Durata Therapeutics (DRTX)

Initiating Coverage with a $20 Price Target - Dalbavancin Not Just Skin Deep

- **We are initiating coverage of DRTX with an OUTPERFORM rating and $20/share price target.** We expect positive data from two acute bacterial skin and skin structure infection (abSSSI) Phase III studies of Durata's IV antibiotic dalbavancin (late 2012 and early 2013) will lead to H1:13 FDA NDA, and H2:13 EMA MAA filings and H1:14 FDA and H2:14 EMA approvals, with the drug achieving peak sales of ~$825 million in the US in 2027 and ~$110 in 2023 ROW.
- **Safety, potency and a convenient once-weekly administration schedule underpin our positive outlook for dalbavancin.** Very low MIC90's against the relevant pathogens, no sentinel safety observations and the potential for patients to be treated with thirty-minute infusions one week apart will, we believe, contribute to dalbavancin's commercial success in patients with suspected or confirmed resistant or sensitive serious gram-positive infections.
- **Based upon dalbavancin's potency and convenient once-weekly administration schedule, we view the drug as ideally suited to treat osteomyelitis.** Osteomyelitis is estimated to occur in approximately 200,000 patients per year in the U.S. and frequently requires many weeks of therapy to ensure cure and prevent recurrence.
- **Three prior successful Phase III studies, and a near-complete FDA review have wrung most of the development and regulatory risk out of dalbavancin, in our opinion.** Dalbavancin has demonstrated non-inferiority to its comparators in three prior Phase III studies and had nearly completed a full FDA review prior to the application being withdrawn. With Phase III results under the new abSSSI development guidance as the primary gating item to approval, we view dalbavancin as exceptionally risk-reduced.
- **Initiating coverage of DRTX with an OUTPERFORM rating and $20 price target.** Our $20 share price target is derived from the net present value (25% discount rate) of our estimate of profits and losses for DRTX through our projection of the end of dalbavancin's exclusivity period in the U.S. and EU in 2027 and 2023, respectively, with no terminal value and cash per share in 12 months.

FYE Dec	2011A	2012E			2013E		
REV	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	N/A	$0.0A		N/AA	$0.0E		$0.0E
Q2 Jun	N/A	$0.0A		0.0A	$0.0E		0.0E
Q3 Sep	N/A	$0.0E		0.0E	$0.0E		0.0E
Q4 Dec	N/A	$0.0E		0.0E	$0.0E		2.5E
Year*	**N/A**	**$0.0E**		**0.0E**	**$0.0E**		**$1.2E**
Change	--	--			--		
	2011A	**2012E**			**2013E**		
EPS	**ACTUAL**	**CURR.**	**PREV.**	**CONS.**	**CURR.**	**PREV.**	**CONS.**
Q1 Mar	N/A	($0.71)A		N/A	($0.34)E		($1.16)E
Q2 Jun	N/A	(1.43)A		N/A	(0.25)E		(1.01)E
Q3 Sep	N/A	(0.66)E		(1.09)E	(0.20)E		(0.41)E
Q4 Dec	N/A	(0.44)E		(0.87)E	(0.25)E		(0.24)E
Year*	**N/A**	**($3.09)E**		**($4.92)E**	**($1.03)E**		**($2.21)E**
P/E	N/	--			--		
Change	--	--			67%		

Consensus estimates are from Thomson First Call.
** Numbers may not add up due to rounding.*

September 10, 2012

Price
$9.71

Rating
OUTPERFORM

12-Month Price Target
$20

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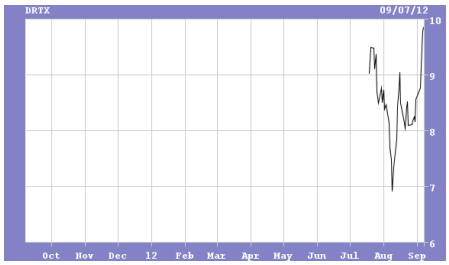
Company Information	
Shares Outst (M)	12.1
Market Cap (M)	$117.5
52-Wk Range	$6.68 - $10.50
Book Value/sh	$0.38
Cash/sh	$5.52
Enterprise Value (M)	$50.7
LT Debt/Cap %	0.0
Cash Burn (M)	$37.7
Current Cash (M)	$66.8

Company Description

Durata was formed to acquire, complete the development of, and commercialize dalbavancin an IV antibiotic with once weekly IV administration.



Source: Thomson Reuters

Investment Thesis

Durata's potent IV once-weekly gram-positive dalbavancin will, we believe, garner meaningful market share in patients with serious skin and skin structure infections (abSSSI) and osteomyelitis, a serious and growing, difficult-to-treat infection that requires multiple weeks of antibiotic therapy. Frequently, physicians treating patients with serious gram-positive infections are faced with choosing an appropriate therapy to overcome an infection not responding to front-line treatment, or, that permits a patient to be discharged and receive the remainder of their therapy outside of the institutional setting. The growth in use of Cubist's (CBST: OUTPERFORM) CUBICIN in the outpatient setting suggests that there is a strong level of demand for a potent IV antibiotic that can be administered outside of the hospital. We believe dalbavancin, with similar potency to CUBICIN, augmented by a convenient once-weekly administration schedule will further grow this segment of the marketplace. Oritavancin, another antibiotic in development with potent activity against gram-positive bacteria is a potential participant in this marketplace however, we believe that this drug's permanent accumulation in the liver, potential to induce septic shock via release of bacterial contents, poor biodistribution and absence of clarity around the potential benefit or risk associated with retreatment will be significant barriers to the mainstream adoption of this product.

We believe Dalbavancin is significantly risk-reduced having already successfully achieved non-inferiority in 3 Phase III clinical trials and completed a substantive review of an NDA at FDA. Only confirmatory Phase III study results with a new endpoint in acute bacterial skin and skin structure infections remain the gating item for approval. We expect that positive Phase III data from the ongoing DISCOVER 1 and 2 clinical trials (late 2012 and early 2013) will lead to H1:13 FDA NDA and H2:13 EMA MAA filings and H1:14 FDA and H2:14 EMA approvals. Dalbavancin's safety, tolerability, potent cidality against important resistant and sensitive gram-positive pathogens, absence of existing or emergent resistance in the relevant pathogens, and convenient once-weekly administration schedule underpin what we believe is a significant opportunity to capture market share and further drive growth of the outpatient IV anti-staph market. With $86.3 million in cash following the recent IPO financing, DRTX is well positioned to complete the development of dalbavancin and launch the product in the U.S. with a focused specialty sales force.

