



COMPANY UPDATE | COMMENT

NOVEMBER 26, 2012

Durata Therapeutics, Inc. (NASDAQ: DRTX)**Expect Positive Data From First Phase III By YE:12****Outperform
Speculative Risk**

Price:	8.08	Price Target:	15.00
Shares O/S (MM):	18.4	Implied All-In Return:	86%
Dividend:	0.00	Market Cap (MM):	149
		Yield:	0.0%

Event

Results from two dalbavancin Phase III studies expected YE:12 and early 2013, respectively; odds of being positive are high

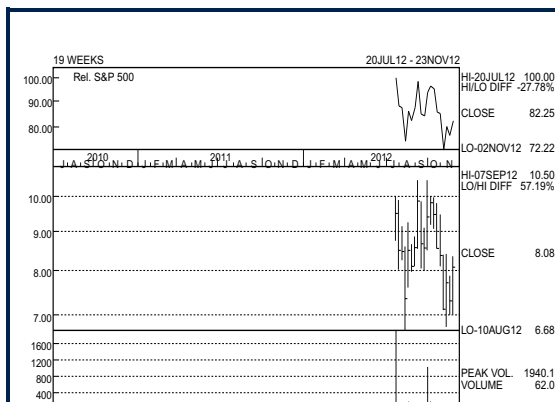
Investment Opinion

Data from the first Phase III study of dalbavancin for the treatment of abSSSI could be out in December with the second study reporting in early 2013. We believe risk/reward is favorable with 85%+ probability of success. DRTX retains all rights to dalbavancin (patent/exclusivity protected through 2023), potentially one of the first long-acting antibiotics, making it an attractive candidate for opportunistic partnership or acquisition. DRTX ended 3Q:12 with ~\$3.35/share in cash, sufficient through both Phase III data sets. Shares are undervalued at an enterprise value of \$71M, in our view.

- **Expect Phase III trials to work (85%+ probability).** Despite differences, prior Phase III studies reflect positively on the ongoing studies. Two of three prior studies exceeded the 10% non-inferiority margin hurdle, and cure rate in all three exceeded the 85% efficacy assumed for current Phase IIIs. Importantly, **reanalysis of one Phase III with new FDA criteria where data was available was promising.**
- **Prior Phase III data was positive, although trials and statistics were somewhat different.** Three different Phase III trials were run with three different comparators in various settings:
 - **Uncomplicated skin/skin structure infections (uSSSI).** Day 28 cure rate – dalbavancin 89.1% vs. cefazolin 89.1%.
 - **Complicated skin/skin structure infections (cSSSI).** Day 28 cure rate – dalbavancin 88.9% vs. linezolid 91.2%.
 - **With new FDA criteria, cessation of lesion spread and resolution of fever** – dalbavancin 83.2% vs. linezolid 87.1% of linezolid patients.
 - **For patients with a 75 cm² or bigger lesion (33% of evaluable)** – dalbavancin 76.3% vs. linezolid 78.8%.
 - **Suspected Methicillin Resistant Staphylococcus Aureus (MRSA).** Day 28 cure rate – dalbavancin 89.9% vs. vancomycin 86.7%.
- **Timeline to data and NDA.** We expect results from the first Phase III study by YE:12 and from the second study in early 2013. We expect an NDA in 1H:13, followed by an MAA, and U.S. approval in 1Q:14 and EU approval in 2H:14.
- **Compelling commercial argument.** Dalbavancin could be the first long-acting antibiotic targeting abSSSI on the market with the potential to increase convenience, compliance, and lower healthcare costs.

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

For Required Conflicts Disclosures, see Page 7.

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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.

