs.78% on vancomycin/linezolid had resolution of fever and stoppage of lesion spread at 48-72 hours (primary endpoint). The non-inferiority margin of 10% was met (95% c.i., -7.4, +4.6). Fewer patients with MRSA responded compared to DISCOVER 1 but 6 of 11 patients were counted as failures due to missing data. The key is that this is the second pivotal study to confirm dalbavancin's non-inferiority to vancomycin / linezolid.
- Safety appears clean. Given that dalbavancin is a long-acting antibiotic (two doses, one week apart), the focus remains on safety where data are clean so far. 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. Drug related treatment emergent adverse events were slightly higher (12% vs. 10%) which is different than the outcome seen in DISCOVER 1 again leading us to conclude that safety is clean for dalbavancin.
- NDA expected; dalbavancin should be approvable. DRTX will file an NDA around mid-2013 and an MAA by YE:13. We believe the regulatory hurdle is low and dalbavancin is approvable. DRTX will submit both Phase III tirals along with QT and VER001-9 studies in its filing.
- 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 6.

## **Details**

# 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 \$3-4/share for the value of EU royalties. We assume that dalbavancin is protected through 2023 with patents and/or exclusivity.
- Upside case: \$20/share. We assume peak dalbayancin market share will be 7-8% up from 5-6% assumed in our base case scenario.
- **Downside case:** \$11/share. Although above the current price level, our downside case assumes that dalbavancin data may not meet EMA requirements for approval and removes the ~\$3-4 per share in value coming from EU royalties in our base case model.

#### Phase III DISCOVER 1 and DISCOVER 2 Top-Line Efficacy

	DISCOVER 1						DISCOVER 2						
		Difference							Difference				
	Patient		Vancomycin /	(95% Confidence	Absolute	Patient		Vancomycin /	(95% Confidence	Absolute			
Endpoint	Population	Dalbavancin	linezolid	Interval)	Difference	Population	Dalbavancin	linezolid	Interval)	Difference			
Primary (early response)	ITT	83.3%	81.8%	1.5% (-4.6, +7.9)	1.6%	ITT	76.8%	78.3%	-1.5% (-7.4, +4.6)	-1.4%			
>20% reduction in lesion area at 48-72 hrs	ITT	89.6%	90.9%	-1.3% (-6.1, +3.7)	-1.3%	ITT	87.6%	85.9%	+1.7% (-3.2, +6.7)	1.7%			
Patients with MRSA		84.1%	82.1%		2.0%		76.1%	85.7%		-9.6%			
Medically Evaluable		85.7%	96.8%		-11.1%		97.7%	100.0%		-2.3%			
Secondary Endpoints													
Clinical status at EOT (day 14-15)*	CE*	87.0%	91.4%	-4.4% (-9.6, +1.6)**	-4.4%	CE*	93.5%	92.7%	+0.8% (-3.3, +4.9)	0.8%			
	ITT	81.9%	86.7%		-4.7%	ITT	88.7%	85.6%	+3.1% (-1.8, +8.0)	3.1%			
Patients with MRSA		85.7%	96.8%		-11.1%		97.7%	100.0%		-2.3%			
Investigator assessment at EOT (day 14-15)	CE	94.7%	97.5%	-2.8% (-6.7, 0.7)	-2.8%	CE	96.9%	96.0%	+0.9% (-2.2, +4.1)	0.9%			
	ITT	90.3%	91.9%		-1.7%	ITT	92.2%	90.2%	+2.0% (-1.9, 6.4)	2.0%			
Clinical status at SFU (day 28)	CE	93.8%	96.1%		-2.3%	CE	96.3%	92.6%		3.6%			
	ITT	83.7%	88.1%		-4.4%	ITT	88.1%	84.5%		3.6%			
Investigator assessment at SFU (day 28)	CE	94.2%	97.4%		-3.1%	CE	95.2%	94.9%		0.4%			
	ITT	86.1%	89.5%		-3.4%	ITT	87.9%	86.1%		1.7%			
*FMA primary endpoint						l							

\*EMA primary endpoint.

Source: Company reports.

