



April 24, 2013

## Durata Therapeutics, Inc.

### Reimbursement Seminar Highlights Dalbavancin Drivers and Opportunity

**Our View:** Dalbavancin is de-risked and differentiated where even niche market share could lead to significant upside.

#### Key Points:

Our takeaway from the reimbursement day is that dalbavancin, if approved by the FDA, could be paid for. The question that remains is whether or not it makes economic sense for hospitals (in- and out-patient) and private practice physicians to use dalbavancin. Here, again the response seems favorable given long-term dynamics, which are emerging and could shift the treatment paradigm toward outcomes-based medicine and outpatient care. DRTX remains an interesting investment opportunity where even limited commercial success for dalbavancin could result in significant potential upside, in our view. DRTX owns dalbavancin outright, which leaves open the opportunity for partnering or selling dalbavancin. Pro forma cash per share is ~\$4/share.

- **Dalbavancin will likely be paid for.** Adequate coding, coverage, and reimbursement pathways are available to get dalbavancin paid for.
- **Focus on using outcomes in place already.** There is a present and increasing focus on using incentives and penalties to improve health outcomes. This could drive use toward dalbavancin, as being a long-acting drug naturally improves patient compliance and theoretically outcomes.
- **Move toward the outpatient setting** The move toward keeping patients outside the hospital is favorable for dalbavancin, as in that setting dalbavancin is paid for separately instead of under a DRG.
- **Private payers likely to follow CMS on penalties.** In 2013, DRG payments are reduced based on 30-day admission rates. Initially these are single percentage reductions, but by 2019 they could be 6% of DRG. This can be a significant amount, as it would be 6% of all DRG payments made by CMS to a particular institution. Private payers would likely follow suit, which means that the impact of not focusing on quality would be amplified. Penalties for failing in 2013 would be applied to 2015 DRG receivables, which would be a bigger number and so on.
- **Even a niche opportunity could lead to significant potential upside.** DRTX estimates that the number of patients eligible for dalbavancin could be 10–50% of the total. According to our estimates, even single-digit market share could make dalbavancin a very successful commercial product with sales of \$100–400M+ at penetration rates between 1% and 5%. Cubist's Cubicin (daptomycin) is a \$800M+ drug based on 10–15% market share alone.

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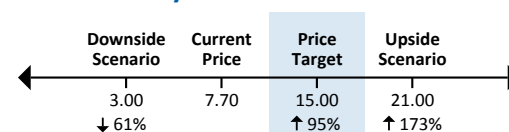
NASDAQ: DRTX

Price Target \$15.00

#### WHAT'S INSIDE

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#### Scenario Analysis\*



\*Implied Total Returns

#### Key Statistics

Shares O/S (MM):	26.6	Market Cap (MM):	205
Dividend:	0.00	Yield:	0.0%

#### RBC Estimates

FY Dec	2012A	2013E	2014E	
Rpt EPS	(7.48)	(2.14)	(1.69)	
Revenue (MM)	0.0	1.3	47.8	
Rpt EPS	Q1	Q2	Q3	Q4
2013	(0.70)E	(0.58)E	(0.49)E	(0.44)E
Revenue (MM)				
2013	0.0E	0.0E	0.0E	1.3E

All values in USD unless otherwise noted.

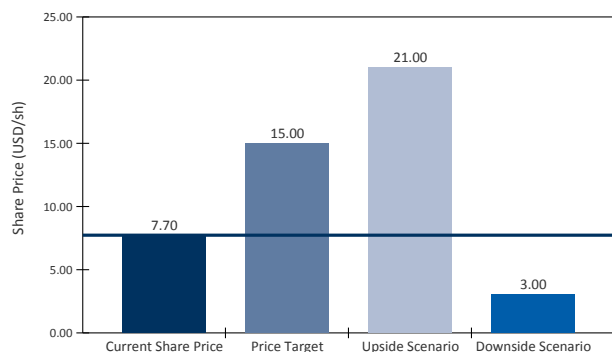
Priced as of prior trading day's market close, EST (unless otherwise noted).

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### Target/Upside/Downside Scenarios

Exhibit 1: Durata Therapeutics, Inc.