It is estimated by the market research firm Arlington Medical Resources (AMR) that there are 35 million days of IV antibiotic therapy for patients at risk of MRSA acute bacterial skin and skin structure (abSSSI) infections and that vancomycin is used for approximately 7.2 million days of treatment in the abSSSI setting. Osteomyelitis is estimated to occur in approximately 200,000 patients per year in the U.S. and with 2-6 weeks of therapy recommended, this setting potentially represents another 7 million days of therapy. Physicians' familiarity with, and vancoymycin's low drug acquisition cost underpin its dominant market share, however its Q6 or Q12 hour IV administration schedule typically necessitates treatment in the in-patient setting. The incredible level of use of the drug since the widespread emergence of methicillin-resistant Staphylococcus aureus has not, as is typical, led to the emergence of relevant levels of frank antibiotic resistance to vancoymycin. However, typical antibiotic susceptibility testing is not predictive of clinical success and treatment failure is common. The success of Cubist's rapidly bactericidal, once-daily IV antibiotic CUBICIN, which we estimate will achieve sales of $813 million this year (half of which are anticipated in the outpatient setting), and exceed $1 billion in 2015 is a clear indicator of the need in the marketplace for additional potent therapies, and that the convenience of once-daily IV administration is facilitating IV therapy outside of the institutional setting.

Valuation Summary and Risks

Our $20 share price target is derived from the net present value (NPV, 25% discount rate) of our estimate of profits and losses for DRTX through our projection of the end of dalbavancin's exclusivity period in the US and EU in 2027 and 2023, respectively, with no terminal value and cash per share in 12 months. Our estimates suggest that the NPV of taxed profits until YE:2027 to Durata at a 25% discount rate yield a $18/share price target and we add $1/share for cash in one year. We project that dalbavancin will achieve peak US sales of $825 million in 2027 the last year of exclusivity (including a five-year exclusivity extension). We also see dalbavancin achieving Ex-US peak sales of $110 million in 2023 the last year of assumed exclusivity outside of the US. We anticipate that dalbavancin can achieve these with only moderate penetration in the abSSSI market of 4.2% at peak, in the diabetic foot ulcer market of 12% and in the osteomyelitis and joint infection market of 15% overall penetration.

Risks to our price target include; 1) dalbavancin to demonstrate non-inferiority ongoing Phase III abSSSI clinical trials, 2) commercial and launch risks, 3) regulatory risks and 4) risks to the IP estate of Durata and dalbavancin in the U.S. and ROW.

Exclusivity

Hatch-Waxman and new rules in the PDUFA-V (Prescription Drug Users Fee Act – 5) should see dalbavancin enjoy at least 10 years of exclusivity in the US and EU markets. The company also has intellectual property claiming the once-weekly dosing schedule that we project will provide protection through 2028 (patents expiring in 2023 with a full five years of Hatch-Waxman extension).

DURATA THERAPEUTICS COMPANY OVERVIEW

Durata was formed to acquire, complete the development of, and commercialize dalbavancin, an asset Pfizer acquired with its $1.9 billion Vicuron transaction in 2005. Dalbavancin was discovered by BioSearch Italia, in-licensed by Versicor (whose name was changed to Vicuron - NASDAQ - MICU), which was subsequently bought by Pfizer ($1.9 billion) in September 2005, primary for MICU's IV antifungal drug anidulafungin. With the sale of dalbavancin to Durata, Pfizer was able to recognize a $566 million write-down on the Vicuron asset, which had a favorable tax effect for the company.

Key Points

- Dalbavancin - the potency of an IV antibiotic with once-weekly IV administration offering the convenience of an oral therapy
- The convenient once-weekly IV administration schedule of dalbavancin may reduce the need for hospital admission to receive IV antibiotic therapy, or reduce the length of stay of patients admitted to hospital for serious skin and other infections
- Dalbavancin's convenient administration schedule and potency against the relevant pathogens make it potentially ideally suited for the treatment osteomyelitis, a serious and growing, difficult-to-treat infection that requires multiple weeks of antibiotic therapy
- Dalbavancin has already generated positive Phase III data in patients with serious skin infections, and had nearly completed its FDA review process prior to the adoption of changes in the endpoints that were considered suitable for approval – Phase III data from two new ongoing global studies being conducted under the Special Protocol Approval (SPA) process is expected late 2012 and early in 2013.
- Durata plans on commercializing dalbavancin in the US and Europe with its own specialized sales force
- Recent US legislation (GAIN Act) will, we believe, ensure that dalbavancin obtains at least 10 years of US market exclusivity (five years Hatch-Waxman, five years GAIN extension as a qualified infectious disease product) – Based on patents to 2023 and our belief that dalbavancin will be afforded the full five-year Hatch-Waxman extension, we assume market exclusivity in the US until 2028.

Durata's dalbavancin purchase from Pfizer

The company originally paid Pfizer $10 million for the worldwide, royalty-free (ex-Japan) rights to the drug (received a $6 million refund due to the requirement to conduct more than one additional Phase III trial) and owes Pfizer only a $25 million milestone payment upon the first commercial sale of the drug in the US or one of 5 major European markets. Durata may elect to defer the $25 million milestone for a period of 5 years with interest accruing at a 10% annual rate. With the sale of dalbavancin to Durata, Pfizer was able to recognize a significant asset write-down and resulting tax-benefit offset.

UPCOMING MILESTONES

Sept. 9-12	Interscience Conference on Antimicriobials and Chemotherapeutics (ICAAC, San Francisco). 3 DRTX presentations: 1. MIC susceptibility testing for dalbavancin, 2. ECG studies of dalbavancin in men and women, 3. Update of dalbavancin's activity in bacteria isolated in the US.
YE:12	Results of 960 patient first Phase III study of oritavancin (SOLO-1) in the abSSSI setting
YE:12	Top-line Phase III results for dalbavancin (DISCOVER 1) in the abSSSI setting
Q1:13	Top-line Phase III results for dalbavancin (DISCOVER 2) in the abSSSI setting
H2:12	Potential completion of enrolment in the second Phase III study of oritavancin (SOLO-2) in the abSSSI setting
H2:12	Potential re-partnering transaction for THRX of Vibativ (telavancin)
Mid:13	Potential EU MAA filing for dalbavancin in the abSSSI setting
Mid:13	Potential US NDA filing for oritavancin in the abSSSI setting with an anticipated 6 month review cycle
H1:13	Potential NDA filing with FDA for dalbavancin