Details

Prior Phase III Data Was Positive, Although Trials and Statistics Were Slightly Different

Vicuron, the original sponsor, ran three different Phase III trials with three different comparators (cefazolin, linezolid, vancomycin) in three settings (uSSSI, cSSSI, MRSA):

- **Uncomplicated skin and skin structure infections (uSSSI).** In uncomplicated skin infections, Vicuron ran a 553-patient study randomizing patients 2:1 to either dalbavancin or cefazolin. Dosing occurred over 7–14 days. The primary endpoint was clinical cure at test of cure (day 28) in clinically evaluable patients. The clinical cure rate was 89.1% for dalbavancin and 89.1% for the comparator. The trial was designed with a 12.5% non-inferiority margin, but the lower end of the confidence interval was -6.8%, which means the trial would have met the more stringent 10% non-inferiority margin the FDA currently accepts.
- **Complicated skin and skin structure infections (cSSSI).** In complicated skin infections, Vicuron ran a 853-patient study randomizing patients 2:1 to dalbavancin or linezolid. Patients in the linezolid arm were permitted to switch from IV to oral on day three if certain criteria were met. Dosing occurred over 14 days. The primary endpoint was clinical cure at day 28 among the clinically evaluable patients. The clinical cure rate was 88.9% for dalbavancin and 91.2% for linezolid. The trial was designed with a 12.5% non-inferiority margin, but the lower end of the confidence interval was -7.3%, which means the trial would have met the more stringent 10% non-inferiority margin the FDA currently accepts.
- **Suspected Methicillin Resistant Staphylococcus Aureus (MRSA).** Vicuron ran a smaller 156-patient trial in both complicated and uncomplicated skin infection where MRSA was suspected or confirmed. Patients were randomized 2:1 to dalbavancin or vancomycin. Dosing occurred over 14 days for patients with cSSSI and over 7–14 days for patients with uSSSI. The primary endpoint was clinical cure at day 28. The clinical cure rate was 89.9% for dalbavancin and 86.7% for vancomycin. The trial was designed with a very wide 20% non-inferiority margin, and the lower end of the confidence interval was -13.0%. The wide confidence interval reflects the relatively small trial size. A larger trial would likely have had a margin of less than 10%, especially because the point estimate was actually higher with dalbavancin compared to vancomycin (89.9% vs. 86.7%).

Completed Dalbavancin Phase III Trials

	VER001-8	VER001-9	VER001-16
Number of patients	553 (2:1)	854 (2:1)	156 (2:1)
Indication	uSSSI	cSSSI	uSSSI/cSSSI with suspected or confirmed MRSA
Comparator	Cefazolin	Linezolid	Vancomycin
Results (evaluable)			
Dalbavancin	89.1%	88.9%	89.9%
Comparator	89.1%	91.2%	86.7%
95% CI	-6.8, +6.8	-7.3, +2.9	-13.0, +19.4
Results (ITT)			
Dalbavancin	76.0%	76.5%	86.0%
Comparator	75.8%	82.7%	65.3%
95% CI	-7.7, +8.2	-12.0, -0.3	+4.3, +37.0

Ongoing Phase IIIs

DISCOVER 1	DISCOVER 2
556 (1:1)	740 (1:1)
ABSSSI	ABSSSI
Vancomycin	Vancomycin

SSSI - skin and skin structure infection, u uncomplicated, c complicated

Source: Company reports and RBC Capital Markets.

Reanalysis of the Phase III Trial with Updated FDA Guidance Demonstrated Encouraging Efficacy

The VER001-9 trial testing dalbavancin in complicated skin infections was re-analyzed based on the new draft guidelines. The new analysis included subgroups based on new entry criteria (lesion size >75cm²) as well as the new endpoints (cessation of lesion spread and absence of fever at 48–72 hours). The results are encouragingly consistent, although the statistical power diminishes with fewer patients in this analysis (220 patients vs. an overall 660 patients in study VER001-9).

- For the entire clinically evaluable population (the original primary analysis population), cessation of lesion spread and resolution of fever occurred in 83.2% of dalbavancin patients and 87.1% of linezolid patients. Among the smaller subset of patients with a 75 cm² or bigger lesion (one-third of the evaluable population), the new primary endpoint was met in 76.3% of dalbavancin patients and 78.8% of linezolid patients.

