

OUTPERFORM\* [V]

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13.00<sup>1</sup> 9.50 - 6.93

144.35

113.58

Rating

Price (13 Aug 12, US\$) Target price (US\$)

52-week price range

Market cap. (US\$ m)

<sup>1</sup>Target price is for 12 months

Enterprise value (US\$ m)

\*Stock ratings are relative to the relevant country benchmark.

IVI = Stock considered volatile (see Disclosure Appendix).

# **Durata Therapeutics (DRTX)**

INITIATION

# Stop Bugging Me--A Better Way to Treat MRSA

- Initiating Coverage of Durata Therapeutics with an Outperform Rating and TP of \$13: Durata is an infectious disease-focused biotech company whose lead product candidate, dalbavancin, is a novel antibiotic for treating highly infective and potentially lethal infections caused by methicillin-resistant Staphylococcus aureus (MRSA). With an extended half-life and convenient 1x/week dosing, we believe that dalbavancin provides a truly differentiated alternative in an otherwise highly genericized and increasingly commoditized therapeutic area.
- Totality of the Dalbavancin Story Frames Our Positive View on DRTX:
  - Once-weekly dosing regimen presents a radically new treatment paradigm with significant value propositions for patients, physicians, hospitals, and payors.
  - Robust historical PIII data and SPA-guided pivotal trials suggest that clinical and regulatory risks are relatively low at this point.
  - MRSA IV therapy market is sufficiently large that even our conservative peak penetration estimate of ~6% still implies peak sales numbers supportive of our valuation (\$635M peak sales in 2024).
  - Outpatient treatment of MRSA, dalbavancin's clinical niche, is growing due to cost-control efforts and the heavy lifting done by the competition.
- Catalysts: Top-line data from DISCOVER-1 and -2 due in 4Q12/1Q13, NDA resubmission in 1H13, and a potential U.S. launch in early 2014.
- Valuation: Our TP of \$13 is based on DCF from U.S. dalbavancin revenues through 2024. We assign a conservative 60% probability risk-weighting to the NPV of cash flows, primarily reflecting the execution risk that the company and management face. We use a standard 10% discount rate with no terminal value.

| Share         | price performance                                     |
|---------------|-------------------------------------------------------|
| 10 —          | Daily Jul 19, 2012 - Aug 13, 2012, 7/19/12 = US\$9.04 |
| 9 4           |                                                       |
| 8 —           |                                                       |
| 7 —           | ~                                                     |
| 6 —<br>Jul-12 | 2                                                     |
|               | Price —— Indexed S&P 500 INDEX                        |

On 08/13/12 the S&P 500 INDEX closed at 1405.87

| Quarterly EPS | Q1    | Q2    | Q3    | Q4    |
|---------------|-------|-------|-------|-------|
| 2011A         | _     | _     | _     | _     |
| 2012E         | -0.78 | -1.19 | -1.27 | -0.47 |
| 2013E         | _     | _     | _     | _     |
|               |       |       |       |       |

| Financial and valuation metrics              |            |                   |         |        |
|----------------------------------------------|------------|-------------------|---------|--------|
| Year                                         | 12/11A     | 12/12E            | 12/13E  | 12/14E |
| EPS (CS adj.) (US\$)                         | -3.40      | -3.73             | -1.90   | -1.62  |
| Prev. EPS (US\$)                             | _          | _                 | _       |        |
| P/E (x)                                      | -2.3       | -2.1              | -4.1    | -4.9   |
| P/E rel. (%)                                 | -16.2      | -15.8             | -34.8   | -45.3  |
| Revenue (US\$ m)                             | _          | _                 | _       | 56.1   |
| EBITDA (US\$ m)                              | -34.4      | -56.0             | -33.0   | -28.4  |
| OCFPS (US\$)                                 | -3.07      | -4.14             | -2.43   | -0.86  |
| P/OCF (x)                                    | _          | -1.9              | -3.2    | -9.2   |
| EV/EBITDA (current)                          | -4.2       | -2.6              | -4.4    | -5.1   |
| Net debt (US\$ m)                            | -11        | -31               | -12     | -13    |
| ROIC (%)                                     | -42,829.44 | -4,110.52         | -527.30 | 584.11 |
| Number of shares (m)                         | 18.37      | IC (current, US\$ | m)      | 0.07   |
| BV/share (Next Qtr., US\$)                   | _          | EV/IC (x)         |         | _      |
| Net debt (Next Qtr., US\$ m)                 | _          | Dividend (Next C  |         | _      |
| Net debt/tot cap (Next Qtr., %)              | _          | Dividend yield (% | (a)     |        |
| Source: Company data, Credit Suisse estimate | es.        |                   |         |        |

**DISCLOSURE APPENDIX CONTAINS ANALYST CERTIFICATIONS AND THE STATUS OF NON-US ANALYSTS.** U.S. Disclosure: Credit Suisse does and seeks to do business with companies covered in its research reports. As a result, investors should be aware that the Firm may have a conflict of interest that could affect the objectivity of this report. Investors should consider this report as only a single factor in making their investment decision.



# **Investment Thesis**

We are initiating coverage of Durata Therapeutics (DRTX) with an Outperform rating and a \$13 DCF-derived target price. Durata is a biopharmaceutical company focused on the development and commercialization of antibiotics for severe life-threatening infections. Durata's lead compound is dalbavancin (acquired from Pfizer in December 2009 and originally developed by Biosearch Italia) for the treatment of infections caused by methicillin-resistant *Staphylococcus aureus* (MRSA), a difficult-to-treat and potentially lethal bacterial pathogen. Dalbavancin is currently being studied in two pivotal Phase III trials (DISCOVER-1 and DISCOVER-2) for acute bacterial skin and skin structure infections (abSSSI) caused by MRSA. Top-line results are expected by the end of 2012, with a possible launch of dalbavancin in the U.S. by 2014. (See Exhibit 1.) The company also intends to study the drug separately in bone infections (osteomyelitis), diabetic foot infections, and hospital-acquired bacterial pneumonia.

Durata is running pivotal trials for dalbavancin, a novel antibiotic for treating highly virulent and potentially lethal MRSA infections.

Dalbavancin's 1x/week dosing regimen, on-par efficacy with the gold standard and competitors, and benign safety profile provide true product differentiation in a highly genericized and increasingly commoditized therapeutic area. The gold standard of treatment for MRSA infections is intravenous vancomycin. It is a several-decades-old antibiotic but is still the most frequently used MRSA drug to date, with ~70% of share. Vancomycin, however, has a rapid half-life and needs to be dosed 2-3x/day for a two-week course in skin infections and potentially longer in other locations. Furthermore, the short half-life necessitates a slow infusion time (60-90 minutes) and therapeutic drug dose monitoring, as the adverse effects of overdosing can be significant (kidney toxicity, allergic reactions, etc.). On the other hand, because of its long half-life, dalbavancin is only given 1x/week over a 30-minute infusion and does not require monitoring or dose adjustment. It has been found to be equally effective to all its comparators in previous Phase III clinical trials and has a comparable safety profile.

Dalbavancin's once-weekly dosing regimen provides true product differentiation in a highly genericized and commoditized space.

While dalbavancin's mechanism-of-action is not novel per se, the dosing regimen presents a new treatment paradigm for MRSA infections, with significant value propositions for patients, physicians, hospitals, and payors. Dalbavancin is essentially a second-generation vancomycin and works in the same way (preventing bacterial cell wall formation) except for the extended half-life. Once-a-week dosing, however, could radically change the way MRSA infections are treated. For example, a patient with abSSSI severe enough to require IV therapy will need to be admitted to hospital for a 14-day treatment course. If vancomycin is effective against the infection, the typical patient responds clinically within two to three days as his/her fever goes down and the skin lesion stops growing or even shrinks. The patient, however, needs to remain in the hospital to continue treatment for the full course to ensure bacterial eradication. With dalbavancin, the same patient could conceivably be discharged much sooner than she would with vancomycin and treatment continued on an outpatient basis. While oral (Zyvox from Pfizer) and once-daily IV (Cubicin from Cubist) alternatives to vancomycin exist, dalbavancin differentiates itself with potentially better patient compliance and even more convenient dosing that lends itself well to outpatient utilization. For hospitals and payors, dalbavancin may impose a high up-front cost versus vancomycin, but factoring in the savings from fewer admissions, less ancillary procedure costs, less readmissions, and less risk of infecting other patients makes the pharmaco-economic argument for dalbavancin.

Dalbavancin's 1x/week dosing regimen is a new treatment paradigm with significant value propositions.

Dalbavancin has a robust (and previously evaluated) historical data package plus agency-guided pivotal trial designs which suggest that clinical and regulatory risk are fairly low at this point. Three separate Phase III trials have already established that dalbavancin is equally effective in abSSSI as several relevant comparators (cefazolin, vancomycin, and Zyvox). The abSSSI NDA was filed in December 2004 (by parent company Vicuron, just prior to being acquired by Pfizer), and the FDA subsequently issued three separate "approvable" letters. The first two letters pertained to manufacturing issues,

A robust, existing data package and agency-guided pivotal trials suggest that dalbavancin is significantly derisked.



which Pfizer addressed. The last letter was issued in December 2007, essentially questioning the validity of the prespecified noninferiority margin in dalbavancin's trial versus cefazolin. The FDA at the time was in the process of establishing guidelines for antibiotic trials, which affected the development of several antibiotics, not just dalbavancin. Similarly, the EMA had questions regarding inclusion criteria and the validity of only submitting data from one pivotal trial, prompting Pfizer subsequently to withdraw its dalbavancin applications globally, with plans to initiate another Phase III trial in abSSSI at a later date.

The current Phase III DISCOVER programs are being run by Durata under a Special Protocol Assessment (SPA) with the FDA, incorporating the guidelines that the agency published in 2010 regarding inclusion criteria, endpoints, noninferiority margins, etc. Recently, a retrospective analysis of the previous Phase III versus Zyvox (VER001-9), applying the current FDA guidelines, suggested that dalbavancin would still have been noninferior to Zyvox. Taken together, we believe that data from DISCOVER and the previously submitted NDA provide strong support for dalbavancin's approval.

The IV therapy market for MRSA is ~\$10B annually, with MRSA infections increasing in prevalence. Even our conservative ~6% peak market share assumption implies significant revenues for dalbavancin. There is an estimated 35M days of IV therapy annually for MRSA in the U.S. across all indications, and that number is growing. The latest estimates suggest that as much as 60% of skin infections are now caused by MRSA. Furthermore, while MRSA has classically been thought of as a hospital-acquired infection, recent studies have shown that it is now increasingly acquired out in the community and arising in people without any known risk factors (e.g. institutionalization, old age, immunocompromised, recent history of healthcare contact) At branded pricing, the current annual spend is ~\$10B, about 70% of which is still attributable to vancomycin, with Zyvox and Cubicin taking ~8% and ~14% market share, respectively. Assuming pricing parity to branded MRSA drugs (~\$3,000 for a two-week course) and modest price increases, we estimate peak sales of ~\$635M for dalbavancin by 2024.

Outpatient therapy of MRSA, dalbavancin's clinical niche, is already expanding, as cost-control efforts shift treatment settings and also due to the heavy lifting done by Durata's competitors. Roughly 25% of MRSA IV therapy occurs in the outpatient setting, where we believe dalbavancin can truly make in-roads because of the advantages of its dosing regimen. Recent trends in Medicare payments and hospital admissions suggest that patients are increasingly being treated as outpatients, given the lower costs. With the likely implementation of healthcare reform legislation, specific provisions and concepts aimed at controlling costs (e.g., ACOs, bundling, financial penalties for readmission and hospital-acquired conditions) imply a further expansion of outpatient treatment. More specifically in MRSA, Cubicin is set to be an ~\$900M drug in 2012, with nearly half of sales coming from outpatient. Given that dalbavancin's MOA is not novel and physicians have become more comfortable with using a vancomycin alternative on an outpatient basis, we expect that dalbavancin can be marketed successfully with a less intensive effort than was necessary with Cubicin (launched in 2003).

Our complete and detailed initiation slide deck is contained in Appendix 1. This slide deck is available from your Credit Suisse sales representative or any member of the team.

We conservatively model peak U.S. sales of ~\$635M by 2024, just ~6% penetration into a market that is roughly worth \$10B annually.

Outpatient therapy, dalbavancin's niche, is expanding and will have tailwinds due to cost-control efforts. Cubist's heavy lifting since Cubicin launch paves the way for dalbavancin in the outpatient setting.



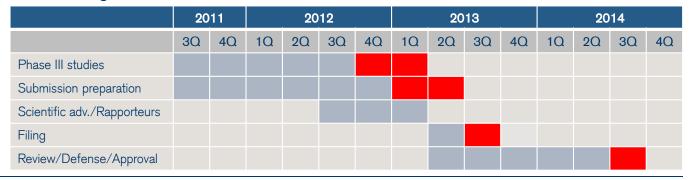
# **Clinical and Regulatory Catalysts**

## **Exhibit 1: Dalbavancin Development Calendar**

## **NDA Timing**

|                        | 20 | 11 |    | 20 | 12 |    |    | 20 | 13 |    |    | 20 | 14 |    |
|------------------------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
|                        | 3Q | 4Q | 1Q | 2Q | 3Q | 4Q | 1Q | 2Q | 3Q | 4Q | 1Q | 2Q | 3Q | 4Q |
| Pre-NDA Meetings       |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| Phase III studies      |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| Submission preparation |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| Filing                 |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| Review/AdCom/Approval  |    |    |    |    |    |    |    |    |    |    |    |    |    |    |

## **MAA Timing**



Source: Company data, Credit Suisse estimates.



# **Valuation**

Our \$13 target price for Durata is based on a discounted cash flow analysis derived from U.S. dalbavancin revenues through 2024. (See Exhibit 2.) We have risk-weighted the NPV of cash flows (60% probability) to reflect primarily the execution risk that the company and management face, given that successful commercialization is contingent upon significantly changing physician practice and habits. We use a standard 10% discount rate to derive the present value of the resulting free cash flows and do not include a terminal value beyond 2024, when dalbavancin's patent protection is expected to run out, assuming no patent term extensions or added data exclusivity. (Please see a discussion of dalbavancin's intellectual property protection in Appendix 4.)

Our \$13 TP (~65% upside) is based on a DCF analysis of dalbavancin revenues through 2024, with NPV of cash flows risk-weighted at 60%. Our baseline peak sales estimate is ~\$635M in the U.S., representing ~6% market share in the MRSA IV therapy space.