Source: RBC Capital Markets estimates

#### Target Price/ Base Case

**Base case: \$15/share.** Our sum-of-the parts analysis for dalbavancin arrives at a value of \$15/share, including approximately \$3/share for the value of EU royalties. We assume that dalbavancin is protected through 2023 with patents and/or exclusivity, reaches peak market penetration of ~5%, receives royalties of 15% on EU sales, which are 15% of US sales, and the effective tax rate is 25%.

#### Upside Scenario

**Upside case: \$21/share.** We assume peak dalbavancin market share will be 7–8%, up from the ~5% assumed in our base case scenario.

#### Downside Scenario

**Downside case: \$3/share.** Our downside case assumes that dalbavancin launch could be delayed in the US and that dalbavancin is not launched in the EU. We also assume a slower ramp and a peak penetration in the US of 4%. However, we note that the current pro forma cash is ~\$4/share.

### Investment Thesis

Durata is developing dalbavancin, a wholly owned asset, for the treatment of abSSSI. Two Phase III trials of dalbavancin have reported positive results, in late 2012 and early 2013, respectively. Dalbavancin could be the first long-acting antibiotic targeting abSSSI on the market with the potential increase convenience, compliance, and lower costs to the healthcare system. Prior Phase III data, extensive regulatory history, and a well understood market provide greater transparency than is typical for a Phase III product candidate. On balance, we see the risk-reward as being highly favorable and expect value to increase pending positive data from the Phase III studies.

## Takeaways for Dalbavancin from the Reimbursement Day

### Short-Term Drivers

- **Dalbavancin will likely be paid for.** Adequate coding, coverage, and reimbursement pathways are available to get dalbavancin paid for (i.e., start with a miscellaneous and move on to a specific code). Payers will pay for dalbavancin if the FDA approves it and utilization management (i.e., prior authorization, etc.) is likely minimal.
- **Hospital outpatient setting is an achievable target.** Hospital outpatient setting is not under a DRG, which means that a drug is billed separately. Medicare also pays separately for each drug costing >\$80 in the outpatient settings (i.e., ASP+6%)
- **Cost burden on patients will not be too high.** Long-acting intravenous antibiotics will be paid under Medicare's medical benefit and the majority have supplemental insurance that mitigates the cost-sharing obligation.

### Medium-Term Drivers

- **Focus on using outcomes in place already.** There is a present and increasing focus on using incentives and penalties to improve health outcomes. This could drive use toward dalbavancin, as being a long-acting drug naturally improves patient compliance and theoretically outcomes.
- **Shift toward observation stays and outpatient care.** Since hospitals are getting increased scrutiny for 1- and 2-day in-patient stays by Medicare and private payers, hospitals are shifting from in-patient to out-patient care or observation stays as observation status is paid as an outpatient visit. Long-acting intravenous antibiotics such as dalbavancin could also enable increasing observation days.
- **Move toward the outpatient setting.** The move toward keeping patients outside the hospital is favorable for dalbavancin, as in that setting dalbavancin is paid for separately instead of under a DRG.

### Long-Term Drivers

- **Private payers likely to follow CMS on penalties.** In 2013, DRG payments are reduced based on 30-day admission rates. Initially these are single percentage reductions, but by 2019 they could be 6% of DRG. This can be a significant amount, as it would be 6% of all DRG payments made by CMS to a particular institution. Private payers would likely follow suit, which means that the impact of not focusing on quality would be amplified. Here, too, a long-acting antibiotic like dalbavancin could be favored as patients receiving a long-acting antibiotic are naturally more compliant with their treatment regimen. Penalties for failing in 2013 would be applied to 2015 DRG receivables, which would be a bigger number and so on.
- **Reducing admissions naturally reduces re-admissions.** If hospitals can avoid or reduce the number of admissions for serious skin and skin structure infections, they can be less concerned about re-admission rates upon which penalties would be assessed. This again could be a driver favoring dalbavancin use, as patient compliance and thereby outcomes could be improved.
- **Differentiated profile vs. current and future products.** Dalbavancin is dosed twice as an i.v. over a two-week period as a 30-minute infusion (e.g., day 1 and 8 of week 1 and 2) vs. once or twice per day over several days for currently approved i.v. or oral drugs.
- **Even a niche opportunity could lead to significant potential upside.** DRTX estimates that the number of patients eligible for dalbavancin could be 10–50% of the total. According to our estimates, even single-digit market share could make dalbavancin a very successful commercial product with sales of \$100–400M+ at penetration rates between 1% and 5%. Cubist's Cubicin (daptomycin) is a \$800M+ drug based on 10–15% market share alone.
- **NDA by mid-2013; expect approval by mid-2014 or sooner.** The expected review timeline in the US is roughly one year although it could be tightened to roughly eight months given that dalbavancin was designated a QIDP.