Dalbavancin Is a Potent Agent Against the Relevant Gram-positive Bacteria

Dalbavancin is a semi-synthetic lipo glycopeptide derivative of the natural product A-40926 (produced by the actinomycete Non-omuria spp.) and belongs to the family of antibiotics including teicoplanin and oritavancin. The drug derives its antibacterial activity by inhibiting cell wall synthesis via the stable complex formation between its heptapeptide backbone and the D-Ala-D-Ala components of cell wall precursors. Dalbavancin and CUBICIN, despite their activity at the cell wall/membrane of bacteria, do not increase membrane permeability which can lead to the release of bacterial intracellular contents. Rapid disruption of bacterial membrane integrity is a potential dangerous consequence for a rapidly bactericidal antibiotic as it can lead to release of intracellular bacterial contents, including toxins, which may have unfavorable consequences to the host (sepsis). As newer antibiotics may find their first use in the salvage setting, a patient population with a potentially high disease burden (bacterial load), and in whom persistent infection has potentially already led to declining performance status, this aspect of the antibiotic activity is particularly important. The observation of increased sepsis and septic shock in patients treated with oritavancin may be due, in part, to that drug's effects on bacterial cell wall permeability.

Dalbavancin has potent activity against the relevant gram-positive pathogens with MIC(90) values of 0.06 mg/L for both methicillin-sensitive and resistant S. aureus. While there is a shared mechanism for bacterial resistance to dalbavancin and vancomycin (facilitated by a change to the expression of the enzyme which catalyzes cell wall construction to replace the D-Ala-D-Ala binding target with an unfavorable amino acid target for the drug), this characteristic is only frequently observed in enterococci (vancomycin-resistant enterococci or VRE – a pathogen more common in intra-abdominal infections). The VanA and VanB genes that drive this resistance are the most prevalent, although since VanB expression is not induced by dalbavancin, only VanA resistance, which is induced by glycopeptides drugs is clinically relevant. Of note, the very rare cases of vancomycin-resistant Staphylococcus aureus (VRSA) have the VanA gene. In vitro studies suggest that, like vancomycin, the potential to induce resistance to dalbavancin via a single step is exceedingly rare. Taken together, rapid potent bactericidal activity, and the absence of a single mutation to drive resistance suggest to us that the emergence of resistance to dalbavancin is unlikely.

Comparative MIC90 (µg/ml) of selected agents tested against worldwide clinical isolates (2002)

	S.Aureus (1,815) OX-S	S.Aureus (1,177) OX-R	β-hemolytic streptococci (234)	Viridans group streptococci (30) PCN-R
Dalbavancin	0.06	0.06	0.06	0.03
Teicoplanin	1	2		
Vancomycin	1	2	0.5	0.5
Oxacillin	S	R	PCN = 0.06	R
Linezolid	2	2	1	1

Source: Company Reports. Streit, et al. DMID 2004, p137

Serious Infections - The Clinical Problem

Serious skin infections require immediate treatment to prevent the potential spread of bacteria into the bloodstream and to distant sites, reduce the potential for irreversible tissue damage and to address systemic symptoms including fever, nausea and vomiting, the latter of which may impair the ability to tolerate oral medication. Clinical studies prove that a delay in appropriate antibiotic therapy has a direct impact on the duration of disease, length of stay in hospital and treatment outcome. As such, in the most ill patients, immediate treatment with antibiotic(s) via an intravenous route of administration ensures that adequate blood and tissue levels of the drug are achieved quickly.

Skin Infections are Common

Skin infections are common, and emergency room physicians are, for the most part, experienced at identifying those patients for whom in-patient care with an IV antibiotic is warranted. These include patients presenting with deep tissue infections, bacteremia and co-morbidities such as, for example, peripheral artery disease. Patients requiring intensive care or with cellulitis requiring surgical debridement or fascial biopsy and necrotizing fasciitis are clear candidates for admission.

It is estimated by the market research company Arlington Medical Research (AMR) that 84% of all acute bacterial skin and skin structure infections, and 94% of cellulitis are caused by gram-positive bacteria. Data from the 2009 National Hospital Ambulatory Medical Care Survey indicates that cellulitis and abscess were the primary diagnosis for patients in approximately 3.1 million emergency department visits. The 2010 National Hospital Discharge Survey (NHDS) indicates that skin and skin structure infections (ICD-9 681, 682) were the primary diagnosis in 1.24 million patients admitted to these institutions who received on average 4.4 days of therapy (for a total of 5.4 million days of in-patient treatment). A further 1.62 million patients whom were admitted for another primary diagnosis also received a diagnosis for skin and skin structure infections, according to the NHDS.

AMR estimates that there are approximately 7.2 million days of vancomycin therapy for patients with abSSSI and Durata's evaluation of AMR and other data suggests that there are approximately 35 million days of therapy with intravenous antibiotics in patients at risk of MRSA with abSSSI.

Beyond Skin Infections - Osteomyelitis is a Chronic, Serious, Difficult to Treat Infection

Osteomyelitis, a chronic infection of the bone, is estimated to occur in approximately 200,000 patients per year in the U.S. and with 2-6 weeks of therapy recommended, this setting potentially represents another 7 million days of therapy. We see dalbavancin as having a clear and significant opportunity in the osteomyelitis setting. S. aureus is the most common pathogen in acute and chronic osteomyelitis, as well as in bone and prosthetic joint infections. While prosthetic joint infections are relatively rare, occurring at a rate of 1-2% of knee and hip replacements, respectively, the total number of days of potential treatment due to these infections is potentially significant. According to the 2009 National Hospital Discharge Survey there were approximately 103 thousand hip, 621 thousand knee and 42 thousand full or partial shoulder replacements.

The incidence of adult osteomyelitis is increasing, primarily as a consequence of the epidemic of diabetes and the potential for these patients, who have poor circulation and reduced pain sensation, to develop serious foot ulcers that are often infected with S. aureus.

Dalbavancin's convenient once-weekly IV administration schedule avoids the need for a patient to have a PICC line in order to receive IV therapy, itself a potential source of infection. While oral therapy is certainly an option for some patients, persistent oral antibiotic therapy can disrupt intestinal flora, placing patients at risk of C. difficile.

Empiric Treatment

As a result of the 2-3 day interval between microbiology sampling and results, physicians often begin "empiric" treatment with multiple antibiotics, the theory being that at least one of the drugs will be effective against the pathogen. Once microbiology is in hand, the inappropriate agents are discontinued and there's also the potential to switch to different appropriate drug based upon other treatment considerations (bacterial susceptibility, anticipated duration of treatment, potential adverse drug/drug or drug/patient interactions, issues of convenience and potential for outpatient receipt of therapy).