## **Exhibit 2: DRTX Discounted Cash Flow Analysis**

| Exhibit 2: DRTX Discounted Cash Flow Analysis                                                                                         |    |                                                        |    |          |    |          |    |          |    |          |    |          |    |         |    |          |    |         |    |         |    |         |    |         |    |         |
|---------------------------------------------------------------------------------------------------------------------------------------|----|--------------------------------------------------------|----|----------|----|----------|----|----------|----|----------|----|----------|----|---------|----|----------|----|---------|----|---------|----|---------|----|---------|----|---------|
| Discounted Cash Flow Analysis<br>\$000's except per share information                                                                 | s  |                                                        |    |          |    |          |    |          |    |          |    |          |    |         |    |          |    |         |    |         |    |         |    |         |    |         |
| Discount rate<br>Current period<br>Terminal growth rate                                                                               |    | 10.0%<br>2012<br>0.0%                                  |    |          |    |          |    |          |    |          |    |          |    |         |    |          |    |         |    |         |    |         |    |         |    |         |
| Period                                                                                                                                |    | 2012E                                                  |    | 2013E    |    | 2014E    |    | 2015E    |    | 2016E    |    | 2017E    |    | 2018E   |    | 2019E    |    | 2020E   |    | 2021E   |    | 2022E   |    | 2023E   |    | 2024E   |
| Net income                                                                                                                            | \$ | (59,060)                                               | \$ | (36,083) | \$ | (31,025) | \$ | (5,822)  | \$ | 33,761   | \$ | 88,204   | \$ | 88,687  | \$ | 127,935  | \$ | 148,513 | \$ | 169,848 | \$ | 186,927 | \$ | 202,094 | \$ | 218,022 |
| Add: D&A expense                                                                                                                      |    | -                                                      |    | -        |    | 224      |    | 638      |    | 1,177    |    | 1,863    |    | 2,630   |    | 3,234    |    | 3,748   |    | 4,220   |    | 5,443   |    | 6,738   |    | 8,131   |
| Add: SBC expense                                                                                                                      |    | 1,049                                                  |    | 990      |    | 2,305    |    | 2,795    |    | 3,633    |    | 4,533    |    | 5,020   |    | 5,104    |    | 4,999   |    | 5,094   |    | 5,155   |    | 5,155   |    | 5,111   |
| Add: (Increase)/decrease in WC                                                                                                        |    | (4,017)                                                |    | (8,060)  |    | 9,551    |    | (7,451)  |    | (11,707) |    | (10,306) |    | (9,359) |    | (10,843) |    | (6,657) |    | (6,536) |    | (2,874) |    | (5,195) |    | (2,278) |
| Less: Capital expenditures                                                                                                            |    | -                                                      | _  | -        | _  | 1,122    |    | 2,070    | _  | 2,691    |    | 3,434    | _  | 3,835   | _  | 4,143    | _  | 4,637   | _  | 5,053   | Ļ  | 9,546   | _  | 10,309  | _  | 11,111  |
| Free cash flow                                                                                                                        | \$ | (62,028)                                               | \$ | (43,153) | \$ | (20,066) | \$ | (11,909) | \$ | 24,172   | \$ | 80,860   | \$ | 83,143  | \$ | 121,288  | \$ | 145,965 | \$ | 167,573 | \$ | 185,105 | \$ | 198,483 | \$ | 217,875 |
| PV of free cash flow                                                                                                                  |    | (62,028)                                               |    | (39,230) |    | (16,583) |    | (8,948)  |    | 16,510   |    | 50,208   |    | 46,932  |    | 62,240   |    | 68,094  |    | 71,067  |    | 71,366  |    | 69,567  |    | 69,422  |
| Total PV of cash flows Risk-weighted @ 60.0% Add: Terminal value Add: YE 2012 cash Equity value  Diluted shares outstanding (YE 2012) | \$ | 398,616<br>239,170<br>-<br>30,769<br>269,938<br>20,289 | -  |          |    |          |    |          |    |          |    |          |    |         |    |          |    |         |    |         |    |         |    |         |    |         |
| Price per share                                                                                                                       | \$ | 13.30                                                  |    |          |    |          |    |          |    |          |    |          |    |         |    |          |    |         |    |         |    |         |    |         |    |         |

Source: Company data, Credit Suisse estimates.

## **Dalbavancin Revenue Assumptions**

Assumptions supporting our peak U.S. sales estimate of ~\$635M by 2024 for dalbavancin include the following:

- Approximately 35M days of IV therapy for MRSA infections (all indications), 25% of which are in the outpatient setting.
- Approval/launch of dalbavancin in the U.S. by 2014 for skin infections, with subsequent expansion of indications into bone, diabetic foot, and pneumonia.
- \$3,300 per 14-day course of therapy at launch (three 500mg vials, \$1,100/vial; assuming average utilization is only 2.5 vials/patient).
- Annual price increases of 5% from launch.
- Patent protection through 2014; a potential four-year Hatch-Waxman extension and five years of additional data exclusivity from the pending GAIN Act legislation represent upside potential to our estimates.
- Potential EU sales are not included in our valuation.



# **Key Risk Factors**

Key risks to our DRTX target price include the following:

#### Dalbavancin Does Not Meet Clinical Trial Endpoints

- Durata is only the second company to incorporate the 2010 FDA draft guidelines on skin infection trials (the first being Trius Therapeutics); therefore, there are no precedents for assessing the trial implications of mandated inclusion and exclusion criteria, non-inferiority margins, skin lesion measurement technique, etc.
- We note that retrospective analysis of a previous dalbavancin trial versus
   Zyvox, though of limited comparability, suggests that DISCOVER-1 and
   -2 have a high probability of providing positive data.

#### Dalbavancin Is Not Approved or Launch Is Significantly Delayed

Dalbavancin is currently Durata's only commercializable asset. Because
of this revenue concentration, non-approval or a significant delay would
materially harm the company's business.

## Dalbavancin Launch Ramp and/or Peak Sales Could Underperform Our Estimates

- We have modeled a modest launch ramp and peak sales estimate for dalbavancin based on the past launches of comparable antibiotics, pricing at parity with branded competitors, and a conservative peak market share of only ~6%.
- For dalbavancin to be broadly adopted, however, physician practice behaviors will need to be changed and the drug's pharmaco-economic benefits effectively communicated, which may prove challenging for the company.

#### Dalbavancin Is Not Adopted for Other MRSA Indications

- Eventual use of dalbavancin outside of skin infections is assumed in our revenue estimates.
- Failure to expand indications could make our estimates too high.



# **Company Financials**

**Exhibit 3: Dalbavancin Revenue Model** 

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 2014E            | 2015E                                   | 2016E                          | 2017E                            | 2018E                  | 2019E           | 2020E                  | 2021E                  | 2022E             | 2023E                  | 2024E                  |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|-----------------------------------------|--------------------------------|----------------------------------|------------------------|-----------------|------------------------|------------------------|-------------------|------------------------|------------------------|
| United States                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                  |                                         |                                |                                  |                        |                 |                        |                        |                   |                        |                        |
| Treatment Days                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                  |                                         |                                |                                  |                        |                 |                        |                        |                   |                        |                        |
| MRSA - US In-patient                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 26,523,913       | 26,656,533                              | 26,789,815                     | 26,923,764                       | 27,058,383             | 27,193,675      | 27,329,643             | 27,329,643             | 27,329,643        | 27,329,643             | 27,329,643             |
| MRSA - US Out-patient                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 9,837,398        | 10,181,707                              | 10,588,975                     | 11,065,479                       | 11,618,753             | 12,199,691      | 12,809,675             | 12,809,675             | 12,809,675        | 12,809,675             | 12,809,675             |
| Non-MRSA - US % of In-patient                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 1,326,196        | 1,332,827                               | 1,339,491                      | 1,346,188                        | 1,352,919              | 1,359,684       | 1,366,482              | 1,366,482              | 1,366,482         | 1,366,482              | 1,366,482              |
| Growth Rate                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                  |                                         |                                |                                  |                        |                 |                        |                        |                   |                        |                        |
| MRSA - US In-patient                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 0.5%             | 0.5%                                    | 0.5%                           | 0.5%                             | 0.5%                   | 0.5%            | 0.5%                   | 0.0%                   | 0.0%              | 0.0%                   | 0.0%                   |
| MRSA - US Out-patient                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 3.0%             | 3.5%                                    | 4.0%                           | 4.5%                             | 5.0%                   | 5.0%            | 5.0%                   | 0.0%                   | 0.0%              | 0.0%                   | 0.0%                   |
| Non-MRSA - US % of In-patient                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 5.0%             | 5.0%                                    | 5.0%                           | 5.0%                             | 5.0%                   | 5.0%            | 5.0%                   | 5.0%                   | 5.0%              | 5.0%                   | 5.0%                   |
| Share of Treatment Days                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                  |                                         |                                |                                  |                        |                 |                        |                        |                   |                        |                        |
| MRSA - US In-patient                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 0.6%             | 1.2%                                    | 2.0%                           | 2.8%                             | 3.2%                   | 3.3%            | 3.4%                   | 3.5%                   | 3.5%              | 3.6%                   | 3.7%                   |
| MRSA - US Out-patient                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 0.8%             | 2.5%                                    | 4.0%                           | 6.0%                             | 7.5%                   | 9.0%            | 9.5%                   | 10.0%                  | 10.5%             | 10.8%                  | 11.0%                  |
| Non-MRSA - US % of In-patient                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 0.6%             | 1.2%                                    | 2.0%                           | 2.8%                             | 3.2%                   | 3.3%            | 3.4%                   | 3.5%                   | 3.5%              | 3.6%                   | 3.7%                   |
| Total Treatment Days                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 251,896          | 590,415                                 | 986,145                        | 1,455,487                        | 1,780,568              | 2,040,233       | 2,202,153              | 2,285,332              | 2,349,380         | 2,416,505              | 2,480,386              |
| Total Share of Treatment Days                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 0.7%             | 1.5%                                    | 2.5%                           | 3.7%                             | 4.4%                   | 5.0%            | 5.3%                   | 5.5%                   | 5.7%              | 5.8%                   | 6.0%                   |
| Dalbavancin Patients (@14-day course)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                  |                                         |                                |                                  |                        |                 |                        |                        |                   |                        |                        |
| MRSA - US In-patient                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 11,894           | 22,848                                  | 38,271                         | 53,848                           | 61,848                 | 64,099          | 67,023                 | 68,324                 | 68,324            | 70,276                 | 72,879                 |
| MRSA - US Out-patient                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 5,504            | 18,182                                  | 30,254                         | 47,423                           | 62,243                 | 78,427          | 86,923                 | 91,498                 | 96,073            | 98,817                 | 100,647                |
| Non-MRSA - US % of In-patient                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 595              | 1,142                                   | 1,914                          | 2,692                            | 3,092                  | 3,205           | 3,351                  | 3,416                  | 3,416             | 3,514                  | 3,644                  |
| Total Dalbavancin Patients                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 17,993           | 42,172                                  | 70,439                         | 103,963                          | 127,183                | 145,731         | 157,297                | 163,238                | 167,813           | 172,608                | 177,170                |
| Total Balbavarion Fatients                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 11,550           | 72,172                                  | 10,400                         | 100,000                          | 127,100                | 140,701         | 101,201                | 100,200                | 101,010           | 112,000                | 177,170                |
| Vials per Patient                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                  |                                         |                                |                                  |                        |                 |                        |                        |                   |                        |                        |
| MRSA - US In-patient                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 2.5              | 2.5                                     | 2.5                            | 2.5                              | 2.5                    | 2.5             | 2.5                    | 2.5                    | 2.5               | 2.5                    | 2.5                    |
| MRSA - US Out-patient                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 2.5              | 2.5                                     | 2.5                            | 2.5                              | 2.5                    | 2.5             | 2.5                    | 2.5                    | 2.5               | 2.5                    | 2.5                    |
| Non-MRSA - US % of In-patient                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 2.5              | 2.5                                     | 2.5                            | 2.5                              | 2.5                    | 2.5             | 2.5                    | 2.5                    | 2.5               | 2.5                    | 2.5                    |
| Number of Vials                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                  |                                         |                                |                                  |                        |                 |                        |                        |                   |                        |                        |
| MRSA - US In-patient                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 29,734           | 57,121                                  | 95,678                         | 134,619                          | 154,619                | 160,248         | 167,557                | 170,810                | 170,810           | 175,691                | 182,198                |
| MRSA - US Out-patient                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 13,761           | 45,454                                  | 75,636                         | 118,559                          | 155,608                | 196,066         | 217,307                | 228,744                | 240,181           | 247,044                | 251,619                |
| Non-MRSA - US % of In-patient                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 1,487            | 2,856                                   | 4,784                          | 6,731                            | 7,731                  | 8,012           | 8,378                  | 8,541                  | 8,541             | 8,785                  | 9,110                  |
| Total Vials                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 44,982           | 105,431                                 | 176,097                        | 259,908                          | 317,959                | 364,327         | 393,242                | 408,095                | 419,532           | 431,519                | 442,926                |
| Stocking                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                  | *************************************** |                                |                                  |                        |                 |                        |                        |                   |                        |                        |
| (2000 hospitals, 7.5 vials per hospital)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 15,000           | -                                       | -                              | -                                | -                      | -               | -                      | -                      | -                 | -                      | -                      |
| According to the Accord | 64.400           | 64.455                                  | *4.040                         | 64.070                           | 64.007                 | *****           | ****                   | *4.540                 | 64.005            | 64 700                 | 64 700                 |
| Avg. Price per Vial Price increase (%)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | \$1,100          | <b>\$1,155</b><br>5.0%                  | <b>\$1,213</b><br>5.0%         | <b>\$1,273</b><br>5.0%           | <b>\$1,337</b><br>5.0% | \$1,404<br>5.0% | <b>\$1,474</b><br>5.0% | <b>\$1,548</b><br>5.0% | \$1,625<br>5.0%   | <b>\$1,706</b><br>5.0% | <b>\$1,792</b><br>5.0% |
| , , , , , , , , , , , , , , , , , , ,                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                  |                                         |                                |                                  |                        |                 |                        |                        |                   |                        |                        |
| Gross Sales (\$000's)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                  |                                         |                                |                                  |                        |                 |                        |                        |                   |                        |                        |
| MRSA - US In-patient                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | \$ 32,708        | \$ 65,975                               | \$ 116,033                     | \$ 171,422                       | \$ 206,735             | \$ 224,974      | \$ 246,996             | \$ 264,382             | \$ 277,601        | \$ 299,809             | \$ 326,459             |
| Stocking                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 16,500           | -                                       | -                              | -                                | -                      | -               | -                      | -                      | -                 | -                      | -                      |
| MRSA - US Out-patient                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 15,137           | 52,499                                  | 91,727                         | 150,971                          | 208,057                | 275,260         | 320,333                | 354,053                | 390,343           | 421,571                | 450,846                |
| Non-MRSA - US % of Hospital                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 1,635            | 3,299                                   | 5,802                          | 8,571                            | 10,337                 | 11,249          | 12,350                 | 13,219                 | 13,880            | 14,990                 | 16,323                 |
| Total Gross Sales                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 65,980           | 121,773                                 | 213,562                        | 330,964                          | 425,129                | 511,483         | 579,679                | 631,654                | 681,824           | 736,370                | 793,628                |
| Gross-to-net spread (%)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 15.0%            | 15.0%                                   | 16.0%                          | 17.0%                            | 18.0%                  | 19.0%           | 20.0%                  | 20.0%                  | 20.0%             | 20.0%                  | 20.0%                  |
| Not Colon (#0000a)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                  |                                         |                                |                                  |                        |                 |                        |                        |                   |                        |                        |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 1                |                                         | 07.400                         | 440,000                          | 169,523                | 182,229         | 197,597                | 211,506                | 222,081           | 239,847                | 261,167                |
| Net Sales (\$000's)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 27 801           | 56,070                                  |                                |                                  |                        |                 |                        |                        |                   |                        |                        |
| MRSA - US In-patient                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 27,801<br>14,025 | 56,079                                  | 97,468                         | 142,280                          | 109,323                | 102,220         | .07,007                |                        |                   | 200,017                | _                      |
| MRSA - US In-patient<br>Stocking                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 14,025           | -                                       | -                              | -                                | -                      | -               | -                      | -                      | -                 | -                      | -                      |
| MRSA - US In-patient                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 1                | 56,079<br>-<br>44,625<br>2,804          | 97,468<br>-<br>77,051<br>4,873 | 142,280<br>-<br>125,306<br>7,114 | 170,607<br>8.476       | 222,960         | 256,267<br>9,880       | 283,242<br>10,575      | 312,274<br>11,104 | 337,256<br>11,992      | 360,677<br>13,058      |

Source: Company data, Credit Suisse estimates.