Re-Analysis of VER001-9 with Updated FDA Guidance

	Dalbavancin	Linezolid	95% CI	Comment
Original response criteria				
Clinical response (d28)	88.9%	91.2%	-7.3, +2.9	
# of pts total	434	226		
New response criteria*				
Clinically evaluable	83.2%	87.1%	-10.6, +2.9	
# of pts total	434	226		
Target population**	76.3%	78.8%	-14.8, +9.7	
# of pts total	135	85		220 patients only

* cessation of spread and absence of fever; ** >75 cm² lesions

Source: Company reports and RBC Capital Markets.

FDA Guidance Based Criteria Used in New Phase III Program

The DISCOVER program compare dalbavancin to vancomycin in two Phase III studies. The primary endpoint is cessation of lesion spread and absence of fever at 48–72 hours with a non-inferiority margin of 10%. Durata has: 1) reanalyzed its prior Phase III trials using the new endpoint and showed that they would have been close to success; 2) run a Phase II trial testing inter and intra reader comparability in their Phase III lesion size measurement methodology; and 3) secured an SPA for each Phase III trial to ensure buy-in from the FDA on the method of data collection.

- **Type of infections.** Major abscess, surgical site infection, traumatic wound infection or cellulitis.
- **Infectious agent.** Suspected or confirmed Gram-positive.
- **Clinical features.** Lesion size of at least 75 cm²; at least two local signs and symptoms and at least one systemic sign of infection.
- **Prescribed clinical treatment.** Requires a minimum of three days of intravenous therapy.
- **Clinical response.** Clinical response is defined as the cessation of the spread of the lesion (redness, edema, and/or induration) at 48–72 hours after enrollment *and* resolution of fever. **Response evaluation.** The best method for measurement of lesion size for the purpose of evaluating the primary endpoint has not been established. Companies are utilizing rulers (width/length measures), tracing tools, photography, and image analysis, all to capture the change in lesion size over time.
- **Non-inferiority margin.** For the purpose of defining non-inferiority, the FDA has accepted a 10% non inferiority margin as acceptable. The original Phase III trials used a larger 12.5% non-inferiority margin in complicated and uncomplicated skin infections, although the actual results were within a 10% margin. In the original MRSA study, the non-inferiority margin was 20%, as that trial was relatively small (156 patients vs. 558 and 854 patients in the other two Phase III trials).

Dalbavancin's Regulatory History

The original NDA for dalbavancin was filed in December 2004, prior to the acquisition of Vicuron by Pfizer for \$1.9 billion in June 2005. Pfizer ultimately received three approvable letters before finally withdrawing the NDA due to a change in priorities away from anti-infectives and the FDA's shifting criteria on approval requirements for abSSSI. Dalbavancin was not alone in its troubles with the FDA. At that time, several other antibiotics ran into delays, rejections, and multiple setbacks, including oritavancin (Intermune; now owned by the Medicines Company), telavancin (Theravance), and others. The fundamental problem was a changing view on how to run Phase III trials for skin infection drugs, which were later described in a draft guidance document, which has formed the basis for most of these drugs to re-enter Phase III development.

Two of Three Approvable Letters Resolved

- **Approvable Letter #1 – Initial CMC issues.** The FDA raised CMC issues related to the stability of intermediates in the synthesis pathway and wanted more detail on release criteria and HPLC testing methodologies. Outcome: Pfizer successfully resolved the manufacturing issue.
- **Approvable Letter #2 – More manufacturing issues.** In addressing the first approvable letter, the manufacturing team at Pfizer (not the same people that originally submitted the NDA at Vicuron) observed unacceptable levels of endotoxin in the commercial lots. This was not an issue raised by the FDA, but Pfizer had some concerns and called it to the attention of the FDA, which caused the second approvable letter. Outcome: Pfizer successfully resolved the manufacturing issue.
- **Approvable Letter #3 – Questions regarding the Phase III trial.** After spending one year resolving the endotoxin issue and responding to the first two approvable letters, the FDA came back with questions regarding the non-inferiority margin used in the Phase III. Vicuron had used a 12.5% margin, but the data came out within a tighter 10% margin. The FDA wanted Pfizer to provide justification for its non-inferiority margin. Outcome: In September 2008, Pfizer withdrew its NDA and MAA for dalbavancin and began discussions around another Phase III trial. Following an internal portfolio review, Pfizer opted to drop dalbavancin and took a



\$560 million tax write-off for the acquisition.