In order to choose the most correct antibiotics as part of the up-front therapy, physicians evaluate the cause and location of the infection (with human or animal bites, and facial areas potentially at greater risk for gram-negative infections, and infections or abscess in the groin/anal/rectal area at higher risk of and infection due to enterococci), the patients' history, with prior association with a healthcare institution putting them at greater risk of infection due to a resistant pathogen.

Empiric Failure – Time to Switch

Historically, infectious disease physicians have been averse to switching antibiotic treatment outside of a treatment failure. Simply put, the risk of an unfavorable drug/patient interaction is doubled with the first change in therapy. The success of CUBICIN (see our discussion below) along with the way treatment guidelines outline the appropriate use of vancomycin suggest to us that with vancomycin, there's an evolving behavior pattern that's seeing earlier and more frequent switching to this potentially more efficacious/convenient/total-cost saving therapy.

Slotting Dalbavancin into the Treatment of Patients with Serious Gram-Positive Infections

MRSA Drugs

The most potent IV MRSA drugs in the US marketplace today include, vancomycin (generic), CUBICIN (daptomycin - Cubist), Tygacil (tygecycline - Pfizer), Teflaro (ceftaroline – Forest), Vibativ (telavancin - Theravance) and Zyvox (linezolid – Pfizer).

Vancomycin is clearly showing its age, although despite its unpredictable efficacy, the familiarity and drug acquisition cost continue to see this as the market leader for front-line treatment coverage of MRSA. The opportunity for new entrants is to motivate physicians and healthcare providers broadly to switch earlier from vancomycin, potentially to an agent that allows for discharge, and may yield a more predictable outcome.

Tygacil, while having MRSA coverage, is more commonly used in patients with suspected VRE.

Teflaro appears to be positioned in "no man's land" without the perception of potency for MRSA to be premium priced like CUBICIN, and too expensive to compete with vancomycin.

Vibativ is best described as the perfect MRSA drug for healthy young men, due to its risk for women who may be pregnant, and potential for renal toxicity, making elderly and diabetic patients less suitable to receive the drug.

Pfizer's Zyvox has been successful primarily as one of the only oral treatment options for MRSA. Rare but serious neuropathies (optic) and predictable hematologic toxicity with treatment beyond 2 weeks limit this drug's potential in settings such as osteomyelitis.

The companies that are developing drugs that could also compete in the resistant (MRSA) serious gram-positive infection space include The Medicines Company (oritavancin – semi synthetic glycopeptide), Trius Therapeutics (tedizolid - oxazolidinone), Rib-X (delafloxacin – fluoroquinolone; radezolid - oxazolidinone), Cempra (fusidic acid), Furiex (JNJ-Q2 - fluoroquinolone), Nabriva/Forest (BC-3781 – pleuromutilin), Paratek (omadacycline - tetracycline), Polymedix (PMX-300063 - defensin) and Tetraphase (TP-434 - tetracycline).

With the exception of oritavancin, none of the MRSA drugs mentioned above offer the potential for infrequent IV administration. Oritavancin, like dalbavancin, is a semi-synthetic lipo glycopeptide. The drug is currently in two Phase III abSSSI studies and has had a long and storied history of ownership, clinical and regulatory development.

We believe CUBICIN's reception and success in the market is informative to the market potential for dalbavancin.

CUBICIN's Launch – "The Switch" and Room for More Branded Premium-Priced Antibiotics

The prevalence of methicillin-resistant gram-positive Staphylococcus aureus and its leading role as the cause of skin and skin structure infections necessitates that empiric therapy have MRSA coverage. It's obvious, with the annual unit volume of vancomycin, CUBICIN and Zyvox, that the existing MRSA marketplace, on a days-of-therapy basis, is significant, but small relative to the potential dollar opportunity if vancomycin is displaced by therapeutics with branded prices. This year, with just low-double-digit market share, CUBICIN sales are likely to exceed $800 million, 9 years from into the product's launch. We believe some of the characteristics of CUBICIN's success and challenges in the marketplace are of note as they may point to both opportunities and challenges for Durata's dalbavancin, and other entrants.

CUBICIN was launched by Cubist into the US marketplace in Q4:03. The drug, a novel lipopeptide, came into the market with a label restricted to skin and skin structure infections and was contraindicated in non-hematogenous pneumonia where the Phase III studies were not successful. While the failure of CUBICIN in pneumonia was explained by the drug's inactivation by lung surfactant, this did not overcome some perception that despite the promising in vitro cidality against the relevant gram-positive pathogens, the drug had only achieved clinical success in skin, a "less serious" setting. The drug's safety profile, when administered once daily, was favorable, with the muscle toxicity the only sentinel safety issue to be attentive to.

We note that at launch, broadly speaking, expectations for CUBICIN's peaks sales were muted as checks suggested physicians were comfortable with vancomycin for patients requiring IV therapy, or oral Zyvox for those with less serious skin and skin structure infections. Additional antibiotic dogma that new antibiotics from a novel class be held in reserve until resistance to existing therapies emerged further muted expectations as at that time (as is today), clinical isolates with resistance to vancomycin were exceptionally rare. We note that CUBICIN represented one of the first IV antibiotics that had garnered the attention of the Street, as most existing IV antibiotics, while successful in their own right, were generally slow-growing, less highly priced products in much larger enterprises.

Amongst the challenges Cubist faced at launch included obtaining formulary approval, which was often on a restricted basis (requiring an infectious disease physician consult), and in the northeastern U.S., formulary decisions were typically not completed until 6 months following the drug's introduction into the marketplace. Despite the high price of therapy on a drug acquisition cost basis, and the "undistinguished" label in skin (non-inferiority), CUBICIN use became widespread, with broad penetration into most of the important hospitals in the country, and sales ticked up quarter over quarter with the first full calendar year coming in at $58.6 million and second year doubling to $113.5 million (despite a shaky start with Q1:05 sales flat to Q4:04). Most CUBICN use was in the salvage setting, typically following treatment with vancomycin and potentially another second-line antibiotic, and market research by Cubist suggested that only half the use was in the on-label skin setting. In June 2005, the positive results from the Phase III endocarditis and bacteremia study confirmed the observations (that were by then, well appreciated in the infectious disease community) that CUBICIN was effective in the most seriously ill patients, and doses of 6 mg/kg QD were safe.

Subsequently, several observations are notable:

1) CUBICIN utilization in the outpatient setting has become a major component of demand, and driver of growth. Our checks suggest that the majority of this outpatient use is in patients who had previously been admitted to hospital.