## **Exhibit 4: Durata Annual Income Statements**

Income Statement

\$000's except per share information

|                                             | FY2012E      | FY2013E     | FY2104E     | FY2015E    | FY2016E    | FY2017E    | FY2018E    | FY2019E    | FY2020E    | FY2021E    | FY2022E    | FY2023E    | FY2024E    |
|---------------------------------------------|--------------|-------------|-------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|
| Total Product Sales                         | \$ -         | \$ -        | \$ 56,083   | \$ 103,507 | \$ 179,392 | \$ 274,700 | \$ 348,606 | \$ 414,301 | \$ 463,744 | \$ 505,323 | \$ 545,459 | \$ 589,096 | \$ 634,902 |
| Royalty revenues                            | -            | -           | -           | -          | -          | -          | -          | -          | -          | -          | -          | -          | -          |
| Net Revenues                                | -            | -           | 56,083      | 103,507    | 179,392    | 274,700    | 348,606    | 414,301    | 463,744    | 505,323    | 545,459    | 589,096    | 634,902    |
| Cost of goods sold                          | -            | -           | 7,852       | 13,456     | 21,527     | 30,217     | 34,861     | 41,430     | 46,374     | 50,532     | 54,546     | 58,910     | 63,490     |
| Gross Profit                                | -            | -           | 48,231      | 90,051     | 157,865    | 244,483    | 313,745    | 372,871    | 417,369    | 454,791    | 490,913    | 530,186    | 571,412    |
|                                             |              |             |             |            |            |            |            |            |            |            |            |            |            |
| Operating Expenses                          |              |             |             |            |            |            |            |            |            |            |            |            |            |
| R&D expense                                 | 46,771       | 16,932      | 17,946      | 20,701     | 22,424     | 27,470     | 34,861     | 41,430     | 46,374     | 50,532     | 54,546     | 58,910     | 63,490     |
| SG&A expense                                | 9,221        | 16,063      | 58,887      | 72,455     | 98,666     | 123,615    | 132,470    | 140,862    | 132,167    | 131,384    | 136,365    | 147,274    | 158,726    |
| Total Operating Expenses                    | 55,992       | 32,995      | 76,833      | 93,156     | 121,090    | 151,085    | 167,331    | 182,292    | 178,541    | 181,916    | 190,911    | 206,184    | 222,216    |
|                                             |              |             |             |            |            |            |            |            |            |            |            |            |            |
| Operating Income (Loss)                     | (55,992)     | (32,995)    | (28,602)    | (3,105)    | 36,775     | 93,398     | 146,414    | 190,578    | 238,828    | 272,874    | 300,003    | 324,003    | 349,196    |
|                                             |              |             |             |            |            |            |            |            |            |            |            |            |            |
| Other Income (Expense)                      |              |             |             |            |            |            |            |            |            |            |            |            |            |
| Interest income                             | 29           | 77          | 31          | 33         | 10         | 78         | 289        | 506        | 709        | 1,073      | 1,492      | 1,962      | 2,459      |
| Interest (expense) - Milestone Payment      | -            | -           | (2,500)     | (2,750)    | (3,025)    | (3,328)    | (3,660)    | 15,263     | -          | -          | -          | -          | -          |
| Other income (expense), net                 | (3,096)      | (3,165)     | -           | -          | -          | -          | -          | -          | -          | -          | -          | -          | -          |
| Total Other Income (Expense)                | (3,068)      | (3,088)     | (2,469)     | (2,717)    | (3,015)    | (3,249)    | (3,371)    | 15,769     | 709        | 1,073      | 1,492      | 1,962      | 2,459      |
|                                             |              |             |             |            |            |            |            |            |            |            |            |            |            |
| Pre-tax Income                              | (59,060)     | (36,083)    | (31,071)    | (5,822)    | 33,761     | 90,149     | 143,043    | 206,347    | 239,536    | 273,948    | 301,495    | 325,965    | 351,655    |
|                                             |              |             |             |            |            |            |            |            |            |            |            |            |            |
| Income tax expense (benefit)                | -            | -           | -           | -          | -          | 1,929      | 54,356     | 78,412     | 91,024     | 104,100    | 114,568    | 123,867    | 133,629    |
|                                             |              |             |             |            |            |            |            |            |            |            |            |            |            |
| Net Income                                  | \$ (59,060)  | \$ (36,083) | \$ (31,071) | \$ (5,822) | \$ 33,761  | \$ 88,220  | \$ 88,687  | \$ 127,935 | \$ 148,513 | \$ 169,848 | \$ 186,927 | \$ 202,098 | \$ 218,026 |
|                                             |              |             |             |            |            |            |            |            |            |            |            |            |            |
| Basic weighted-average shares outstanding   | 14,400       | 17,384      | 17,558      | 17,734     | 17,911     | 18,090     | 18,271     | 18,454     | 18,638     | 18,825     | 19,013     | 19,203     | 19,395     |
| y/y grow th (%)                             | 48.3%        | 20.7%       | 1.0%        | 1.0%       | 1.0%       | 1.0%       | 1.0%       | 1.0%       | 1.0%       | 1.0%       | 1.0%       | 1.0%       | 1.0%       |
| Diluted w eighted-averge shares outstanding | 15,831       | 19,036      | 19,227      | 19,419     | 19,613     | 19,809     | 20,007     | 20,207     | 20,410     | 20,614     | 20,820     | 21,028     | 21,238     |
| y/y grow th (%)                             | 63.0%        | 20.2%       | 1.0%        | 1.0%       | 1.0%       | 1.0%       | 1.0%       | 1.0%       | 1.0%       | 1.0%       | 1.0%       | 1.0%       | 1.0%       |
| Basic earnings (loss) per share             | \$ (4.10)    | \$ (2.08)   | \$ (1.77)   | \$ (0.33)  | \$ 1.88    | \$ 4.88    | \$ 4.85    | \$ 6.93    | \$ 7.97    | \$ 9.02    | \$ 9.83    | \$ 10.52   | \$ 11.24   |
| • , ,,                                      | <del> </del> |             |             |            |            |            |            |            |            |            |            |            |            |
| Diluted earnings (loss) per share           | \$ (4.10)    | \$ (2.08)   | \$ (1.77)   | \$ (0.33)  | \$ 1.72    | \$ 4.45    | \$ 4.43    | \$ 6.33    | \$ 7.28    | \$ 8.24    | \$ 8.98    | \$ 9.61    | \$ 10.27   |

Source: Company data, Credit Suisse estimates.

## **Exhibit 5: Durata Cash Flow Statements**

Cash Flow Statement \$000's except per share information

|                                                     | FY2011      | FY2012E     | FY2013E     | FY2104E     | FY2015E    | FY2016E   | FY2017E    | FY2018E    | FY2019E    | FY2020E    | FY2021E    | FY2022E    | FY2023E    | FY2024E      |
|-----------------------------------------------------|-------------|-------------|-------------|-------------|------------|-----------|------------|------------|------------|------------|------------|------------|------------|--------------|
| Net Income                                          | \$ (33,033) | \$ (59,060) | \$ (36,083) | \$ (31,025) | \$ (5,822) | \$ 33,761 | \$ 88,204  | \$ 88,687  | \$ 127,935 | \$ 148,513 | \$ 169,848 | \$ 186,927 | \$ 202,094 | \$ 218,022   |
|                                                     |             |             |             |             |            |           |            |            |            |            |            |            |            |              |
| Adjustments to Net Income                           |             |             |             |             |            |           |            |            |            |            |            |            |            |              |
| Prepaid Expenses                                    | (948)       | (359)       | -           | -           | -          | -         | -          | -          | -          | -          | -          | -          | -          | - [          |
| Deposit - Rent Other Asset                          | -           | (8)         | -           | -           | -          | -         | -          | -          | -          | -          |            | -          | -          | -            |
| Depreciation - PP&E                                 | -           | - [         | -           | 224         | 638        | 1,177     | 1,863      | 2,630      | 3,234      | 3,748      | 4,220      | 5,443      | 6,738      | 8,131        |
| Amortization - License Fees                         | -           | -           | -           | -           | -          | -         | -          | -          | -          | -          | -          | -          | -          | -            |
| Amortization - In Process R&D                       | -           | - [         | -           | -           | -          | -         | -          | -          | -          | -          |            | -          | -          | - [          |
| Other Assets - Deferred Offering Costs              | -           | -           | -           | -           | -          | -         | -          | -          | -          | -          | -          | -          | -          | -            |
| Interest Expense - Milestone Pmt.                   | -           | -           | -           | 2,500       | 2,750      | 3,025     | 3,328      | 3,660      | (15,263)   | -          | -          | -          | -          | - [          |
| Change in Deferred Income Tax                       | (2,511)     | -           | -           | -           | -          | -         | -          | -          | -          | -          | -          | -          | -          | -            |
| Stock Based Compensation Expense                    | 781         | 1,049       | 990         | 2,305       | 2,795      | 3,633     | 4,533      | 5,020      | 5,104      | 4,999      | 5,094      | 5,155      | 5,155      | 5,111        |
| Acquisition Related Charges                         | 221         | (3,096)     | (3,165)     | -           | -          | -         | -          | -          | -          |            | -          | -          | -          | -            |
| Contingent receivable                               | 3,900       | -           | -           | -           | -          | -         | -          | -          | -          |            | -          | -          | -          | -            |
| Changes in w orking capital accounts:               |             |             |             |             |            |           |            |            |            |            |            |            |            |              |
| + (increase)/decrease in Inventory                  | -           | (8,250)     | (8,230)     | 8,628       | (5,604)    | (8,071)   | (5,668)    | (4,179)    | (5,913)    | (2,131)    | (3,534)    | (684)      | (3,491)    | (490)        |
| + (increase)/decrease in Accounts Receivable        |             | -           | -           | (4,610)     | (3,898)    | (6,237)   | (7,834)    | (6,074)    | (5,400)    | (4,064)    | (3,417)    | (3,299)    | (3,587)    | (3,765)      |
| + increase/(decrease) in Accounts Payable           | 1,250       | 843         | (88)        | 3,603       | 1,342      | 2,296     | 2,465      | 1,335      | 1,230      | (308)      | 277        | 739        | 1,255      | 1,318        |
| + increase/(decresase) in Accrued Expenses          | 561         | 3,390       | 258         | 1,929       | 710        | 305       | 731        | (441)      | (760)      | (154)      | 139        | 370        | 628        | 659          |
| Net Cash Provided by Operating Activities           | (29,779)    | (65,491)    | (46,318)    | (16,444)    | (7,089)    | 29,888    | 87,621     | 90,638     | 110,168    | 150,602    | 172,626    | 194,650    | 208,792    | 228,985      |
| Cash Flows from Investment Activities               |             |             |             |             |            |           |            |            |            |            |            |            |            |              |
| Other Investment (Milestone)                        |             |             |             |             |            |           |            |            | (25,000)   |            |            |            |            |              |
| Other Receivables                                   | 3.000       | - 1         | - 1         | -           |            | -         | -          | -          | (23,000)   | -          |            | -          | -          | - 1          |
| Acquisition of PP&E                                 | 3,000       | -           | -           | (1,122)     | (2,070)    | (2,691)   | (3,434)    | (3,835)    | (4,143)    | (4,637)    | (5,053)    | (9,546)    | (10,309)   | (11,111)     |
| Acquisition of Frace Acquisition of in process R&D  | -           | - 1         | - 1         | (1,122)     | (2,070)    | (2,091)   | (3,434)    | (3,033)    | (4,143)    | (4,037)    | (5,055)    | (9,540)    | (10,309)   | (11,111)     |
| Licensing Fees - Non Core Territories               | -           | -           | -           | -           | -          | -         | -          | -          | -          | -          | -          | -          | -          | -            |
| Purchase of marketing rights                        | -           | - 1         | -           | -           | -          | -         |            | -          | 1          | -          |            | 1 -        | -          | -            |
|                                                     | 3.000       | -           |             | (4.400)     | (0.070)    | (0.004)   | (0.404)    | (0.005)    | (00.440)   | (4.007)    | (5.050)    | (0.540)    | (40,000)   | (11,111)     |
| Net Cash Used by Investing Activities               | 3,000       | -           | -           | (1,122)     | (2,070)    | (2,691)   | (3,434)    | (3,835)    | (29,143)   | (4,637)    | (5,053)    | (9,546)    | (10,309)   | (11,111)     |
| Cash Flows from Financing Activities                |             |             |             |             |            |           |            |            |            |            |            |            |            |              |
| Contingent Consideration                            | -           | _           | - 1         | _           |            |           |            | -          |            |            |            | 1 -        |            |              |
| Proceeds from Issuance of Series A Convertible Stoc | 36,000      | 22,000      | - 1         | -           |            | _         |            |            |            |            |            |            |            | _ [          |
| Proceeds from receipt of contingent receivable      | ,           |             | -           | -           |            |           |            |            |            |            |            |            |            | -            |
| Common Stock                                        | -           | 62,775      | 46,500      | _           |            |           |            | -          |            |            |            |            |            | - 1          |
| Net Cash Provided by Financing Activities           | 36,000      | 84,775      | 46,500      | -           |            | -         | -          | -          | -          | -          | -          | -          | -          | -            |
|                                                     |             |             |             |             |            |           |            |            |            |            |            |            |            |              |
| Net Cash Increase (Decrease)                        | 9,221       | 19,284      | 182         | (17,566)    | (9,159)    | 27,197    | 84,187     | 86,803     | 81,025     | 145,965    | 167,573    | 185,105    | 198,483    | 217,875      |
| Beginning Cash                                      | 2,264       | 11,485      | 30,769      | 30,951      | 13,386     | 4,226     | 31,423     | 115,611    | 202,414    | 283,440    | 429,405    | 596,977    | 782,082    | 980,564      |
| Ending Cash                                         | \$ 11,485   | \$ 30,769   | \$ 30,951   | \$ 13,386   | \$ 4,226   | \$ 31,423 | \$ 115,611 | \$ 202,414 | \$ 283,440 | \$ 429,405 | \$ 596,977 | \$ 782,082 | \$ 980,564 | \$ 1,198,439 |

Source: Company data, Credit Suisse estimates.