### Valuation

Our sum-of-the parts analysis for dalbavancin arrives at a value of \$15/share, including approximately \$3/share for the value of EU royalties. We assume that dalbavancin is protected through 2023 with patents and/or exclusivity, reaches peak market penetration of ~5%, receives royalties of 15% on EU sales, which are 15% of US sales, and the effective tax rate is 25%.

### Price Target Impediments

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 takeover.

### Company Description

Durata Therapeutics is focused on the development and commercialization of novel therapeutics for patients with infectious diseases and acute illnesses. Dalbavancin, DRTX's primary value driver, for the treatment of acute bacterial skin and skin structure infections (abSSSI) has reported positive data from two Phase III studies. 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 mid-2013 and an MAA to the EMA in 2H:13. Currently, the company plans to commercialize Dalbavancin directly in the US and likely partner outside the US.



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	4Q12A	2012A	1Q13E	2Q13E	3Q13E	4Q13E	2013E	2014E	2015E	2016E	2017E	2018E	2019E
Fiscal Year Ends December																	
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	-
<b>Total Revenues</b>	-	-	-	-	-	-	-	-	-	<b>1.3</b>	<b>1.3</b>	<b>47.8</b>	<b>115.5</b>	<b>172.6</b>	<b>284.3</b>	<b>388.3</b>	<b>457.6</b>
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	9.4	51.7	9.2	9.0	8.8	8.7	35.7	29.0	33.0	38.0	43.0	47.0	54.9
SG&A	4.3	1.2	2.4	2.6	3.6	9.8	3.7	3.9	4.1	4.3	16.0	58.0	73.0	88.0	103.0	110.0	115.0
Contingent consideration	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
<b>Total Operating Expenses</b>	<b>35.6</b>	<b>8.3</b>	<b>19.2</b>	<b>21.8</b>	<b>13.3</b>	<b>62.6</b>	<b>13.1</b>	<b>13.1</b>	<b>13.1</b>	<b>13.2</b>	<b>52.5</b>	<b>94.2</b>	<b>121.2</b>	<b>145.5</b>	<b>178.0</b>	<b>200.7</b>	<b>221.8</b>
<b>Operating Income (Loss)</b>	<b>(35.6)</b>	<b>(8.3)</b>	<b>(19.2)</b>	<b>(21.8)</b>	<b>(13.3)</b>	<b>(62.6)</b>	<b>(13.1)</b>	<b>(13.1)</b>	<b>(13.1)</b>	<b>(12.0)</b>	<b>(51.3)</b>	<b>(46.4)</b>	<b>(5.7)</b>	<b>27.1</b>	<b>106.3</b>	<b>187.6</b>	<b>235.8</b>
Interest income	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.2	0.2	0.3	0.8	2.2	0.4	0.5	0.6	1.0	2.0
Interest expense	-	-	-	-	-	-	(0.1)	(0.4)	(0.4)	(0.4)	(1.4)	(3.0)	(4.2)	(4.2)	(2.5)	(2.5)	(1.3)
Total Other Income (expense)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	(0.3)	(0.2)	(0.1)	(0.6)	(0.8)	(3.8)	(3.7)	(1.9)	(1.5)	0.8
Income before Tax	(35.5)	(8.3)	(19.2)	(21.8)	(13.3)	(62.5)	(13.1)	(13.4)	(13.3)	(12.1)	(51.8)	(47.2)	(9.5)	23.4	104.4	186.1	236.6
Provision for taxes	(2.5)	-	-	-	-	-	-	-	-	-	-	-	-	8.2	36.5	65.1	82.8
<b>Net Income (Loss)</b>	<b>(33.0)</b>	<b>(8.3)</b>	<b>(19.2)</b>	<b>(21.8)</b>	<b>(13.3)</b>	<b>(62.5)</b>	<b>(13.1)</b>	<b>(13.4)</b>	<b>(13.3)</b>	<b>(12.1)</b>	<b>(51.8)</b>	<b>(47.2)</b>	<b>(9.5)</b>	<b>15.2</b>	<b>67.8</b>	<b>121.0</b>	<b>153.8</b>
EPS - Basic (GAAP)	(\$27.22)	(\$132.12)	(\$260.25)	(\$1.47)	(\$0.72)	(\$7.48)	(\$0.70)	(\$0.58)	(\$0.49)	(\$0.44)	(\$2.14)	(\$1.69)	(\$0.33)	\$0.52	\$2.27	\$3.97	\$4.95
EPS - Diluted* (GAAP)	(\$27.22)	(\$132.12)	(\$260.25)	(\$1.47)	(\$0.72)	(\$6.06)	(\$0.70)	(\$0.58)	(\$0.49)	(\$0.44)	(\$2.14)	(\$1.69)	(\$0.33)	\$0.48	\$2.10	\$3.67	\$4.58
Shares Outstanding - Basic (MM)	1.2	0.1	0.1	14.8	18.5	8.4	18.6	23.1	27.4	27.6	24.2	27.9	28.7	29.3	29.9	30.5	31.1
Shares Outstanding - Diluted (MM)	-	-	-	20.3	21.0	10.3	21.1	25.6	29.9	30.1	26.7	30.4	31.2	31.8	32.4	33.0	33.6