2) There appears to be relative price insensitivity in the marketplace for the product. CUBICIN's use in the salvage setting on an in-patient basis is generally in patients for whom another therapeutic failure could result in a significant mortality or morbidity risk, and the cost of continued hospitalization for a persistent infection far outweighs the price per day for CUBICIN treatment. We believe in the outpatient setting, the economics of receiving treatment outside of the institution, combined with the financial incentives associated with billing for treatment on an ASP + % are clearly the tailwinds for the product.

3) Since the launch of CUBICIN, a significant body of literature has emerged calling into question the merits of vancomycin treatment in patients with suspected or confirmed MRSA infections. Beginning with the relative imprecision of commonly used susceptibility tests for properly identifying patients with reduced vancomycin susceptibility, to correlations with vancomycin exposure and renal damage, the absence of susceptibility tests to predict clinical outcome and finally relatively high clinical failure rates (25%+), we remain somewhat puzzled that with these shortcomings, vancomycin's market share on a days-of-therapy basis remains relatively steady at approximately 70%. It appears to us that the potent and predictable salvage therapy CUBICIN, enables vancomycin to maintain significant front-line market share as it functions to rescue patients not benefitting from this 54-year-old treatment.

Oritavancin on the Horizon – One Dose, but Higher Risks

Discovered by Lilly, the drug was purchased by Intermune ($125 million - 2001) who completed the Phase III studies in 2004, but did not file the NDA, purportedly due to the observation of injection site reactions (phlebitis). Intermune divested the drug to Targanta ($9 million up front, $25 million promissory note - 2005), which generated additional safety data around longer infusion schedules and filed the drug with the FDA, leading to a November 2008 advisory committee meeting which did not result in a recommendation for approval, largely due to the absence of contemporary pathogens in the Phase III dataset that was considered (the Phase III studies had been completed ~5 years earlier). Targanta was acquired by the Medicines Company in early 2009 ($42 million upfront, plus contingent payments).

We are negative on oritavancin as a drug, although based upon the 2008 ADCOM, anticipate that positive clinical data from the ongoing Phase III studies could support approval. The FDA in their complete response letter (CRL) noted that confirmatory clinical studies should evaluate the impact of oritavancin on macrophage function and monitor patients for subsequent infections that could possibly be related to macrophage dysfunction. The FDA also requested MDCO collect data on infusion site reaction (phlebitis). The FDA expressed concerns about the greater number of treated patients who died or had a serious adverse event of sepsis or septic shock and related events.

Although oritavancin and dalbavancin are both lipo glycopeptides, and their activity is mediated via an impact on the bacterial cell wall, oritavancin causes an increase in cell wall permeability, while dalbavancin (and CUBICIN) do not. Increases in membrane permeability, while contributing to bacterial kill, also cause the release of bacterial intracellular contents. Rapid disruption of bacterial membrane integrity can lead to release of a significant amount of this material, which can include toxins and other components that may have unfavorable consequences for the host (sepsis). This aspect of oritavancin's activity is important as it is common for newer antibiotics to find their first use in the salvage setting, a patient population with a high disease burden (bacterial load), and in whom persistent infection has potentially already led to declining performance status. The FDA's observation of increased sepsis and septic shock in patients treated with oritavancin may be due, in part, to that drug's effects on bacterial cell wall permeability.

Oritavancin has a terminal serum half life of 393 hours (more than 2 weeks) however this variable does not fully elucidate the drug's odyssey in the human body. Oritavancin accumulates in the liver, kidney, spleen and lungs, and in vitro studies suggest extensive accumulation in macrophages. Based on the drug's absence of metabolism, and the low level of excretion in urine or feces, we believe that most of the administered dose of oritavancin is retained by the patient. This contention is supported by the observation that in pre-clinical studies, 70% of the administered dose of oritavancin remained "associated with the carcass" (FDA Briefing Document) 6 weeks from the administration of the drug, and in 13-week dog and rat studies, the levels of oritavancin in the liver 2 months after administration did not differ from those noted immediately following receipt of the drug. We believe this strong tissue association of the drug may lead to an unfavorable biodistribution, potentially blunting the drug's efficacy. To this point, human blister fluid studies, a proxy for a drug's ability to distribute and penetrate abscesses, demonstrate that oritavancin achieves a relatively unfavorable 19% of plasma drug concentration vs. dalbavancin's 60% rate.

Of some concern, and related to the FDA's comments from its CRL, preclinical studies suggest that at clinically significant drug concentrations, oritavancin elicits morphologic changes in the lysosomes of macrophages and fibroblasts. The potential for the drug to cause impaired macrophage function could acutely reduce clinical success rates or worsen the disease course in treatment failures, and chronically increase a patient's risk for subsequent infections. Lastly, in vitro studies investigating intracellular accumulation of cholesterol and phospholipids suggest the potential for oritavancin to cause a mixed lipid storage disorder.

Although not concerns raised by FDA in their CRL, or the ADCOM that considered oritavancin, we believe the following questions are also important to the potential safety and utility of oritavancin.

1. **Retreatment** – When is retreatment with oritavancin recommended or appropriate? In the absence of a clinical response, is retreatment with oritavancin indicated, or contraindicated? What is the appropriate time point in which to consider the potential that there was a treatment failure? If retreatment is dangerous, what methods could be successful to prevent oritavancin-treated patients from inadvertently being retreated over the rest of their life?
2. **Drug/Drug Interactions** – If oritavancin remains persistent in the body, what drug/drug interaction studies are appropriate (i.e., should all or many of the drugs that a patient might be exposed to for the rest of their life be evaluated for their potential to interact with oritavancin).

Dalbavancin for Serious Gram-Positive Infections

Dalbavancin's potent bactericidal activity, well appreciated mechanism of action, and clinical safety profile suggest to us that there are no fundamental barriers to the product's adoption. Market research conducted by Durata has yielded favorable results, with hospital physicians scoring the length of therapy, efficacy against MRSA, administration schedule, and potential for improved compliance as the most favorable aspects of the product's profile. Physician and hospital policies drive demand for parenteral medicine and the positive up-front perception of the product's profile is an important aspect of our favorable view of the drug's commercial opportunity.

In addition to the drug's safety and efficacy, a key feature of dalbavancin is obviously the potential for infrequent (weekly) administration. From a clinical outcome perspective, with compliance to treatment engineered into the drug, and the long half-life ensuring a pharmacokinetic profile with blood and tissue levels at persistently bactericidal levels, the product should enjoy the perception that dalbavancin therapy is less likely to fail. From a pharmacoeconomic perspective, infrequent dosing reduces administration costs, and will, we believe, facilitate treatment in the outpatient setting.