## **Exhibit 6: Durata Balance Sheets**

Balance Sheet \$000's except per share information

|                                                                                          | FY2011             | FY2012E   | FY2013E   | FY2104E   | FY2015E   | FY2016E             | FY2017E    | FY2018E    | FY2019E    | FY2020E    | FY2021E    | FY2022E    | FY2023E      | FY2024E      |
|------------------------------------------------------------------------------------------|--------------------|-----------|-----------|-----------|-----------|---------------------|------------|------------|------------|------------|------------|------------|--------------|--------------|
| ASSETS                                                                                   |                    |           |           |           |           |                     |            |            |            |            |            |            |              |              |
| Current Assets                                                                           |                    |           |           |           |           |                     |            |            | l          |            |            |            |              |              |
| Total Cash                                                                               | \$ 11,485          | \$ 30,769 | \$ 30,951 | \$ 13,386 | \$ 4,226  | \$ 31,423           | \$ 115,611 | \$ 202,414 | \$ 283,440 | \$ 429,405 | \$ 596,977 | \$ 782,082 | \$ 980,564   | \$ 1,198,439 |
| Prepaid Insurance - Other Prepaid                                                        | 996                | 1,356     | 1,356     | 1,356     | 1,356     | 1,356               | 1,356      | 1,356      | 1,356      | 1,356      | 1,356      | 1,356      | 1,356        | 1,356        |
| Deferred Offering Costs                                                                  | -                  | -         | -         | -         | -         | -                   | -          | -          | -          |            | -          | -          | -            |              |
| Accounts receivable                                                                      | -                  | -         |           | 4,610     | 8,507     | 14,745              | 22,578     | 28,653     | 34,052     | 38,116     | 41,533     | 44,832     | 48,419       | 52,184       |
| Other Receivable                                                                         | -                  | -         | -         | -         | -         | -                   | -          | -          |            | -          | -          | -          | -            | -            |
| Total Current Assets                                                                     | 12,482             | 32,125    | 32,307    | 19,351    | 14,089    | 47,524              | 139,545    | 232,422    | 318,847    | 468,876    | 639,867    | 828,270    | 1,030,339    | 1,251,979    |
| Inventory                                                                                |                    | 8,250     | 16.480    | 7.852     | 13.456    | 21.527              | 27.195     | 31.375     | 37.287     | 39.418     | 42,952     | 43,637     | 47.128       | 47.618       |
| In Progress R&D                                                                          | 15,292             | 15,292    | 15,292    | 15,292    | 15,292    | 15,292              | 15,292     | 15,292     | 15,292     | 15,292     | 15,292     | 15,292     | 15,292       | 15,292       |
| PP&E. net                                                                                | -                  | -         | -         | 897       | 2,329     | 3,843               | 5,414      | 6,618      | 7,527      | 8,416      | 9,249      | 13,352     | 16,923       | 19,903       |
| Goodw ill                                                                                | 5,811              | 5,811     | 5,811     | 5,811     | 5,811     | 5,811               | 5,811      | 5,811      | 5,811      | 5,811      | 5,811      | 5,811      | 5,811        | 5,811        |
| Other Assets                                                                             | 40                 | 48        | 48        | 48        | 48        | 48                  | 48         | 48         | 48         | 48         | 48         | 48         | 48           | 48           |
| TOTAL ASSETS                                                                             | 33,625             | 61,525    | 69,938    | 49,250    | 51,025    | 94,045              | 193,305    | 291,566    | 384,812    | 537,862    | 713,219    | 906,409    | 1,115,541    | 1,340,650    |
|                                                                                          |                    |           |           |           |           |                     |            |            |            |            |            |            |              |              |
| LIABILITIES & EQUITY                                                                     |                    |           |           |           |           |                     |            |            |            |            |            |            |              |              |
| Current Liabilities                                                                      |                    |           |           |           |           |                     |            |            |            |            |            |            |              |              |
| Accounts Payable                                                                         | 1,957              | 2,800     | 2,712     | 6,315     | 7,657     | 9,953               | 12,418     | 13,753     | 14,983     | 14,675     | 14,952     | 15,691     | 16,947       | 18,264       |
| Accrued Expenses                                                                         | 1,369              | 4,759     | 5,017     | 6,947     | 7,657     | 7,962               | 8,693      | 8,252      | 7,491      | 7,337      | 7,476      | 7,846      | 8,473        | 9,132        |
| Total Current Liabilities                                                                | 3,326              | 7,559     | 7,729     | 13,262    | 15,313    | 17,915              | 21,111     | 22,005     | 22,474     | 22,012     | 22,428     | 23,537     | 25,420       | 27,396       |
| Contingent Consideration - Int. Payable                                                  | -                  | -         | -         | 2,500     | 5,250     | 8,275               | 11,603     | 15,263     | -          | -          | -          | -          | -            | -            |
| Deferred Income Tax Liability                                                            | -                  | -         | -         | -         | -         | -                   | -          | -          | -          | -          | -          | -          | -            | - 1          |
| Contingent Consideration - Long Term                                                     | 18,739             | 21,835    | 25,000    | 25,000    | 25,000    | 25,000              | 25,000     | 25,000     | 0          | 0          | 0          | 0          | 0            | 0            |
| Total Liabilities                                                                        | 22,065             | 29,394    | 32,729    | 40,762    | 45,563    | 51,190              | 57,713     | 62,268     | 22,474     | 22,012     | 22,428     | 23,537     | 25,420       | 27,396       |
|                                                                                          |                    |           |           |           |           |                     |            |            |            |            |            |            |              |              |
| Equity                                                                                   |                    |           |           |           |           |                     |            |            |            |            |            |            |              |              |
| Common Stock; \$0.01 par value                                                           | 1                  | 172       | 584       | 607       | 635       | 671                 | 716        | 767        | 818        | 868        | 919        | 970        | 1,022        | 1,073        |
| Series A Pref Stock - Redeemable Preferred Stock                                         | 6,000              |           |           |           |           |                     |            |            |            | -          | -          | -          | -            |              |
| Additional Paid in Capital - Common Stock                                                | 492                | 135,780   | 176,529   | 178,811   | 181,578   | 185,174             | 189,661    | 194,631    | 199,684    | 204,633    | 209,676    | 214,779    | 219,882      | 224,942      |
| Additional Paid in Capital - Preferred Stock<br>Retained Earnings / (Accumlated Deficit) | 49,829<br>(44,761) | (103,821) | (139,904) | (170,929) | (176,751) | (142,990)           | (54,786)   | 33,901     | 161.836    | 310.349    | 480.196    | 667.123    | 869.217      | 1.087.239    |
| Total Equity                                                                             | 11,560             | 32,131    | 37.209    | 8,489     | 5,462     | (142,990)<br>42.855 | 135,592    | 229,298    | 362,338    | 515,850    | 690,791    | 882,872    | 1.090.121    | 1,087,239    |
| i otai Equity                                                                            | 11,560             | 32,131    | 37,209    | 6,469     | 5,462     | 42,855              | 135,592    | 229,298    | 362,338    | 313,830    | 090,791    | 002,072    | 1,090,121    | 1,313,254    |
| TOTAL LIABILITIES & EQUITY                                                               | \$ 33,625          | \$ 61,525 | \$ 69,938 | \$ 49,250 | \$ 51,025 | \$ 94,045           | \$ 193,305 | \$ 291,566 | \$ 384,812 | \$ 537,862 | \$ 713,219 | \$ 906,409 | \$ 1,115,541 | \$ 1,340,650 |

Source: Company data, Credit Suisse estimates.



# Management

Chief Executive Officer: Paul R. Edick has served as CEO since July 2010. From 2008 to 2010, Mr. Edick was CEO of GANIC Pharmaceuticals, Inc. From 2006 to 2008, Mr. Edick served as CEO of MedPointe Inc. until its acquisition by Meda AB. Mr. Edick also serves as a member of the board of directors of Newlink Genetics Corporation. From 2008 to 2011, Mr. Edick served as chairman of the board of directors of LifeCycle Pharma A/S.

Chief Operating Officer and Chief Financial Officer: Corey N. Fishman has served as COO since August 2010 and as CFO since June 2012. From 2008 to 2010, Mr. Fishman served as CFO of GANIC Pharmaceuticals, Inc. From 2006 to 2008, he served as CFO of MedPointe, Inc., until its acquisition by Meda AB.

Chief Medical Officer: Michael W. Dunne, M.D., has served as CMO since September 2010. He also served as CMO on a consulting basis from December 2009 to September 2010. From 1992 to 2009, Dr. Dunne served in a variety of roles in connection with the clinical development of numerous infectious disease compounds at Pfizer, including as vice president, therapeutic head of development for infectious disease from 2001 to 2009. Dr. Dunne holds a B.A. in economics from Northwestern University and an M.D. from the State University of New York Health Sciences Center. He completed his internal medicine residency and fellowships in infectious diseases and pulmonary medicine at Yale University School of Medicine.

Chief Commercial Officer: John Shannon has served as CCO since March 2012. From 2002 until 2012, Mr. Shannon served in a variety of roles at Baxter International, Inc., including as general manager, U.S. biopharm business from 2010 to 2011; vice president marketing, North America, from 2004 to 2010; and vice president, renal U.S. marketing and business development from 2002 to 2004.



# **Appendix 1**

## **Detailed Initiation Slide Deck**

Exhibit 7: Initiating on DRTX with an Outperform Rating; Target Price of \$13



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Source: Credit Suisse Global Biotechnology Team

## **Exhibit 8: DRTX Investment Thesis**

### **Investment Thesis**

- We are initiating coverage of Durata Therapeutics (DRTX) with an Outperform rating and \$13 DCF-derived target price
- Durata is an Infectious Disease-focused biopharmaceutical company
  - Founded in 2009 specifically to acquire and commercialize promising clinical-stage infectious disease drug assets
  - Lead compound is dalbavancin (acquired from Pfizer in 2009) for treating infections caused by methicillin-resistant Staphylococcus aureus, a difficult-to-treat and potentially lethal bacterial pathogen
- Totality of the dalbavancin story frames our positive view on Durata
  - Dalbavancin's 1x/week dosing, efficacy on par with gold-standard and competitors, and better safety profile provides true product differentiation in a highly genericized and commoditized market
  - Dalbavancin's MOA is not novel. Rather, the dosing regimen presents a radically new treatment paradigm with significant value propositions for patients, physicians, hospitals, and payors
  - Very robust historical data package (previously evaluated by the FDA) and agency-guided pivotal study designs (U.S. & EU) suggest that clinical and regulatory risk is fairly low at this point
  - MRSA infection market is sufficiently large that even very conservative market share estimates imply significant peak sales numbers for dalbavancin
  - Out-patient therapy of MRSA, dalbavancin's clinical niche, is already expanding due to cost-control
    efforts as well as some heavy lifting being done by Durata's competitors

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Source: Company data, Credit Suisse estimates



#### **Exhibit 9: DRTX Valuation**

#### **DRTX Valuation**

| Discounted Cash Flow Analysi                                                                    | is |                                              |        |     |             |    |          |    |          |    |          |    |         |    |          |    |         |    |         |    |         |    |         |               |
|-------------------------------------------------------------------------------------------------|----|----------------------------------------------|--------|-----|-------------|----|----------|----|----------|----|----------|----|---------|----|----------|----|---------|----|---------|----|---------|----|---------|---------------|
| \$000's except per share information                                                            | _  |                                              |        |     |             |    |          |    |          |    |          |    |         |    |          |    |         |    |         |    |         |    |         |               |
| Discount rate                                                                                   |    | 10.0%                                        |        |     |             |    |          |    |          |    |          |    |         |    |          |    |         |    |         |    |         |    |         |               |
| Current period                                                                                  |    | 2012                                         |        |     |             |    |          |    |          |    |          |    |         |    |          |    |         |    |         |    |         |    |         |               |
| Terminal growth rate                                                                            |    | 0.0%                                         |        |     |             |    |          |    |          |    |          |    |         |    |          |    |         |    |         |    |         |    |         |               |
| Period                                                                                          |    | 2012E                                        | 2013E  | П   | 2014E       |    | 2015E    |    | 2016E    |    | 2017E    |    | 2018E   |    | 2019E    |    | 2020E   |    | 2021E   |    | 2022E   |    | 2023E   | 2024E         |
| Net income                                                                                      | \$ | (59,060) \$                                  | (36,08 | 3)  |             | \$ | (5,822)  | \$ | 33,761   | \$ | 88,204   | \$ |         | \$ | 127,935  | \$ | 148,513 | \$ | 169,848 | \$ |         | \$ |         | \$<br>218,022 |
| Add: D&A expense                                                                                | 1  | - 1                                          |        | - [ | 224         | 1  | 638      |    | 1,177    |    | 1,863    |    | 2,630   |    | 3,234    | 1  | 3,748   | 1  | 4,220   |    | 5,443   |    | 6,738   | 8,131         |
| Add: SBC expense                                                                                | 1  | 1,049                                        | 99     |     | 2,305       | 1  | 2,795    |    | 3,633    |    | 4,533    |    | 5,020   |    | 5,104    |    | 4,999   |    | 5,094   |    | 5,155   |    | 5,155   | 5,111         |
| Add: (Increase)/decrease in WC                                                                  | 1  | (4,017)                                      | (8,06  | 0)  | 9,551       | 1  | (7,451)  |    | (11,707) |    | (10,306) |    | (9,359) |    | (10,843) |    | (6,657) |    | (6,536) |    | (2,874) |    | (5,195) | (2,278)       |
| Less: Capital expenditures                                                                      | ╙  |                                              |        | -   | 1,122       | 1  | 2,070    | ╙  | 2,691    | _  | 3,434    | L  | 3,835   | _  | 4,143    | _  | 4,637   | _  | 5,053   | _  | 9,546   | _  | 10,309  | 11,111        |
| Free cash flow                                                                                  | \$ | (62,028) \$                                  | (43,15 | 3)  | \$ (20,066) | \$ | (11,909) | \$ | 24,172   | \$ | 80,860   | \$ | 83,143  | \$ | 121,288  | \$ | 145,965 | s  | 167,573 | \$ | 185,105 | \$ | 198,483 | \$<br>217,875 |
| PV of free cash flow                                                                            | ┖  | (62,028)                                     | (39,23 | 0)  | (16,583)    |    | (8,948)  |    | 16,510   |    | 50,208   |    | 46,932  |    | 62,240   |    | 68,094  |    | 71,067  |    | 71,366  |    | 69,567  | 69,422        |
| Total PV of cash flows Risk-weighted @ 60.0% Add: Terminal value Add: YE 2012 cash Equity value | \$ | 398,616<br>239,170<br>-<br>30,769<br>269,938 |        |     |             |    |          |    |          |    |          |    |         |    |          |    |         |    |         |    |         |    |         |               |
| Diluted shares outstanding (YE 2012)                                                            |    | 20,289                                       |        |     |             |    |          |    |          |    |          |    |         |    |          |    |         |    |         |    |         |    |         |               |
| Price per share                                                                                 | \$ | 13.30                                        |        |     |             |    |          |    |          |    |          |    |         |    |          |    |         |    |         |    |         |    |         |               |

Our \$13 TP for DRTX is derived from a DCF analysis of dalbavancin revenues through 2024 (peak sales \$635M). We risk-weight the NPV of cash flows (60% probability). Probability adjustment primarily reflects the execution risk that Durata management faces, given that successful commercialization of dalbavancin is contingent upon significantly changing physician practice and habits. We use a standard 10% discount rate with no terminal value.

