

May 9, 2013

Durata Therapeutics, Inc.

Dalbavancin Appears On Track For US And EU Regulatory Filings In 2013

Our View: Dalbavancin is a de-risked and differentiated, long-acting antibiotic where even niche market share, assuming approval, could beat Street expectations and lead to significant upside.

Key Points:

DRTX continues to make progress towards dalbavancin NDA and MAA filings in 2013 and US approval in 2014. We believe it is an attractive opportunity as even limited commercial success could result in significant upside. There is low clinical and regulatory risk with pivotal studies being positive and an SPA. The next perceived hurdle, assuming approval, is commercial risk where investor expectations remain very cautious regarding commercial success. Currently, DRTX owns dalbavancin outright, which leaves open the opportunity for partnering or selling dalbavancin as well. Pro forma net cash per share is ~\$3/share

Dalbavancin NDA and MAA filings on track. An NDA is expected around mid-2013 and an MAA is to follow by YE:13. The review timeline in the US could be as tight as 8 months given that dalbavancin was designated a QIDP. We estimate a PDUFA date could be around Feb.-Apr. depending upon when the NDA is filed.

Commercial prep underway as review could be speedy. DRTX estimates roughly 100 US sales reps and 130 selling professionals. Approval is possible in 1H:14. Current plans are to market dalbavancin in US and possibly partner for EU and Asia. Currently we assume a partnership outside the US around YE:13.

Expect detailed data on Phase III studies later in 2013. Details from previously top-lined positive Phase III studies will be presented at medical meetings (possibly ICACC in Sep. and IDSA in Oct.). Planned studies include a pediatric pK study, completion of the bone penetration study, a bronchoalveolar lavage study, with results expected in 2013 and 2014. A Phase II/III pediatric osteomyelitis study could also begin in 2014 pending FDA discussion.

Even a niche opportunity could lead to significant upside. DRTX estimates patients eligible for dalbavancin could be 10-50% of total market. 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 1-5%.

1Q:13 financial results and guidance. Higher expenses drove a loss of (\$0.86) vs. RBC at (\$0.70). Guidance is for lower R&D expenses in 2013. Key metric is cash which we estimate is ~\$100M or \$3.76/share (~\$3/share net of debt). While our tax assumptions remain conservative, DRTX reiterated tax rate could be teens 2-years post launch given its corporate structure.

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Outperform

Speculative Risk

NASDAQ: DRTX; USD 7.08

Price Target USD 15.00

WHAT'S INSIDE	
☐ Rating/Risk Change	☐ Price Target Change
☐ In-Depth Report	☑ Est. Change
☐ Preview	✓ News Analysis

Scenario Analysis*

4	Downside Scenario	Current Price	Price Target	Upside Scenario	
	2.00	7.08	15.00	21.00	—
	↓ 72%		† 112%	† 197%	

*Implied Total Returns

Key Statistics

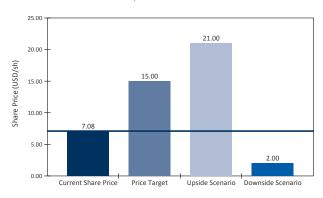
Shares O/S (MM):	26.6	Market Cap (MM):	188
Dividend:	0.00	Yield:	0.0%

RBC Estimates

FY Dec Rpt EPS	2012A (7.48)	2013E (2.36)	2014E (1.71)	
Prev.		(2.14)	(1.69)	
Revenue (MM)	0.0	1.3	47.8	
Rpt EPS	Q1	Q2	Q3	Q4
2012	(132.12)A (260.25)A	(1.47)A	(0.72)A
2013	(0.86)A	(0.64)E	(0.51)E	(0.44)E
Prev.	(0.70)E	(0.58)E	(0.49)E	
Revenue (MM)				
2012	0.0A	0.0A	0.0A	0.0A
2013	0.0A	0.0E	0.0E	1.3E
All values in USD unles	s otherwise noted	d.		

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: \$2/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 to 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 potential risk-reward as being highly favorable and expect value to increase pending positive data from the Phase III studies.



1Q:13 Financial Results: Actual vs. Estimated

(\$ in millions, except per share)	Actual	Estimated	Variance
Fiscal Year Ends December			
Total Revenues	-	-	-
Cost of goods sold	-	-	-
Research & development	11.1	9.2	1.9
SG&A	4.1	3.7	0.4
Contingent consideration	-	-	-
Total Operating Expenses	15.4	13.1	2.3
Operating Income (Loss)	(15.4)	(13.1)	(2.3)
Interest income	-	0.2	(0.2)
Interest expense	(0.1)	(0.1)	0.0
Total Other Income (expense)	(0.1)	0.0	(0.1)
Income before Tax	(15.5)	(13.1)	(2.5)
Provision for taxes	0.2	-	0.2
Net Income (Loss)	(15.8)	(13.1)	(2.7)
EPS - Basic (GAAP)	(\$0.86)	(\$0.70)	(\$0.16)
EPS - Diluted* (GAAP)	(\$0.86)	(\$0.70)	(\$0.16)
Shares Outstanding - Basic (MM)	18.4	18.6	(0.3)
Shares Outstanding - Diluted (MM)	20.9	21.1	(0.3)

Source: Company reports and RBC Capital Markets estimates.