Skin and Skin Structure Setting

In the skin and skin structure setting, we see three distinct patient populations for which dalbavancin will compete for market share.

1. Patients presenting at the emergency room for whom admission to hospital is unnecessary, but for whom use of a potent IV gram-positive therapeutic may provide the expectation of a superior outcome in terms of cure, and convenience.

2. Patients receiving vancomycin in the in-patient setting, who subsequently improve and are proven to have a gram-positive pathogen requiring further treatment, but are suitable for discharge.

3. Patients admitted to hospital who fail to improve on vancomycin and require a different antibiotic and are proven to have a susceptible gram-positive pathogen.

Dalbavancin's Clinical History - Safety and Efficacy

Dalbavancin appears safe

In addition to the near-complete FDA review that concluded with no outstanding safety observations, adverse events reported from clinical studies in patients exposed to dalbavancin are notable for their absence of any sentinel safety/tolerability findings. Importantly, a review of adverse event duration does not show any persistent AE's which could be a concern with a long half-life product.

Adverse Events Occurring in More Than 2% of Patients Receiving Dalbavancin
Phase 2/3 Integrated Database
(Number (%) of Patients)

Adverse Event	Total Dalbavancin (N = 1126)	Total Comparator (N = 573)
Patients with at least one adverse event	585 (52.0%)	326 (56.9%)
Nausea	69 (6.1%)	47 (8.2%)
Diarrhea NOS	63 (5.6%)	39 (6.8%)
Headache	54 (4.8%)	33 (5.8%)
Constipation	40 (3.6%)	29 (3.3%)
Vomiting NOS	40 (3.6%)	26 (4.5%)
Urinary tract infection NOS	34 (3.0%)	12 (2.1%)
Anemia NOS	31 (2.8%)	12 (2.1%)
Rash NOS	29 (2.6%)	13 (2.3%)
Pruritus	25 (2.2%)	14 (2.4%)

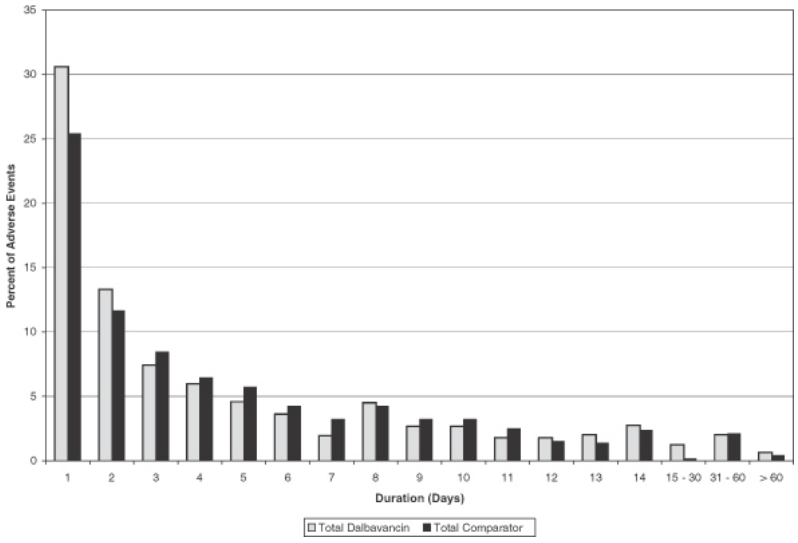
Source: Company Reports

Overview of Adverse Events
Phase 2/3 Integrated Database
(Number (%) of Patients)

Patients With:	Total Dalbavancin (N = 1126)	Total Comparator (N = 573)
At least one adverse event	585 (52.0%)	362 (56.9%)
At least one treatment-related adverse event	248 (22.0%)	157 (27.4%)
At least one serious adverse event	92 (8.2%)	54 (9.4%)
At least one treatment-related serious adverse event	2 (0.2%)	5 (0.9%)
At least one adverse event leading to discontinuation of study drug	39 (3.5%)	22 (3.8%)
Deaths	9 (0.8%)	7 (1.2%)
Deaths due to treatment-related adverse event	0	0

Source: Company Reports

Overview of Duration of Adverse Events
Phase 2/3 Integrated Database



Source: Company Reports

Dalbavancin has reproducibly produced positive clinical results

First Phase III

This randomized, double-blind, controlled study in patients with uncomplicated skin and skin structure infections (uSSSI) compared the efficacy and safety of dalbavancin, 1000 mg IV on day 1 with the potential for a second 500 mg dose on day 8, to cefazolin, 500 mg (IV) q8 hours, with the potential for step-down therapy to oral cephalexin (q6 hours). Both treatment arms were to receive therapy for 7-14 days. The primary endpoint efficacy was assessed in the per protocol patient population by determining clinical and microbiological responses at the test of cure time point, 14 days after end of therapy. The pre-specified non-inferiority margin was -12.5%.

Per Protocol (Number (%) of Patients)			Intent to Treat (Number (%) of Patients)		
Dalbavancin (N=266)	Cefazolin (N=147)	(95% CI)	Dalbavancin (N=367)	Cefazolin (N=186)	(95% CI)
237 (89.1%)	131 (89.1%)	(-6.8, 6.8)	279 (76.0%)	141 (75.8%)	(-7.7, 8.2)

Source: Company Reports

Second Phase III

This randomized double-blind, controlled study in patients with complicated skin and skin structure infections (cSSSI) compared dalbavancin, 1000 mg IV on day 1, 500 mg IV on day 8, to 600 mg IV linezolid (Zyvox) q12 hours, then the potential to receive 600 mg oral linezolid q12 hours for a total of 14 days. The primary endpoint was clinical and microbiological response in the clinically evaluable per protocol population at the test of cure (14 days after therapy) endpoint. The study achieved its pre-specified non-inferiority margin of -12.5%.

Original Analysis

Per Protocol (Number (%) of Patients)			Intent to Treat (Number (%) of Patients)		
Dalbavancin (N=434)	Linezolid (N=226)	(95% CI)	Dalbavancin (N=571)	Linezolid (N=283)	(95% CI)
386 (88.9%)	206 (91.2%)	(-7.3, 2.9)	437 (76.5%)	234 (82.7%)	(-12.0, - 0.3)

FDA Analysis

Per Protocol (Number (%) of Patients)			Intent to Treat (Number (%) of Patients)		
Dalbavancin (N=392)	Linezolid (N=211)	(95% CI)	Dalbavancin (N=523)	Linezolid (N=263)	(95% CI)
346 (88.3%)	189 (89.6%)	(-6.9, 4.3)	383 (73.2%)	198 (75.3%)	(-8.8, -4.7)

Source: Company Reports

Third Phase III Study

This randomized open-label controlled study compared dalbavancin, 1000 mg IV day 1, 500 mg IV day 8, to vancomycin, 1000 mg IV q12 hours (with the potential for step-down treatment to oral cephalexin), 500 mg q6 hours in patients with either complicated or uncomplicated skin and skin structure infections known or suspected to be due to methicillin-resistant Staphylococcus aureus (MRSA). Patients were to receive 14 days of therapy in the complicated settings, and 7-14 days for therapy in the uncomplicated settings. The study met its pre-specified non-inferiority margin of -20%.