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Sources: Company data, Credit Suisse analysis

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Source: Company data, Credit Suisse estimates

#### **Exhibit 10: DRTX Key Risk Factors**

## **Key Risk Factors**

#### Dalbavancin does not meet clinical trial endpoints in abSSSI

- Durata is only the second company to incorporate the 2010 FDA draft guidelines on skin infection trials, hence there are no precedents for assessing the trial implications of mandated inclusion and exclusion criteria, non-inferiority margins, skin lesion measurement technique, etc.
- We note that retrospective analysis of a previous dalbavancin trial vs. Zyvox, though of limited comparability, suggests that DISCOVER-1 and -2 have a high probability of providing positive data

#### Dalbavancin is not approved or launch is significantly delayed

 Dalbavancin is currently Durata's only commercializable asset. Because of this revenue concentration, non-approval or a significant delay would materially harm the company's business.

#### Dalbavancin launch ramp and/or peak sales could underperform our estimates

- We have modeled in a modest launch ramp and peak sales estimate for dalbavancin based on the past launches of comparable antibiotics, pricing at parity with branded competitors on a per treatment course basis, and a very conservative peak market share of ~6%.
- For dalbavancin to be broadly adopted, however, physician practice behaviors will need to be changed and the drug's pharmaco-economic benefits effectively communicated—which may prove challenging for the company

#### Dalbavancin is not adopted for other MRSA indications

- Eventual use of dalbavancin outside of skin infections is assumed in our revenue estimates.
- Failure to expand indications could make our estimates too high.

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Source: Credit Suisse Global Biotechnology Team

#### Exhibit 11: Background on abSSSI and MRSA

### What are abSSSI and MRSA? How are they treated?



Relatively mild MRSA infection on a hand



Severe MRSA infection that started on the foot

- Acute bacterial skin and skin structure infection (abSSSI)
  - Acute spreading infection of the skin with possible involvement of subcutaneous tissue; also known as cellulitis
  - Mostly traumatic in origin or associated with a previous more superficial infection
  - Commonly mild-to-moderate in severity but clinical spectrum extends to severe cases characterized by faster spread, larger/deeper lesions, and systemic signs such as fever or spreading to the bloodstream
- Methicillin-resistant S. aureus (MRSA) is the most common causative bacterium
  - MRSA is much harder to treat than run-of-the-mill S. aureus because it has developed resistance mechanisms to standard gram-positive antibiotics
  - Standard-of-care for MRSA skin infection is IV vancomycin, infused 2x/day for 14 days; PK and side effects make drug monitoring and dose adjustments for renal patients mandatory
  - More recently, newer antibiotics like Zyvox (2x/day oral) and Cubicin (1x/day IV) have allowed for more convenient treatment, including in the outpatient setting



Mandell et al. Principles and Practice of Infectious Disease. 7th ed., Credit Suisse analysis

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Sources: Mandell et al. Principles and Practice of Infectious Disease and Credit Suisse analysis; images from www.sciencephoto.com and www.uscellulitistreatment.us.

## **Exhibit 12: Background on Dalbavancin**

#### What is Dalbavancin?

- Dalbavancin is a 2<sup>nd</sup>-generation semisynthetic lipoglycopeptide antibiotic
  - Similar mechanism of action as vancomycin, the gold-standard of treatment for abSSSI caused by MRSA
  - Like vancomycin, dalbavancin has broad spectrum activity against gram-positive bacteria, particularly specie that cause abSSSI
  - Antibiotics like vancomycin and dalbavancin are important in the treatment of abSSSI because of the increasing incidence of MRSA, which is very difficult to treat
  - Studies in culture show that dalbavancin is several-fold more potent (minimum inhibitory concentration; MIC) than vancomycin
- While MRSA is still sensitive to vancomycin, resistant strains have been reported and there is emerging evidence of an upward vancomycin MIC "creep" in Staphylococcus

|                                                                  |              | No. (C             | umulative % | ) inhibited at | Dalbava | ncin MIC      | (μg/ml)  |   |    |
|------------------------------------------------------------------|--------------|--------------------|-------------|----------------|---------|---------------|----------|---|----|
| Pathogen/subset<br>(no. tested) <sup>a</sup>                     | ≤0.03        | 0.06               | 0.12        | 0.25           | 0.5     | 1             | 2        | 4 | >4 |
| S. aureus                                                        |              |                    |             |                |         | Vancomyc      | I- MICOO |   |    |
| All (11,658)                                                     | 2,773 (23.8) | 7,987 (92.3)       | 863 (99.7)  | 35 (100.0)     | -       | vancomyc<br>- | in MIC90 | - | -  |
| MRSA (3,183)                                                     | 914 (28.7)   | 2,018 (92.1)       | 238 (99.6)  | 13 (100.0)     | -       | -             | -        | - | -  |
| MSSA (8,475)                                                     | 1,859 (21.9) | 5,969 (92.4)       | 625 (99.7)  | 22 (100.0)     | -       | -             | -        | - | -  |
| MRSA = methicillin-resistant S.  Source: RN Jones, DJ Farrell, F |              | usceptible S. aure | eus         |                |         |               |          |   |    |
|                                                                  |              |                    |             |                |         |               |          |   |    |

Source: RN Jones, DJ Farrell, HS Sader; ECCMID 2011.

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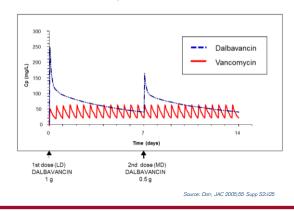
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#### Exhibit 13: Dalbavancin Pharmacokinetics and Dosing Regimen

## How is Dalbavancin Differentiated?

- Long-acting pharmacokinetics of dalbavancin allow once weekly IV dosing (at day 1 then day 8) vs. every 8-12 hours IV x 14 days for vancomycin
- Also, dalbavancin is infused over only 30mins vs. 60-90mins for vancomycin (due to risk of "red-man syndrome" infusion reaction)



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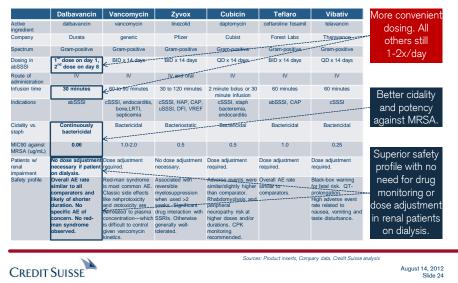
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Source: Dorr, JAC 2005;55 Supp S2:ii25.

Exhibit 14: Comparing Dalbavancin to Approved Competitors in abSSSI

#### How is Dalbavancin Differentiated?

Arguably superior clinical profile versus currently approved competitors in abSSSI

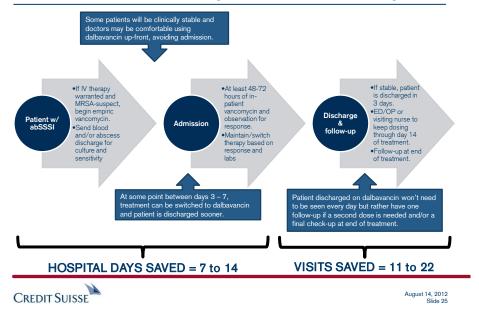


Source: Product inserts, Company data, Credit Suisse analysis.



#### Exhibit 15: Changing the MRSA Treatment Paradigm with Dalbavancin

## How Can Dalbavancin Change the Treatment Paradigm?

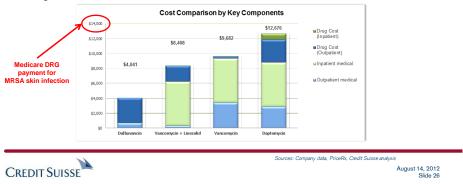


Source: Credit Suisse analysis.

## **Exhibit 16: Using Dalbavancin May Provide Significant Cost Savings**

## The Economic Argument to Hospitals and Payors

- Comparing the cost of 3 common clinical scenarios vs. using dalbavancin up-front to avoid admission provides a compelling pharmaco-economic argument
  - Dalbavancin x 14 days on out-patient basis (drug cost = \$3,300) versus...
  - Vancomycin x 3d in-patient (\$300), x 11d oral linezolid out-patient (\$2,340);
  - Vancomycin x 3d in-patient (\$300), x 11d out-patient (\$1,100);
  - Daptomycin x 3d in-patient (\$860), x 11d out-patient (\$3,138)
- Drug costs are comparable across branded meds but total treatment costs are potentially much lower for a patient given dalbavancin even vs. vancomycin
- Framing the value proposition in this manner should help get dalbavancin on hospital and managed care formularies



Source: Company data, PriceRx, Credit Suisse estimates.



#### Exhibit 17: Dalbavancin's Broad Value Proposition

#### Dalbavancin's Value Proposition Runs Across the Board CLINICAL **Patients** Hospitals • Can get treated in ED/OP Discharge patients sooner Reduce or avoid hospital and minimize or avoid hospital stay. or avoid admission completely. No need for an indwelling catheter (PICC line). patients. Reduce costs resulting No need for drug from drug monitoring, using a PICC, and nursing Frequency of follow-up is markedly decreased. monitoring or dose adjustment. Easier compliance with therapy vs. even oral Minimize hospital exposure to MRSA. Better compliance means antibiotics less readmission and development of resistance Good safety w/o need for drug monitoring. penalties resulting from follow-up visits. nosocomial

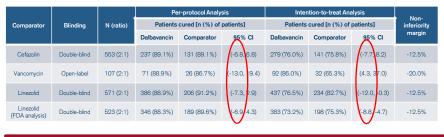
Source: Credit Suisse analysis.

### Exhibit 18: Dalbavancin's Previous Phase III Data Were Positive

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## Dalbavancin Has a Robust, Existing Data Package

- Three separate Phase III trials have already established dalbavancin's equivalent efficacy in abSSSI vs. relevant comparator antibiotics
- Primary efficacy endpoint in all three was non-inferiority vs. comparator in terms of clinical and microbiological responses at end of treatment (day 14) and test-of-cure visit (day 28), on a per-protocol basis. ITT analysis also performed
- The non-inferiority margin (lower-bound of 95% CI) was pre-specified
- Primary endpoint was met in all 3 trials
- For the trial vs. linezolid, FDA re-analyzed the data and the lower-bound actually improved



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Sources: Company data, Credit Suisse analysis

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Source: Company data, Credit Suisse analysis.

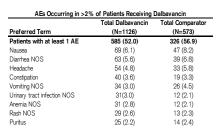


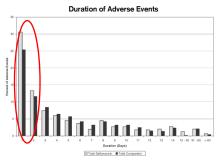
## Exhibit 19: Dalbavancin May Have a Better Safety Profile than Comparators

## Dalbavancin's Safety Profile

Integrated safety database from completed Phase II and Phase III programs show comparable, if not slightly better, safety vs. tested comparators

| Overview of Adverse Event Incidence |                   |                  |  |  |  |  |  |  |  |  |  |  |
|-------------------------------------|-------------------|------------------|--|--|--|--|--|--|--|--|--|--|
|                                     | Total Dalbavancin | Total Comparator |  |  |  |  |  |  |  |  |  |  |
| Preferred Term                      | (N=1126)          | (N=573)          |  |  |  |  |  |  |  |  |  |  |
| ≥1 AE                               | 585 (52.0)        | 326 (56.9)       |  |  |  |  |  |  |  |  |  |  |
| ≥1 treatment-related AE             | 248 (22.0)        | 157 (27.4)       |  |  |  |  |  |  |  |  |  |  |
| ≥1 SAE                              | 92 (8.2)          | 54 (9.4)         |  |  |  |  |  |  |  |  |  |  |
| ≥1 treatment-related SAE            | 2 (0.2)           | 5 (0.9)          |  |  |  |  |  |  |  |  |  |  |
| ≥1 AE leading to discontinuation    | 39 (3.5)          | 22 (3.8)         |  |  |  |  |  |  |  |  |  |  |
| Number (%) deaths                   | 9 (0.8)           | 7 (1.2)          |  |  |  |  |  |  |  |  |  |  |
| Number (%) of deaths due to TAE     | 0                 | 0                |  |  |  |  |  |  |  |  |  |  |





Dalbavancin AEs have a shorter duration vs. comparators.

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Sources: Company data, Credit Suisse analysi.

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Source: Company data, Credit Suisse analysis.