Upcoming Events

Timing	Expected News Flow	Program
1H:13	Initiate bone penetration study	Dalbavancin
Mid 2013	File NDA	Dalbavancin
Mid 2013	Second Phase III trial in abSSSI	Competitor: MDCO Oritavancin
2H:13	File MAA	Dalbavancin
Sep. / Oct. 2013	Detailed Phase III data at ICACC or IDSA	Dalbavancin
2013	Phase I osteomyelitis results	Dalbavancin
2013	Initiate lung penetration study	Dalbavancin
2013/2014	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		
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Source: Company reports and RBC Capital Markets estimates.

Products and Pipeline

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

Source: Company reports.

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 $^{\sim}5\%$, 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 takeout.

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 outpatient 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.



Adnan Butt (415) 633-8588 Durata Therapeutics (Nasdaq: DRTX)

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Annual and Quarterly Income Statement																Adnan.Butt@	≬rbccm.com
(\$ in millions, except per share)																	
Fiscal Year Ends December	2011A	1Q12A	2Q12A	3Q12A	4Q12A	2012A	1Q13A	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	9.4	51.7	11.1	10.0	9.2	8.7	39.0	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	4.1	4.2	4.3	4.3	16.8	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	13.3	62.6	15.4	14.4	13.7	13.2	56.7	94.2	121.2	145.5	178.0	200.7	221.8
Operating Income (Loss)	(35.6)	(8.3)	(19.2)	(21.8)	(13.3)	(62.6)	(15.4)	(14.4)	(13.7)	(12.0)	(55.4)	(46.4)	(5.7)	27.1	106.3	187.6	235.8
Interest income	0.0	0.0	0.0	0.0	0.0	0.0	-	0.2	0.2	0.3	0.7	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	(0.1)	(0.3)	(0.2)	(0.1)	(0.7)	(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)	(15.5)	(14.7)	(13.9)	(12.1)	(56.1)	(47.2)	(9.5)	23.4	104.4	186.1	236.6
Provision for taxes	(2.5)	-	-	-	-	-	0.2	-	-	-	0.2	-	-	8.2	36.5	65.1	82.8
Net Income (Loss)	(33.0)	(8.3)	(19.2)	(21.8)	(13.3)	(62.5)	(15.8)	(14.7)	(13.9)	(12.1)	(56.4)	(47.2)	(9.5)	15.2	67.8	121.0	153.8
EPS - Basic (GAAP)	(\$27.22)	(\$132.12)	(\$260.25)	(\$1.47)	(\$0.72)	(\$7.48)	(\$0.86)	(\$0.64)	(\$0.51)	(\$0.44)	(\$2.36)	(\$1.71)	(\$0.33)	\$0.52	\$2.29	\$4.01	\$5.00
EPS - Diluted* (GAAP)	(\$27.22)	(\$132.12)	(\$260.25)	(\$1.47)	(\$0.72)	(\$6.06)	(\$0.86)	(\$0.64)	(\$0.51)	(\$0.44)	(\$2.36)	(\$1.71)	(\$0.33)	\$0.48	\$2.12	\$3.70	\$4.62
Shares Outstanding - Basic (MM)	1.2	0.1	0.1	14.8	18.5	8.4	18.4	22.8	27.2	27.3	23.9	27.7	28.4	29.0	29.6	30.2	30.8
Shares Outstanding - Diluted (MM)	-	-	-	20.3	21.0	10.3	20.9	25.3	29.7	29.8	26.4	30.2	30.9	31.5	32.1	32.7	33.3
Dalbavancin - Revenues	2011A	1Q12A	2Q12A	3Q12A	4Q12A	2012A	1Q13A	2Q13E	3Q13E	4Q13E	2013E	2014E	2015E	2016E	2017E	2018E	2019E
Dalbavancin - US								_	7		- 1	42.8	102.8	155.9	259.8	357.7	425.7
Dalbavancin - EU							- (J -			-		51.4	78.0	129.9	178.9	212.8
Dalbavancin Royalties - EU								7			_		7.7	11.7	19.5	26.8	31.9
Margin Analysis	2011A	1Q12A	2Q12A	3Q12A	4Q12A	2012A	1Q13A	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											3119%	61%	29%	22%	15%	12%	12%
Sales, general & administrative											1344%	121%	63%	51%	36%	28%	25%
Operating margin											l		-5%	16%	37%	48%	52%
Tax rate											0%	35%	35%	35%	35%	35%	35%
Net margin	1 1												-8%	9%	24%	31%	34%

Net margin
Source: Company reports and RBC Capital Markets estimates.

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