Per Protocol (Number (%) of Patients)			Intent to Treat (Number (%) of Patients)		
Dalbavancin (N=79)	Vancomycin (N=30)	(95% CI)	Dalbavancin (N=107)	Vancomycin (N=49)	(95% CI)
71 (88.9%)	26 (86.7%)	(-13.0, 19.4)	92 (86.0%)	32 (65.3%)	(4.3, 37.0)

Source: Company Reports

DISCOVER 1 and 2

Dalbavancin is currently in two global Phase III studies, each of which is being conducted under an SPA. Each study is expected to enroll 556 patients (1:1 randomization) with cellulitis/erysipelas, wound infection, major cutaneous abscess or burns and with documented fever. Patients are to be randomized to dalbavancin, 1000 mg IV day 1 and 500 mg IV day 8 or vancomycin (IV, 1 g or 15 mg/kg, 3d) with the potential for oral linezolid step-down therapy. The primary endpoint, consistent with the new FDA guidance for studies in the abSSSI setting, is the cessation of spread of lesion and absence of fever at 48-72 hours from the initiation of treatment. For the primary endpoint, lesion size will be evaluated by the physician using a ruler, with supplemental data from imaging also collected. Secondary endpoints include the evaluation at day 14-15 of clinical status, per-patient microbiological efficacy, efficacy by pathogen, pathogen eradication rate and investigator assessment of clinical response. Safety and tolerability will be followed to day 70. The non-inferiority delta is 10%.

Financial Model

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Gregory Wade, Ph.D.
9/10/2012

DURATA THERAPEUTICS, INC.
Annual Financial Results & Projections
($ in thousands except per share data)
Ticker: DRTX

	FY:12E	FY:13E	FY:14E	FY:15E	FY:16E	FY:17E	FY:18E	FY:19E	FY:20E	FY:21E	FY:22E	FY:23E	FY:24E	FY:25E	FY:26E	FY:27E
REVENUES																
Dalbavancin (US)	0	0	45,132	128,193	229,717	350,350	457,184	535,552	591,102	633,935	662,462	692,272	723,425	755,979	789,998	825,548
Dalbavancin (EU)	0	0	0	5,546	11,997	20,717	30,321	38,332	44,076	48,201	51,264	53,571	0	0	0	0
Dalbavancin (ROW	0	0	0	0	3,475	10,768	19,296	31,882	41,604	48,735	53,790	57,688	0	0	0	0
TOTAL	0	0	45,132	133,739	245,189	381,835	506,802	605,765	676,782	730,871	767,516	803,532	723,425	755,979	789,998	825,548
EXPENSES																
COGS	0	0	6,770	20,061	36,778	57,275	76,020	90,865	101,517	109,631	115,127	120,530	108,514	113,397	118,500	123,832
Sales, General & Marketing	7,913	2,000	16,750	34,250	54,571	84,004	111,496	133,268	148,892	160,792	168,854	176,777	159,153	166,315	173,800	181,620
Research and Development	37,299	12,000	16,025	32,483	49,709	49,709	49,709	49,709	49,709	49,709	49,709	49,709	37,282	18,641	9,320	4,660
Other	540	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TOTAL	45,752	21,000	39,545	86,794	141,058	190,988	237,226	273,842	300,118	320,131	333,690	347,016	304,949	298,353	301,620	310,113
Operating Income	(45,752)	(21,000)	5,587	46,945	104,130	190,847	269,576	331,923	376,663	410,740	433,826	456,516	418,476	457,626	488,378	515,435
Interest (expense) and other, net	16	18	18	69	172	326	584	934	1,355	1,827	2,337	2,875	3,425	3,953	4,526	5,136
PRETAX INCOME	**(45,736)**	**(20,982)**	**5,605**	**47,015**	**104,303**	**191,173**	**270,161**	**332,858**	**378,018**	**412,566**	**436,163**	**459,391**	**421,900**	**461,579**	**492,905**	**520,571**
Tax	0	0	0	0	40,678	74,557	105,363	129,814	147,427	160,901	170,103	179,162	164,541	180,016	192,233	203,023
GAAP NET INCOME	**(45,736)**	**(20,982)**	**5,605**	**47,015**	**63,625**	**116,616**	**164,798**	**203,043**	**230,591**	**251,666**	**266,059**	**280,228**	**257,359**	**281,563**	**300,672**	**317,548**
Non-GAAP Net Income	**(45,736)**	**(20,982)**	**5,605**	**47,015**	**104,303**	**191,173**	**270,161**	**332,858**	**378,018**	**412,566**	**436,163**	**459,391**	**421,900**	**461,579**	**492,905**	**520,571**
Non-GAAP diluted EPS	(3.09)	(1.03)	0.27	2.29	5.06	9.22	12.97	15.91	17.98	19.53	20.55	21.54	19.69	21.44	22.79	23.96
GAAP diluted EPS	(3.09)	(1.03)	0.27	2.29	3.08	5.63	7.91	9.70	10.97	11.91	12.54	13.14	12.01	13.08	13.90	14.62
Basic Shares Outstanding	12,472	18,425	18,525	18,625	18,725	18,825	18,925	19,025	19,125	19,225	19,325	19,425	19,525	19,625	19,725	19,825
Diluted Shares Outstanding	14,818	20,325	20,425	20,525	20,625	20,725	20,825	20,925	21,025	21,125	21,225	21,325	21,425	21,525	21,625	21,725
Cash	47,715	47,715	26,858	69,163	126,306	236,496	395,906	594,915	822,385	1,071,904	1,335,883	1,619,122	1,874,570	2,154,159	2,452,790	2,768,228

Source: Wedbush PacGrow Life Sciences

Covered Companies Mentioned

Covered public companies mentioned in this report (intraday 09/10/12):

Company	Ticker	Price	Rating	Fair Value/PT
CUBIST PHARMACEUTICALS, INC.	CBST	$ 47.50	O	$ 55
DURATA THERAPEUTICS, INC.	DRTX	$ 9.79	O	$ 20