## Exhibit 20: Retrospective Analysis Suggests Positive DISCOVER Outcomes

## Retrospective Analysis of VER001-9

- Company-sponsored retrospective analysis of dalbavancin Phase III vs. linezolid recently presented at ECCMID 2011
- Study applied 2010 FDA guidelines on primary endpoint (early assessment timepoint of 3-4 days post-initiation of treatment) and inclusion criteria (lesion size + one systemic sign)
- Results show that the magnitude of difference in cure rates between dalbanvancin and Zyvox are similar regardless of which timepoint is used (i.e. early or late assessment @ day
- While retrospective analysis is always limited in applicability, this re-analysis of VER001-9 supports our view that dalbavancin will meet its primary endpoint in the DISCOVER trials

| Timepoint | Analysis Population                  | Endpoint                                              | Dalbavancin, n/N (%)               | Linezolid, n/N (%)                 | Difference   | 95% CI                      |
|-----------|--------------------------------------|-------------------------------------------------------|------------------------------------|------------------------------------|--------------|-----------------------------|
| Day 3/4   | Clinically evaluable                 | Cessation of spread + afebrile<br>Cessation of spread | 283/340 (83.2%)<br>312/340 (91.8%) | 155/178 (87.1%)<br>165/178 (92.7%) | -3.8<br>-0.9 | (-10.6, 2.9)<br>(-6.2, 4.3) |
|           | + >75cm2 lesions                     | Cessation of spread + afebrile<br>Cessation of spread | 212/258 (82.2%)<br>237/258 (91.9%) | 109/135 (80.7%)<br>121/135 (89.6%) | 1.4<br>2.2   | (-7.3, 10.1)<br>(-4.5, 8.9) |
|           | + >75cm2 lesions + one systemic sign | Cessation of spread + afebrile<br>Cessation of spread | 103/135 (76.3%)<br>120/135 (88.9&) | 67/85 (78.8%)<br>76/85 (89.4%)     | -2.5<br>-0.5 | (-14.8, 9.7)<br>(-9.9, 8.9) |
| Day 28    | Clinically evaluable                 | Clinical response at test-of-cure                     | 386/434 (88.9%)                    | 206/226 (91.2%)                    | -2.2         | (-7.3, 2.9)                 |



Sources: Dunne, MW et al. Poster presented at ECCMID 2011

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Source: Dunne, MW et al. Poster presented at ECCMID 2011.

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#### Exhibit 21: Development Delays Were Not Specific to Dalbavancin

## So What's Been Taking So Long?

- Pfizer acquired dalbavancin through its purchase of Vicuron in 2005, after Vicuron filed an NDA in 2004 (subsequent MAA in the EU filed in 2007)
- Between 2005-2007, Pfizer received 3 APPROVABLE letters from the FDA
  - First 2 letters related to manufacturing issues (which were resolved)
  - Third approvable letter questioned the justification of the -12.5% inferiority margin used in the dalbavancin vs. cefazolin Phase III
  - EMA subsequently questioned approvability because patients in pivotal trial were not that sick
- Given the regulatory uncertainty around anti-infectives at the time (NOT specific to dalbavancin), Pfizer decided to withdraw its applications in 2008
- Durata resumed dalbavancin development in 2010 after discussions with the FDA and also getting scientific advice from the EMA
- Durata has initiated 2 pivotal Phase III trials under SPAs, taking into account the FDA's draft guidance on abSSSI trials released in 2010
- Both agencies determined that DISCOVER programs will be adequate for approval
- Strong historical Phase III data and very likely similar results from new pivotal trials make us believe that dalbavancin has been significantly de-risked from a regulatory standpoint

Sources: Company data, Credit Suisse analysis

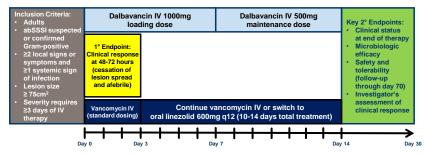
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Source: Company data, Credit Suisse analysis.

#### Exhibit 22: DISCOVER Programs Incorporate 2010 FDA Guidelines on abSSSI Trials

## DISCOVER-1 & -2 Phase III Trial Design



- Trials are 90% powered for non-inferiority with 85% point estimate of treatment effect.
- N=556 for each study from multiple global centers; DISCOVER-1 is >75% enrolled and -2 is at >40% enrolled.
- More stringent non-inferiority margin of -10% (lower-bound of 95% Cl).
- Lesion size measured with a ruler but also backed up by Aranz digital camera and Canfield tracings to account for inter-/intra-observer variability.
- Primary endpoint for EMA is clinical status at end of therapy.

Sources: Company data, www.clinicaltrials.gov, Credit Suisse analysis

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Source: Company data, Credit Suisse analysis.



## Additional Data Updates to Dalbavancin NDA/MAA

- Updated microbiology package with European surveillance data (ECCMID 2011)
- Additional Phase I studies completed
  - QT-interval not prolonged by dalbavancin (DUR001-102)
  - PK studies in Japanese cohort
- Additional Phase II completed
  - Study to develop methods for measuring lesion size (DUR000-201)
  - Lesion size was previously not a component of skin infection trial endpoints
  - With changing guidelines, FDA encouraged sponsors to validate measurement techniques prior to starting new studies
  - DUR000-201 results suggest near-perfect correlations of paired intra- and paired inter-observer ruler measurements
  - Also developed use of digital photography and manual tracings as back-up measurement methods
  - Strengthened methods training and protocols for investigators
- FDA requires one new Phase III and re-analysis of previous trial vs. linezolid
- EMA confirmed that previously submitted package confirms claim and DISCOVER program with separate EU analysis will be sufficient

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Sources: Company data, Credit Suisse analysis

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Source: Company data, Credit Suisse analysis.

Exhibit 24: Potential Dalbavancin News Flow through Approval and Launch

## Clinical and Regulatory Catalysts





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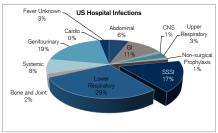
Source: Company data, Credit Suisse analysis.

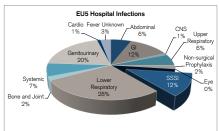


#### Exhibit 25: Significant Number of Patients Present to Hospital with Skin Infections

## What is Dalbavancin's Commercial Opportunity?

- Skin infections account for a significant percentage of hospital infections treated annually.
  - ~17% of hospital infections in the U.S. or 3.3M patients per year.
  - Of these, ~60% (~2M patients) had cellulitis, traumatic wound or surgical wound infections.
  - EU5 percentages are roughly similar to the U.S. and the equivalent population is ~1M.





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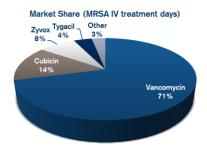
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Source: Company data, Credit Suisse estimates.

## Exhibit 26: Commercial Opportunity in IV MRSA Therapy Is Sizable

## What is Dalbavancin's Commercial Opportunity?

- The size of the IV therapy market for MRSA is very significant.
  - Estimated 35M days of IV therapy annually for MRSA in the U.S. alone (all indications).
  - At branded pricing, this market is worth ~\$10B annually.
  - ~26% of this market is in the out-patient setting, a natural fit for dalbavancin.
  - At least 70% of treatment days are still generic vancomycin but branded drugs with a differentiated profile, such as Cubicin, have already made in-roads (Cubicin has ~14% share).
  - Dalbavancin's highly differentiated dosing regimen should help it penetrate the market and our very conservative 6% market share estimate implies peak revenues of \$635M.



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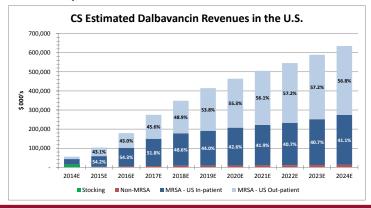
Source: Company data, Credit Suisse estimates.



## Exhibit 27: Dalbavancin Likely to Capture Greater Share in Outpatient

## What is Dalbavancin's Commercial Opportunity?

- We model dalbavancin to capture more share in out-patient, given its dosing regimen.
- Launch will be at pricing parity to branded drugs but we have very conservative price increase estimates of only 5% annually (vs. 8-10% historically for Cubicin).
- Valuation does not yet account for ex-US sales.



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Source: Company data, Credit Suisse estimates.

#### Exhibit 28: Increasing Prevalence of MRSA and Increased Outpatient Utilization Provide Tailwinds

## **Emerging Trends in MRSA and its Treatment**

- Increasing prevalence of community-acquired (CA)-MRSA implies expansion of out-patient treatment.
- In 2008, 59% of skin infections were MRSA, 98% were of a CA-MRSA genotype (in a network of 12 urban emergency departments).
- In 2010, 50% of in-patient MRSA infections classified as CA-MRSA vs. 30% in 2006, even as hospital-associated MRSA prevalence went down (in 590 healthcare facilities across the U.S.).
- More MRSA skin infections occurring in people without known risk factors (i.e. young, healthy, no recent history of healthcare contact).
- The shift of utilization from in-patient to out-patient and the overall push for controlling healthcare costs provide a tailwind for dalbavancin.
  - Medicare payments for out-patient services have grown faster than in-patient over the past decade.
  - Also manifested in hospital admission trends over the past few years.
  - Provisions and concepts in healthcare reform law point to the increasing focus on cost-control (ACOs, bundling, preventable readmission penalties, hospital-acquired condition penalties, etc.).
- Competitors already doing the heavy lifting to expand out-patient treatment of MRSA.
  - Cubicin consensus sales estimate of ~\$900M for 2012 (launched 2003).
  - Current out-patient sales already at 47% of total U.S. Cubicin revenues, on the back of QD dosing.
  - We expect dalbavancin can be marketed effectively with a smaller sales force and marketing budget as compared to Cubicin

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Sources: Company data, Credit Suisse analysi.

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Source: Company data, Credit Suisse analysis.

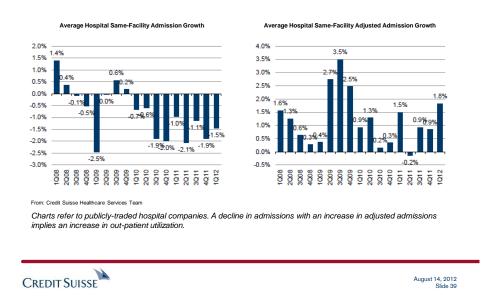
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## Exhibit 29: Hospitals Shifting Care to Outpatient for Cost Savings

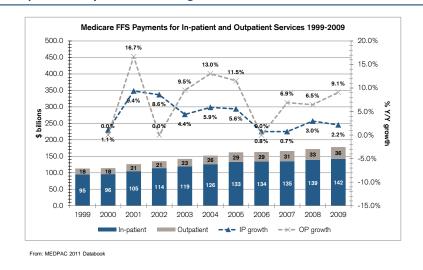
## Hospital Services Shifting to Out-patient



Source: Credit Suisse Healthcare Services Team.

**Exhibit 30: Outpatient Spending Is Growing Faster than Inpatient** 

## Out-patient Spend Growing at Faster Pace



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Source: MEDPAC 2011 Databook.