- **EU issue with MAA – Questions regarding robustness of Phase III.** In addition, the EMA questioned whether a single pivotal trial in cSSSI provided sufficient robustness and whether the patients were sick enough to support the targeted indication. Outcome: Pfizer withdrew its MAA and considered conducting a second pivotal study in cSSSI patients.

Timeline to data and NDA. We continue to expect results from the first Phase III study by YE:12 and from the second study in early 2013. DISCOVER 1 completed enrollment in September, so data around December is possible while DISCOVER 2 completed enrollment in October so data could be available in early 1Q:13 although it is a larger study. DRTX has previously maintained the guidance of filing an NDA in 1H:13, which would be followed by an MAA in the EU. We currently forecast U.S. approval in 1Q:14 and EU approval in 2H:14.

Dalbavancin potential in other indications. Preliminary plans are in place to evaluate dalbavancin's ability to penetrate the bone in a small study starting around YE:12/early 2013. A study to evaluate dalbavancin's penetration into the lungs could also begin to assess its ultimate potential in pneumonia. Finally, the most direct path forward could be a pivotal pediatric osteomyelitis study. We expect development to be measured with positive data being upside as the focus stays on ongoing Phase III trials.

Compelling commercial argument. 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.

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 \$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.

Required Disclosures

Conflicts Disclosures

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Ratings

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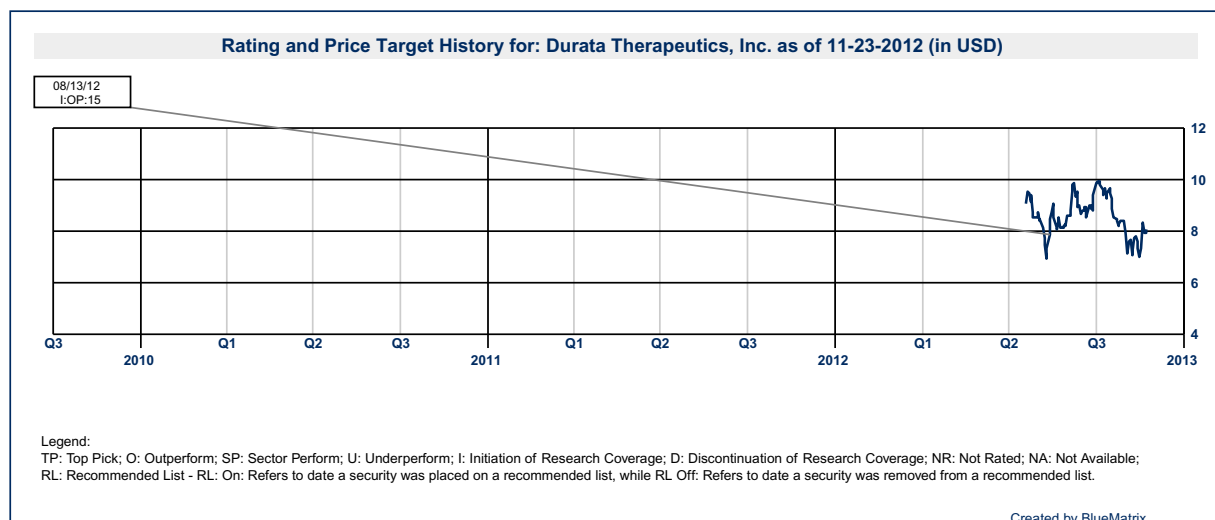
Above Average Risk (AA): Volatility and risk expected to be above sector; below average revenue and earnings predictability; may not be suitable for a significant class of individual equity investors; may have negative cash flow; low market cap or float.

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Distribution of Ratings RBC Capital Markets, Equity Research				
Rating	Count	Percent	Investment Banking Serv./Past 12 Mos.	
			Count	Percent
BUY[TP/O]	785	50.62	259	32.99
HOLD[SP]	690	44.49	177	25.65
SELL[U]	76	4.90	8	10.53



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