Analyst Biography

Greg's Venture (Helix) Industry (Isis Pharmaceuticals and Procyon BioPharma) and sell-side experience across 11 years and 40 companies provide him with a well considered perspective. In depth financial models accurate tracking of events/catalysts and strong industry and medical contacts provide for key insights into clinical regulatory and financial outcomes. Well known amongst the Buyside Greg has good information flow on investor sentiment on his names and the group. Edge over the Street BMTI CBST CYTK EBS NGSX SIGA OGXI XNPT Coverage ADLR FOLD ANAC AVNR AVII BMTI CLDX CBLI CBST DCTH DNDN EBS ECYT GENT HALO IMMU IRWD NGSX NVAX OGXI ONCY ONTY PCYC PARD RPTP SIGA XNPT ZLCS

Mr. Wade joined Wedbush from Pacific Growth Equities where he was a Senior Equity Research Analyst. Prior to Pacific Growth he was the Associate Director of Business Development at Isis Pharmaceuticals. Prior to Isis he was the Manager of Corporate Development for Procyon BioPharma Inc. and with Helix Investments Inc. a Toronto based venture capital firm. Dr. Wade received his B.Sc. (Medical Biophysics) and Ph.D. (Physiology) from the University of Western Ontario (London Canada).

Analyst Certification
I, Gregory R. Wade, Ph.D., David M. Nierengarten, Ph.D., Christopher N. Marai, Ph.D., certify that the views expressed in this report accurately reflect my personal opinion and that I have not and will not, directly or indirectly, receive compensation or other payments in connection with my specific recommendations or views contained in this report.

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Investment Rating System:
Outperform: Expect the total return of the stock to outperform relative to the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.
Neutral: Expect the total return of the stock to perform in-line with the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.
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The Investment Ratings are based on the expected performance of a stock (based on anticipated total return to price target) relative to the other stocks in the analyst's coverage universe (or the analyst's team coverage).*

Rating Distribution (as of June 30, 2012)	**Investment Banking Relationships (as of June 30, 2012)**
Outperform:58% Neutral: 36% Underperform: 6%	Outperform:14% Neutral: 0% Underperform: 0%

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Wedbush Equity Research Disclosures as of September 10, 2012

Company	Disclosure
Durata Therapeutics Cubist Pharmaceuticals	1,3,4,5,7 1,10,12

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2. WS managed a public offering of securities within the last 12 months.
3. WS co-managed a public offering of securities within the last 12 months.
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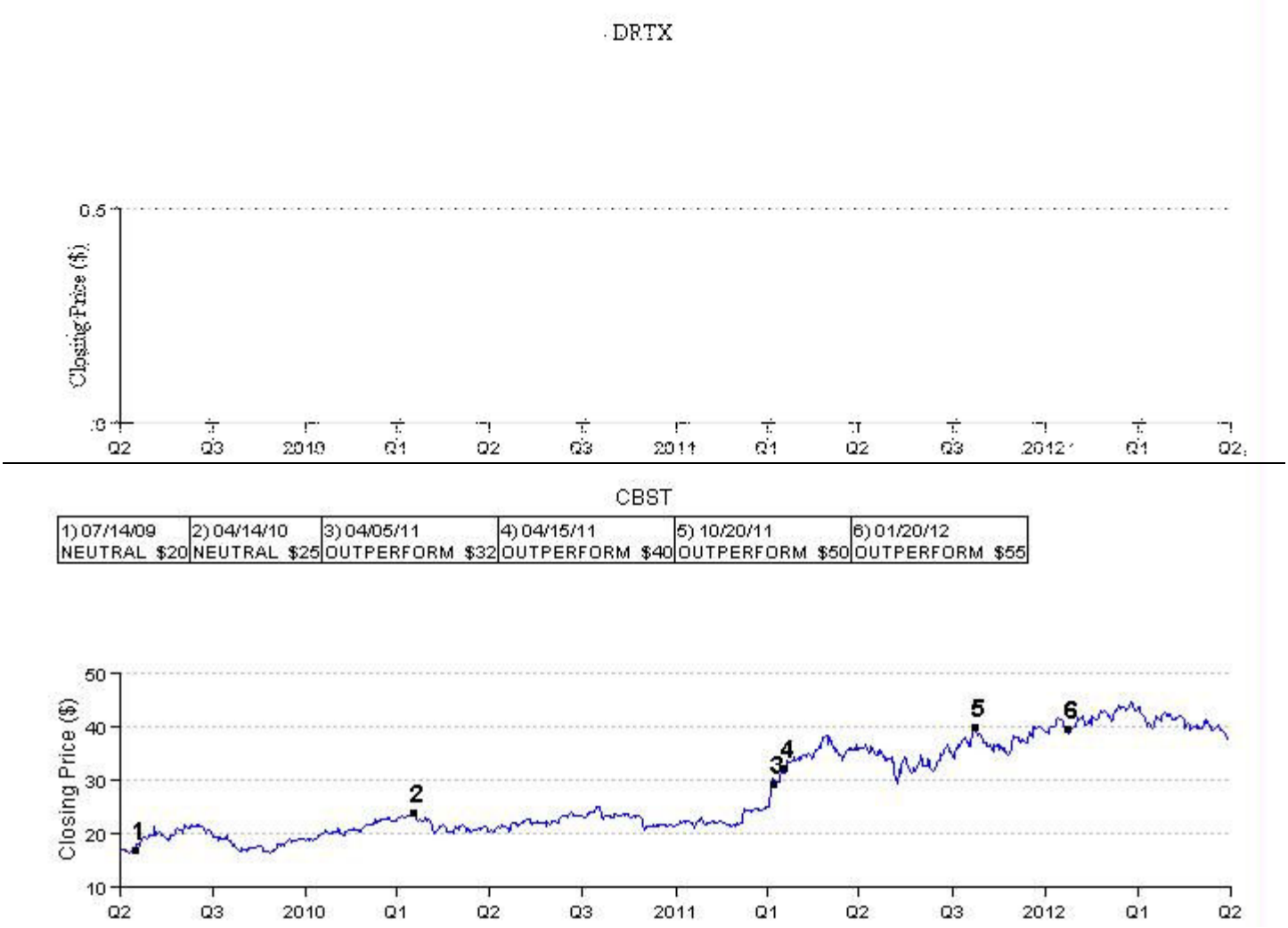

* WS changed its rating system from (Strong Buy/Buy/Hold/Sell) to (Outperform/ Neutral/Underperform) on July 14, 2009.

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