#### Exhibit 31: Dalbavancin Revenue Model through 2024

## **Dalbavancin Revenue Model**

|                                                      | 2014       | 2015       | 2016       | 2017       | 2018       | 2019       | 2020       | 2021       | 2022       | 2023       | 2024       |   |                                         |
|------------------------------------------------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|---|-----------------------------------------|
| United States                                        |            |            |            |            |            |            |            |            |            |            |            |   |                                         |
| Treatment Days                                       |            |            |            |            |            |            |            |            |            |            |            |   |                                         |
| MRSA - US Hospital                                   | 26,523,913 | 26,656,533 | 26,789,815 | 26,923,764 | 27,058,383 | 27,193,675 | 27,329,643 | 27,329,643 | 27,329,643 | 27,329,643 | 27,329,643 |   | Peak sales                              |
| MRSA - US Outpatient<br>Non-MRSA - US % of Hospital  | 9,837,398  | 10,181,707 | 10,588,975 | 11,065,479 | 11,618,753 | 12,199,691 | 12,809,675 | 12,809,675 | 12,809,675 | 12,809,675 | 12,809,675 | • | reak sales                              |
| Non-NPGA - US % of Hospital                          | 1,320,196  | 1,332,027  | 1,339,491  | 1,346,186  | 1,352,919  | 1,359,664  | 1,300,402  | 1,366,462  | 1,366,462  | 1,300,402  | 1,300,402  |   |                                         |
| Growth Rate                                          | 1 1        |            |            |            |            |            |            |            |            |            |            |   | estimate of \$635M                      |
| MRSA - US Hospital                                   | 0.5%       | 0.5%       | 0.5%       | 0.5%       | 0.5%       | 0.5%       | 0.5%       | 0.0%       | 0.0%       | 0.0%       | 0.0%       |   | 0011111010 01 4000111                   |
| MRSA - US Outpatient                                 | 3.0%       | 3.5%       | 4.0%       | 4.5%       | 5.0%       | 5.0%       | 5.0%       | 0.0%       | 0.0%       | 0.0%       | 0.0%       |   | by 2024 is based                        |
| Non-MRSA - US % of Hospital                          | 5.0%       | 5.0%       | 5.0%       | 5.0%       | 5.0%       | 5.0%       | 5.0%       | 5.0%       | 5.0%       | 5.0%       | 5.0%       |   | Dy 2024 is based                        |
| Share of Treatment Days                              |            |            |            |            |            |            |            |            |            |            |            |   | 00/                                     |
| MISSA - US Heavited                                  | 0.6%       | 1.2%       | 2.0%       | 2.8%       | 3.2%       | 3.7%       | 3.4%       | 35%        | 3.5%       | 3.6%       | 37%        |   | on ~6%                                  |
| MRSA - US Outputient                                 | 0.8%       | 2.5%       | 4.0%       | 6.0%       | 7.5%       | 9.0%       | 9.5%       | 10.0%      | 10.5%      | 10.8%      | 11.0%      |   |                                         |
| Non-MRSA - US % of Hospital                          | 0.6%       | 1.2%       | 2.0%       | 2.8%       | 3.2%       | 3.3%       | 3.4%       | 3.5%       | 3.5%       | 3.6%       | 3.7%       |   | penetration into the                    |
|                                                      | 1 1        |            |            |            |            |            |            |            |            |            |            |   | penelialion into the                    |
| Total Treatment Days                                 | 251,896    | 590,415    | 985,145    | 1,455,487  | 1,780,568  | 2,040,233  | 2,202,153  | 2,285,332  | 2,349,380  | 2,416,505  | 2,480,386  |   | MDCA IV/ thorony                        |
| Total Share of Treatment Days                        | 0.7%       | 1.5%       | 2.5%       | 3.7%       | 4.4%       | 5.0%       | 5.3%       | 5.5%       | 5.7%       | 5.8%       | 6.0%       |   | MRSA IV therapy                         |
| Dabavancin Patients (@14-day course)                 |            |            |            |            |            |            |            |            |            |            |            |   |                                         |
| MRSA - US Hospital                                   | 11,894     | 22.848     | 38.271     | 53,848     | 61.848     | 64,099     | 67.023     | 68,324     | 68.324     | 70.276     | 72.879     |   | market.                                 |
| MRSA - US Outpatient                                 | 5,504      | 18,182     | 30,254     | 47,423     | 62,243     | 78,427     | 86,923     | 91,498     | 95,073     | 98,817     | 100,647    |   | *************************************** |
| Non-MRSA - US % of Hospital                          | 595        | 1,142      | 1,914      | 2,692      | 3,092      | 3,205      | 3,351      | 3,416      | 3,416      | 3,514      | 3,644      |   | Baseline                                |
| Total Dalbavancin Patients                           | 17,993     | 42,172     | 70,439     | 103,963    | 127,183    | 145,731    | 157,297    | 163,238    | 167,813    | 172,608    | 177,170    | _ | Dascillic                               |
| Visits per Patient                                   |            |            |            |            |            |            |            |            |            |            |            |   | and a comment and the                   |
| MRSA - US Hospital                                   | 2.5        | 2.5        | 2.5        | 2.5        | 2.5        | 2.5        | 2.5        | 2.5        | 2.5        | 2.5        | 2.5        |   | assumption is                           |
| MRSA - US Outpatient                                 | 2.5        | 2.5        | 2.5        | 2.5        | 2.5        | 2.5        | 2.5        | 2.5        | 2.5        | 2.5        | 2.5        |   |                                         |
| Non-MRSA - US % of Hospital                          | 2.5        | 2.5        | 2.5        | 2.5        | 2.5        | 2.5        | 2.5        | 2.5        | 2.5        | 2.5        | 2.5        |   | patent expiration in                    |
| Number of Visits                                     |            |            |            |            |            |            |            |            |            |            |            |   | paterit expiration in                   |
| Number of Visits MRSA - IS Hounited                  | 29.734     | 57 121     | 95 678     | 134 619    | 154 619    | 160 248    | 967 557    | 170.810    | 170 810    | 125 601    | 182 198    |   | 2024 but H-W                            |
| MRSA - US Outputient                                 | 13.761     | 45,454     | 75.636     | 118,559    | 155,608    | 195,055    | 217,307    | 228.744    | 240,181    | 247,044    | 251,619    |   | 2024 DUL 11-11                          |
| Non-MRSA - US % of Hospital                          | 1.487      | 2.856      | 4.784      | 6.731      | 7.731      | 8,012      | 8,378      | 8,541      | 8,541      | 8.785      | 2.110      |   |                                         |
| Total Vials                                          | 44,982     | 105,431    | 175,097    | 250,908    | 317,959    | 364,327    | 393,242    | 408,025    | 419,532    | 431,519    | 442,926    |   | patent-term                             |
|                                                      |            |            |            |            |            |            |            |            |            |            |            |   |                                         |
| Stocking<br>(2000 hospitals, 7.5 visis per hospital) | 15,000     |            |            |            |            |            |            |            |            |            |            |   | extension through                       |
| (2000 hospess, 7.5 vais per nospesi)                 | 15,000     |            |            |            |            |            |            |            |            |            |            |   | CALCITISION LINGUIGH                    |
| Avg. Price per Vial                                  | \$1,100    | \$1,155    | \$1,213    | \$1,273    | \$1,337    | \$1,404    | \$1,474    | \$1,548    | \$1,625    | \$1,706    | \$1,792    |   | 2028 and                                |
| Price increase (%)                                   |            | 5.0%       | 5.0%       | 5.0%       | 5.0%       | 5.0%       | 5.0%       | 5.0%       | 5.0%       | 5.0%       | 5.0%       |   | 2026 and                                |
|                                                      |            |            |            |            |            |            |            |            |            |            |            |   | 1.000                                   |
| Gross Sales (\$000's)<br>MRSA - US Hospital          | \$ 32,708  | \$ 65,975  | \$ 116,033 | \$ 171.422 | \$ 206,735 | \$ 224,974 | \$ 246,996 | \$ 264.382 | \$ 277,601 | \$ 299,809 | \$ 326,459 |   | additional data                         |
| Stocking                                             | 16,500     | \$ 65,975  | \$ 110,033 | \$ 171,422 | \$ 206,735 | 5 224,974  | \$ 240,990 | \$ 264,362 | \$ 277,001 | \$ 299,009 | \$ 320,409 |   |                                         |
| MRSA - US Outputient                                 | 15,137     | 52,499     | 91.727     | 150,971    | 208.057    | 275.260    | 320,333    | 354.053    | 390,343    | 421.571    | 450.846    |   | exclusivity through                     |
| Non-MRSA - US % of Hospital                          | 1,635      | 3,299      | 5,802      | 8,571      | 10,337     | 11,249     | 12,350     | 13,219     | 13,880     | 14,990     | 16,323     |   | exclusivity trilough                    |
| Total Gross Sales                                    | 65,980     | 121,773    | 213,562    | 330,964    | 425,129    | 511,483    | 579,679    | 631,654    | 681,824    | 736,370    | 793,628    |   | the OAINLAST sus                        |
|                                                      |            |            |            |            |            |            |            |            |            |            |            |   | the GAIN Act are                        |
| Gross-to-net spread (%)                              | 15.0%      | 15.0%      | 16.0%      | 17.0%      | 18.0%      | 19.0%      | 20.0%      | 20.0%      | 20.0%      | 20.0%      | 20.0%      |   |                                         |
| Net Sales (\$000's)                                  |            |            |            |            |            |            |            |            |            |            |            |   | highly probable.                        |
| MRSA - US Hospital                                   | 27.801     | 55.079     | 97.468     | 142,280    | 169.523    | 182,229    | 197,597    | 211.506    | 222.081    | 239.847    | 261.167    |   | riigiliy probabic.                      |
| Stocking                                             | 14,025     |            |            |            |            |            |            |            |            |            |            |   |                                         |
| MRSA - US Outpatient                                 | 12,866     | 44,625     | 77,051     | 125,306    | 170,607    | 222,950    | 256,267    | 283,242    | 312,274    | 337,256    | 360,677    |   |                                         |
| Non-MRSA - US % of Hospital                          | 1,390      | 2,804      | 4,873      | 7,114      | 8,476      | 9,111      | 9,880      | 10,575     | 11,104     | 11,992     | 13,058     |   |                                         |
| Total Net Sales                                      | \$ 56,083  | \$ 103,507 | \$ 179,392 | \$ 274,700 | \$ 348,606 | \$ 414,301 | \$ 463,744 | \$ 505,323 | \$ 545,450 | \$ 589,096 | \$ 634,902 |   |                                         |
|                                                      |            |            |            |            |            |            |            |            |            |            |            |   |                                         |

Sources: Company data, Credit Suisse analysis

Sources: Company data, Credit Suisse analysis

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Source: Company data, Credit Suisse estimates.

## Exhibit 32: Dalbavancin Income Statements through 2024

## **Durata Income Statement**

\$ 414,301 \$ 463,744 \$ 505,323 \$ 545,459 63,490 571,412 30,217 41,430 372,871 46,374 417,369 SG&A expense Total Operating Expenses Operating Income (Loss) 349,196 Other Income (Expense)
Interest income
Interest (expense) - Miestone Paymer
Other income (expense), net
Total Other Income (Expense) 10 (3,025) 289 1,073 1,492 2,459 33 (2,750) 506 15,263 (2,50 (3,328 (36,083 (31,071 (5,822) 33,76 90,149 143,043 206,347 239,536 273,948 325,965 351,655 133,629 218,026 Sank: w eighted-average shares outsi y/y grow th (%) Diluted w eighted-averge shares outsi y/y grow th (%) 1.0% 21,238 1.0% 20.7% 19,036 20.2% 1.0% 19,613 1.0% Basic earnings (loss) per share Diluted earnings (loss) per share

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Source: Company data, Credit Suisse estimates.

23 **Durata Therapeutics (DRTX)** 

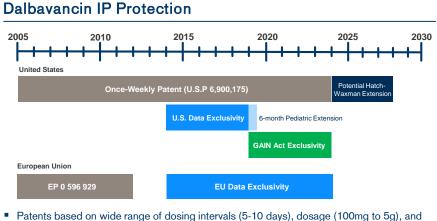
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#### Exhibit 33: Dalbavancin IP Protected through 2024, with Possible Patent-Term and Data Exclusivity Extensions



- dosage ratios (loading dose 2x maintenance dose)
- Patent protection for conceivably 10+ years after launch
- GAIN Act in PDUFA V is specific to data exclusivity grants for anti-infectives for specific pathogens (i.e. MRSA)—additional exclusivity may delay any ANDA filers in the U.S.

Sources: Company data, Credit Suisse analysis

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Source: Company data, Credit Suisse analysis.

## Exhibit 34: Durata's Management Team Has Significant Executive Experience in Biopharmaceuticals

## Management Team and Current Investors

- Leadership with deep and broad experience across every facet of the drug industry:
  - Paul Edick, CEO: President for Asia-Pac/LatAm at Searle and Pharmacia, CEO of MedPointe Healthcare (acquired by Meda AB), CEO of GANIC Pharmaceuticals (Warburg Pincus)
  - Corey Fishman, COO: >\$1B of transactions negotiated and closed in pharmaceuticals, Head of Financial Planning and Analysis at Monsanto, CFO of MedPointe, CFO of GANIC
  - Michael Dunne MD, CMO: VP/Head of Clinical Development of Anti-infectives for Pfizer; dalbavancin
    and it's competitor Zyvox (linezolid) were in his portfolio at the time
  - John Shannon, CCO: GM for global hemophilia and U.S. biopharma businesses at Baxter, Executive Director for global cardiovascular at Searle, VP of marketing at Caremark
- Current investors include several top healthcare VC/PE firms:



Source: Company data.



#### Exhibit 35: Durata Is in the Process of Securing Secondary API and Drug Manufacturing

## CMC and Supply Chain

- Active Pharmaceutical Ingredient
  - Current approved supplier is Gnosis S.P.A.
    - Site was a Vicuron-built facility that was included in dalbavancin NDA filing in 2007
    - Gnosis purchased the facility from Pfizer
    - DISCOVER programs are using new batches from Gnosis and the company will also provide API for launch in 2014
  - Durata will also seek approval for Lonza as a second API supplier
    - Larger capacity and potentially more cost-effective in the long-term
    - Tech-transfer on-going but it is unlikely that FDA will approve the batches prior to launch
- Fill & Finish
  - Current contract with Hospira
    - Providing drugs for DISCOVER programs and for launch in 2014
    - Durata has identified potential secondary contractors but has not finalized anything yet



Sources: Company data, Credit Suisse analysis

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Source: Company data.

## Exhibit 36: Dalbavancin Will Also Be Developed for Orthopedic and Pulmonary Indications

## Life-cycle Management

| Indication           | Rationale                                                                                                                                                                                                                                       | Possible Regimen                                        | Total<br>Sample Size | Est. U.S.<br>Patient Population |
|----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|----------------------|---------------------------------|
|                      | Dalbavancin has sufficient bone penetration; MICs vs. staph are low; 1x/week dosing attractive for long-term treatment                                                                                                                          | 1 gram q weekly for 4-6<br>weeks                        | 550                  | 200,000                         |
| infected joint space | MRSA and streptococcal species are frequently seen in joint<br>space infections; treatment duration can be prolonged so<br>Ix/week dosing with dalbavanch in sattractive; 80% and 66%<br>success rates seen in two stage procedures (hip, knee) | Dalbavancin 1 gram q<br>weekly x 4-6 weeks              | 800                  | 320,000                         |
| infection            |                                                                                                                                                                                                                                                 | Dalbavancin 1 gram q<br>weekly x 4 weeks                | 500                  | 340,000                         |
|                      | Dalbavancin with potent S. pneumoniae activity; could avoid hospitalization if medical condition otherwise manageable                                                                                                                           | Dalbavancin IV +<br>azithromycin x 1 wk                 | 500                  | 5,600,000                       |
|                      | Dalbavancin with activity versus MRSA; excellent activity in<br>animal models; 1x/week dosing helpful in ICU                                                                                                                                    | Dalbavancin 1 gram IV x<br>1 wk then 500 mg on<br>day 8 | 400                  | 250,000                         |
|                      |                                                                                                                                                                                                                                                 | Dalbavancin 1 gram on<br>day 1, 500 mg on day 8         | 25                   | 850,000                         |

- The 3 orthopedic indications highlighted above have the most compelling rationale for use of dalbavancin because of the need for extended treatment
- Durata is also developing other dalbavancin formulations

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Sources: Company data, Credit Suisse analysis

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Source: Company data.



## Exhibit 37: Dalbavancin Is Better Differentiated than Other MRSA Antibiotics in Development

## Competitive Products in Development

|                                  | Oritavancin                                                                                              | TR-700                                       | Taksta                                                                                                               | Omadacycline                                          | BC-3781                                   | Delafloxacin                                | RX-1741                                                                         |
|----------------------------------|----------------------------------------------------------------------------------------------------------|----------------------------------------------|----------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|-------------------------------------------|---------------------------------------------|---------------------------------------------------------------------------------|
| Active ingredient                | oritavancin                                                                                              | tedizolid                                    | fusidic acid                                                                                                         | omadacycline                                          | BC-3781                                   | delafloxacin                                | radezolid                                                                       |
| Company                          | Medicines<br>Company                                                                                     | Trius                                        | Cempra                                                                                                               | Paratek                                               | Nabriva/Forest Labs                       | Rib-X                                       | Rib-X                                                                           |
| Spectrum                         | Gram-positive                                                                                            | Gram-positive                                | Gram-positive                                                                                                        | Broad-spectrum                                        | Broad-spectrum                            | Broad-spectrum                              | Gram-positive                                                                   |
| Dosing                           | Single Dose                                                                                              | QD x 6 days                                  | BID                                                                                                                  | QD                                                    | BID                                       | BID                                         | QD                                                                              |
| Form                             | IV                                                                                                       | IV and Oral                                  | Oral                                                                                                                 | IV and Oral                                           | IV and Oral                               | IV                                          | Oral                                                                            |
| Infusion time                    | 3 Hours                                                                                                  | 60 minutes                                   | N/A                                                                                                                  | Bolus injection                                       | Unknown                                   | Unknown                                     | N/A                                                                             |
| Indications                      | anstesi                                                                                                  | abSSSI, HAP                                  | abSSSI                                                                                                               | SSSI, CABP                                            | alosssi, CABP                             | abSSSI                                      | abSSSI, CABP                                                                    |
| Cidality                         | Continuously<br>bactericidal                                                                             | Static                                       | Static                                                                                                               | Static                                                | Bactericidal                              | Bactericidal                                | Static                                                                          |
| Development<br>phase             | Phase III                                                                                                | Phase III                                    | Phase II                                                                                                             | Phase II                                              | Phase II                                  | Phase II                                    | Phase II                                                                        |
| Possible launch date if approved | Late 2014-early 2015                                                                                     | 2015                                         | Looking for partner to continue development                                                                          | Novartis withdrew from<br>partnership in July<br>2011 | Phase III to initiate in 2013             | Looking for partner to continue development | Looking for partner<br>to continue<br>development                               |
| Safety                           | Infusion site phlebitis,<br>higher serious adverse<br>event rate than<br>comparator in previous<br>PIIIs | Adverse events were<br>similar to comparator | Overall similar to<br>comparator except for<br>a higher rate of<br>jaundice and liver<br>dysfunction<br>(reversible) | Adverse events were<br>similar to comparator          | Adverse events were similar to comparator | Adverse events were similar to comparator   | Adverse events<br>were similar to<br>comparator<br>(modest data set to<br>date) |
|                                  | ed CRL in                                                                                                |                                              | fusion time l                                                                                                        |                                                       | lore frequer                              |                                             | _                                                                               |
| ,                                | officacy and not shown.                                                                                  | ,                                            | key segmen<br>d out-patien                                                                                           |                                                       | dalbavancir<br>and limit the              |                                             |                                                                                 |

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Source: Company data, Credit Suisse analysis.