Dalbavancin - Revenues	2011A	1Q12A	2Q12A	3Q12A	4Q12A	2012A	1Q13E	2Q13E	3Q13E	4Q13E	2013E	2014E	2015E	2016E	2017E	2018E	2019E
Dalbavancin - US							-	-	-	-	-	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	4Q12A	2012A	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											2856%	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													-8%	9%	24%	31%	34%

Source: Company reports and RBC Capital Markets estimates.



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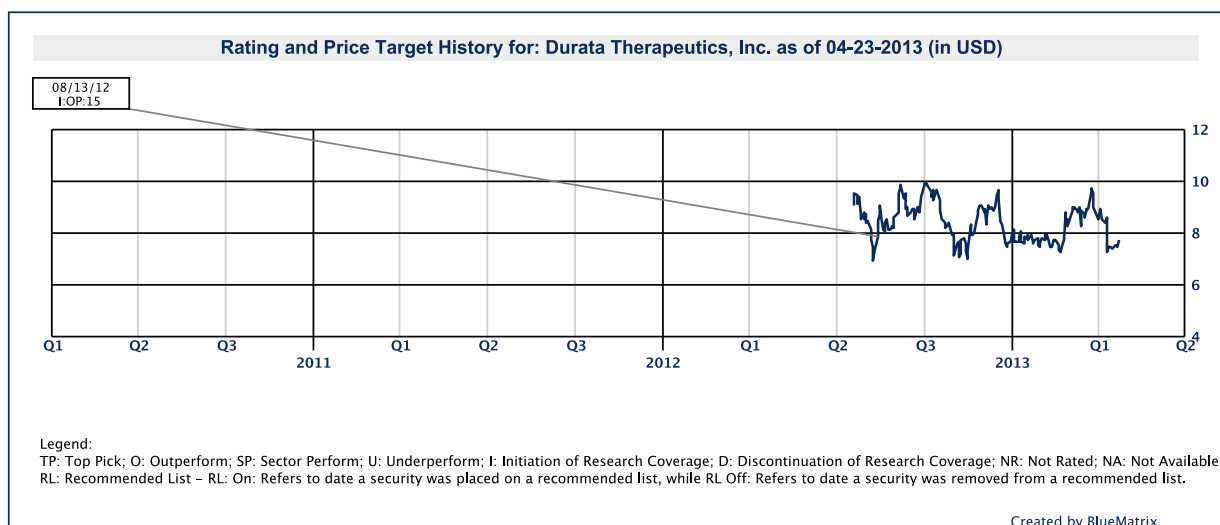
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