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# Phase III DISCOVER 1 and 2 Top-Line Safety

	DISCO	VER 1	DISC	COVER 2
		Vancomycin /		Vancomycin /
	Dalbavancin	linezolid	Dalbavancin	linezolid
N	284	284	368	367
Adverse events	39.8%	41.2%	33.2%	39.2%
Treatment emergent adverse events	34.9%	39.4%	31.3%	36.8%
TEAE with onset through D28 visit	33.8%	38.0%	29.3%	34.1%
TEAE with onset after D28 visit	4.2%	8.5%	3.8%	5.7%
Drug related TEAE	12.3%	18.3%	12.2%	10.1%
TESAE	1.8%	4.2%	3.3%	3.8%
Drug related SAE	0.0%	0.7%	0.5%	0.5%
TESAE leading to death	0.0%	1.8%	0.3%	0.5%
TEAE leading to discontinuation	1.8%	2.1%	2.4%	1.9%

	Unrelated	Unrelated	Unrelated	Unrelated
Patients with at least one TEAE through D28	21.5%	19.7%	17.1%	24.0%
TEAE at >= 2% in any arm				
Nausea	1.8%	0.4%	1.6%	2.2%
Diarrhea	0.7%	0.7%	0.3%	0.3%
Headache	1.8%	2.5%	2.2%	1.6%
Pruritis	0.0%	0.7%	0.5%	0.3%
Hypertension	2.5%	2.5%		
Rash	0.7%	0.4%		
Asthenia	0.4%	1.8%		
Vomiting			1.6%	0.5%

Source: Company reports.

## **Valuation**

Our sum-of-the parts analysis for dalbavancin arrives at a value of \$15/share, including approximately \$3-4/share for the value of EU royalties. We assume that dalbavancin is protected through 2023 with patents and/or exclusivity.

**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

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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.

February 25, 2013 Durata Therapeutics, Inc.

## Durata Therapeutics (Nasdaq: DRTX)

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Annual and Quarterly Income Statement

(\$ in millions, except per share)																	
Fiscal Year Ends December	2011A	1Q12A	2Q12A	3Q12A	4Q12E	2012E	1Q13E	2Q13E	3Q13E	4Q13E	2013E	2014E	2015E	2016E	2017E	2018E	2019E
Dalbavancin sales (US) (probability adj.)	-	-	-	-	-	-	-	-	-	-	-	42.8	102.8	155.9	259.8	357.7	425.7
Dalbavancin (royalties) (probability adj.)	-	-	-	-	-	-	-	-	-	-	-	-	7.7	11.7	19.5	26.8	31.9
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	47.8	115.5	172.6	284.3	388.3	457.6
Cost of goods sold	-	-	-	-	-	-	-	-	-	-	-	6.4	14.4	18.7	31.2	42.9	51.1
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	94.2	121.2	145.5	178.0	200.7	221.8
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)	(46.4)	(5.7)	27.1	106.3	187.6	235.8
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)	(45.5)	(7.8)	25.1	104.4	186.1	236.6
Provision for taxes	(2.5)	-	-	-	-	-	-	-	-	-	-	-	-	8.8	36.5	65.1	82.8
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)	(45.5)	(7.8)	16.3	67.8	121.0	153.8
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)	(\$1.74)	(\$0.29)	\$0.60	\$2.43	\$4.24	\$5.29
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)	(\$1.74)	(\$0.29)	\$0.56	\$2.30	\$4.03	\$5.03
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
				1	3 10		91	10.7	9	717				•	•		
Dalbavancin - Revenues	2011A	1Q12A	2Q12A	3Q12A	4Q12E	2012E	1Q13E	2Q13E	3Q13E	4Q13E	2013E	2014E		2016E	2017E	2018E	2019E
Dalbavancin - US		- N		1			9				-	42.8	102.8	155.9	259.8	357.7	425.7
Dalbavancin - EU							-	-	-	-	-	-	51.4	78.0	129.9	178.9	212.8
Dalbavancin Royalties - EU							-	-	-	-	-	-	7.7	11.7	19.5	26.8	31.9

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%	61%	29%	22%	15%	12%	12%
Sales, general & administrative											1280%	121%	63%	51%	36%	28%	25%
Operating margin													-5%	16%	37%	48%	52%
Tax rate											0%	35%	35%	35%	35%	35%	35%
Net margin													-7%	9%	24%	31%	34%

Source: Company reports and RBC Capital Markets estimates.



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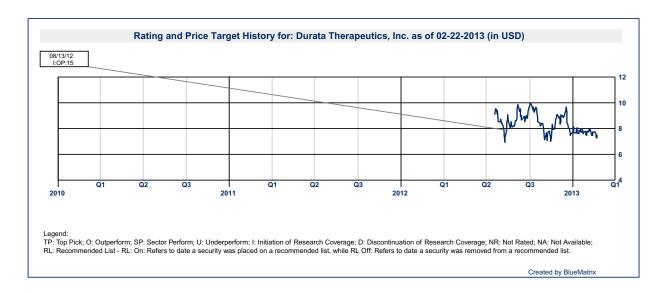
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Distribution of Ratings RBC Capital Markets, Equity Research										
		Invest Serv.								
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BUY[TP/O]	783	50.68	283	36.14						
HOLD[SP]	693	44.85	185	26.70						
SELL[U]	69	4.47	8	11.59						

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