# **Appendix 2**

## What Are abSSSI and MRSA?

Acute bacterial skin and skin structure infections (abSSSI) are acute spreading infections of the skin with possible involvement of the deeper subcutaneous tissue. AbSSSIs have a broad range of severity, primarily determined by the depth of infection. (See Exhibit 38 and Exhibit 39.) Superficial infections may involve hair follicles (carbuncles) or cause boils (furuncles), while deeper, more severe infections (e.g., cellulitis, surgical site infection) are characterized by faster spread and systemic signs such as fever, elevated white blood cell counts, and bacterial spread into the bloodstream (bacteremia). AbSSSIs are also called skin and soft tissue infections (SSTI), classified as either complicated (cSSTI) or uncomplicated (uSSTI), but abSSSI is currently the preferred catch-all term.

Exhibit 38: Relatively Mild MRSA Infection on a Hand



Source: www.sciencephoto.com.

Exhibit 39: Severe MRSA Infection that Started on the

**Foot** 



Source: www.cellulitistreatment.us.

AbSSSI is generally traumatic in origin and often starts out as a superficial infection. It is commonly mild-to-moderate in severity, but infections caused by methicillin-resistant *Staphylococcus aureus* (MRSA) tend to be more severe and can be potentially lethal if left untreated or if the infective strain is multidrug-resistant. MRSA is the most common causative bacterial pathogen for skin infections, responsible for ~60% of cases. MRSA strains are much more difficult to treat than drug-sensitive *S. aureus* strains because they have developed resistance mechanisms to the usual antibiotics active against gram-positive bacteria, such as penicillins and cephalosporins.

MRSA has classically been considered a hospital-acquired or hospital-associated infection, particularly in patients who have surgical site infections, are on mechanical ventilation, have implanted devices, or have compromised immune systems. Outside of hospitals, MRSA was also often seen in institutionalized settings such as prisons, military barracks, or nursing homes. It was very infrequently seen out in the community, but recent trends in the Unites States point to an increasing prevalence of community-acquired MRSA, specifically in abSSSI even in young otherwise healthy people without any risk factors (e.g. IV drug use, history of recent healthcare contact). Today, it is not uncommon for someone to get MRSA from a small cut sustained at the gym or minor abrasions like turf burn.



## **How Is MRSA Currently Treated?**

Mild cases of MRSA skin infections can be treated with oral antibiotics (e.g., Zyvox), while more severe cases (i.e. cellulitis) do require IV therapy, particularly if a patient presents with a fever or a high neutrophil count. Because MRSA is so prevalent and has dire consequences if left unchecked, initial IV therapy is immediate and empiric and subsequently guided by bacterial culture and sensitivity tests that typically do not come back from the lab for two to three days. The clinical gold standard of treatment is vancomycin, a several-decades-old glycopeptide antibiotic that is active against most gram-positive organisms including MRSA. Vancomycin dosing is weight-based, and infusions are 2-3x/day over 60-90 minutes with a typical 14-day treatment course.

While vancomycin is the gold standard in MRSA, it is notoriously cumbersome to administer. The drug has a rapid half-life, which not only necessitates frequent dosing, but also makes it challenging to maintain therapeutic plasma levels while not overdosing the patient. As such, therapeutic drug monitoring is necessary. Because vancomycin is excreted by the kidneys, dose adjustment is required in patients with renal impairment. The more common adverse effects associated with vancomycin are nephro- and ototoxicity, as well as an anaphylactic infusion reaction called "red man syndrome" that occurs when vancomycin is infused too rapidly.

The last decade has seen the development of several alternatives to vancomycin, the most commonly used of which are Pfizer's Zyvox (linezolid oral and IV) and Cubist's Cubicin (daptomycin IV). None of the new antibiotics against MRSA have been shown to be superior from an efficacy standpoint, but the ones that have garnered significant market share have provided advantages primarily through dosing convenience; Zyvox has an oral formulation, while Cubicin is infused once a day. The dosing convenience of these relatively newer antibiotics allows doctors to shift patients initially treated with IV vancomycin to Zyvox or Cubicin and potentially discharge these patients sooner than if the patient had remained on vancomycin. However, an oral drug does not necessarily ensure compliance, while a once-a-day IV drug still requires daily treatment visits in an outpatient setting.



# **Appendix 3**

## What Is Dalbavancin?

Dalbavancin is a second-generation semisynthetic glycopeptide antibiotic. It has a similar mechanism of action as vancomycin, which is inhibition of bacterial cell wall synthesis. Like vancomycin, dalbavancin has broad activity against gram-positive bacteria, particularly specie that cause abSSI. Studies in culture show that dalbavancin is several-fold more potent than vancomycin in terms of minimum inhibitory concentration (MIC; Exhibit 40). MRSA is still broadly sensitive to vancomycin, but resistant strains have been reported, and there is emerging evidence which suggests that there may be an upward "MIC creep" for vancomycin in *Staphylococcus*.

Exhibit 40: Dalbavancin Is More Potent Against MRSA than Vancomycin In Vitro

|                                              | No. (Cumulative %) inhibited at Dalbavancin MIC (μg/ml) |              |            |            |           |              |            |                           |                             |  |
|----------------------------------------------|---------------------------------------------------------|--------------|------------|------------|-----------|--------------|------------|---------------------------|-----------------------------|--|
| Pathogen/subset<br>(no. tested) <sup>a</sup> | ≤0.03                                                   | 0.06         | 0.12       | 0.25       | 0.5       | 1            | 2          | 4                         | >4                          |  |
| S. aureus                                    |                                                         |              |            |            |           | Vancom       | voin MICOO |                           |                             |  |
| All (11,658)                                 | 2,773 (23.8)                                            | 7,987 (92.3) | 863 (99.7) | 35 (100.0) | -         | -            | ycin MIC90 | -                         | -                           |  |
| MRSA (3,183)                                 | 914 (28.7)                                              | 2,018 (92.1) | 238 (99.6) | 13 (100.0) | -         | -            | -          | -                         | -                           |  |
| MSSA (8,475)                                 | 1,859 (21.9)                                            | 5,969 (92.4) | 625 (99.7) | 22 (100.0) | -         | -            | -          | -                         | -                           |  |
| CoNS                                         |                                                         |              |            |            |           |              |            |                           |                             |  |
| All (4,343)                                  | 1,690 (38.9)                                            | 1,906 (82.8) | 575 (96.0) | 153 (99.6) | 14 (99.9) | 4<br>(>99.9) | 1 (100.0)  | -                         | -                           |  |
| Enterococcus spp.                            |                                                         |              |            |            |           |              |            |                           |                             |  |
| All (4,982)                                  | 1,430 (287)                                             | 2,359 (76.1) | 693 (90.0) | 90 (91.8)  | 15 (92.1) | 26<br>(92.6) | 39 (93.4)  | 73<br>(94.8)              | 257<br>(100.0)              |  |
| VAN-S (4,457)                                | 1,412 (31.7)                                            | 2,301 (83.3) | 655 (98.0) | 80 (99.8)  | 7 (>99.9) | 1<br>(>99.9) | 1 (100.0)  | -                         | -                           |  |
| VAN-NS (525)                                 | 18 (3.4)                                                | 58 (14.5)    | 38 (21.7)  | 10 (23.6)  | 8 (25.1)  | 25<br>(29.9) | 38 (37.1)  | 73<br>(51.1) <sup>b</sup> | 257<br>(100.0) <sup>b</sup> |  |
| Viridans gr strep                            |                                                         |              |            |            |           |              |            |                           |                             |  |
| All (845)                                    | 744 (88.1)                                              | 95 (99.3)    | 6 (100.0)  | -          | -         | -            | -          | -                         | -                           |  |
| β-haemolytic strep                           |                                                         |              |            |            |           |              |            |                           |                             |  |
| All (1,995)                                  | 1,893 (94.8)                                            | 85 (99.1)    | 15 (99.8)  | 4 (100.0)  | -         | -            | -          | -                         | -                           |  |
| S. pyogenes (793)                            | 781 (98.5)                                              | 10 (99.8)    | 1 (99.9)   | 1 (100.0)  | -         | -            | -          | -                         | -                           |  |
| S. agalactiae (817)                          | 740 (90.6)                                              | 61 (98.2)    | 12 (99.6)  | 3 (100.0)  | -         | -            | -          | -                         | -                           |  |

MRSA=methicillin-resistant S. aureus, MSSA=methicillin-susceptible S. aureus, CoNS=coagulase-negative Staphylococcus, VAN-S=vancomycin-susceptible, VAN-NS=vancomycin nonsusceptible.

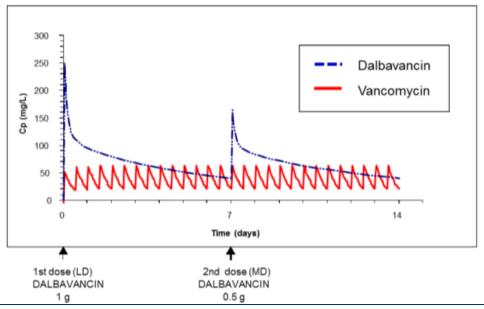
Source: RN Jones, DJ Farrell, HS Sader; ECCMID 2011.

## **How Is Dalbavancin Differentiated?**

The most important difference between dalbavancin and vancomycin is dalbavancin's significantly extended half-life of 9-12 days versus 4-11 hours for vancomycin. The long-acting pharmacokinetics of dalbavancin allow once-weekly IV dosing (loading dose of 1000mg on day one with a maintenance dose of 500mg on day eight) as compared to vancomycin dosing of at least twice a day. (See Exhibit 41.) Dalbavancin can also be infused faster than vancomycin (30 versus 60-90 minutes) without risk of red man syndrome. Finally, dalbavancin dosing is not weight-based, and dose adjustments are not necessary for renal failure patients as long as they are on dialysis.



Exhibit 41: Dalbavancin's Extended Half-life Allows Once-Weekly Dosing



Source: Dorr, JAC 2005;55 Supp S2:ii25, Company data.

As compared to other approved MRSA antibiotics, dalbavancin has the most convenient dosing regimen, better cidality and potency against MRSA, and a generally more tolerable safety profile. (See Exhibit 42.)

Exhibit 42: Dalbavancin Has an Arguably Better Clinical Profile than Other Approved MRSA Drugs

|                                    | Dalbavancin                                                     | Vancomycin                                                                                                                                       | Zyvox                                                                                                                                        | Cubicin                                                                                                                                                                  | Teflaro                   | Vibativ                               | More                                                         |
|------------------------------------|-----------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|---------------------------------------|--------------------------------------------------------------|
| Active ingredient                  | dalbavancin                                                     | vancomycin                                                                                                                                       | linezolid                                                                                                                                    | daptomycin                                                                                                                                                               | ceftaroline fosamil       | telavancin                            | convenient                                                   |
| Company                            | Durata                                                          | generic                                                                                                                                          | Pfizer                                                                                                                                       | Cubist                                                                                                                                                                   | Forest Labs               | Theravance                            | dosing. All                                                  |
| Spectrum                           | Gram-positive                                                   | Gram-positive                                                                                                                                    | Gram-positive                                                                                                                                | Gram-positive                                                                                                                                                            | Gram-positive             | Gram-positive                         | _                                                            |
| Dosing in abSSSI                   | 1 <sup>st</sup> dose on day 1,<br>2 <sup>nd</sup> dose on day 8 | <bid 14="" days<="" td="" x=""><td>BID x 14 days</td><td>QD x 14 days</td><td>BID-x 14 days</td><td>QD x 14 days</td><td>others still</td></bid> | BID x 14 days                                                                                                                                | QD x 14 days                                                                                                                                                             | BID-x 14 days             | QD x 14 days                          | others still                                                 |
| Route of administration            | IV                                                              | IV                                                                                                                                               | IV and oral                                                                                                                                  | IV                                                                                                                                                                       | IV                        | IV                                    | 1-2x/day                                                     |
| Infusion time                      | 30 minutes                                                      | < 60 to 90 minutes                                                                                                                               | 30 to 120 minutes                                                                                                                            | 2 minute bolus or 30 minute infusion                                                                                                                                     | 60 minutes                | 60 minutes                            | Better cidality                                              |
| Indications                        | abSSSI                                                          | cSSSI, endocarditis,<br>bone,LRTI,<br>septicemia                                                                                                 | cSSSI, HAP, CAP,<br>uSSSI, DFI, VREF                                                                                                         | cSSSI, staph<br>bacteremia,<br>endocarditis                                                                                                                              | abSSSI, CAP               | cSSSI<br>                             | and potency against MRSA.                                    |
| Cidality vs.<br>staph              | Continuously<br>bactericidal                                    | Bactericidal                                                                                                                                     | Bacteriostatic                                                                                                                               | <del>Bacte</del> ricidal                                                                                                                                                 | Bactericidal              | Bactericidal                          | <u> </u>                                                     |
| MIC90 against<br>MRSA (ug/mL)      | 0.06                                                            | 1.0-2.0                                                                                                                                          | 0.5                                                                                                                                          | 0.5                                                                                                                                                                      | 1.0                       | 0.25                                  | Superior safety profile with no                              |
| Patients w/<br>renal<br>impairment | No dose adjustment<br>necessary if patient<br>on dialysis.      |                                                                                                                                                  | No dose adjustment necessary.                                                                                                                |                                                                                                                                                                          | Dose adjustment required. | Dose adjustment required.             | need for drug                                                |
| Safety profile                     | specific AE of<br>concern. No red-<br>man syndrome              | Classic side effects like nehprotoxicity and ototoxicity are                                                                                     | Associated with reversible myelosuppression when used \$2weeks. Significant drug interaction with SSRIs. Otherwise generally well-tolerated. | Adverse events were similar/slightly higher than comparator. Phabdomyolysis and peripheral neuropathy risk at higher doses and/or durations. CPK monitoring recommended. | similar to comparators.   | Black-box warning for fetal Tisk: 197 | monitoring or dose adjustment in renal patients on dialysis. |

Source: Company data, Credit Suisse estimates.

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# How Can Dalbavancin Change the MRSA Treatment Paradigm?

In our view, the primary value of dalbavancin lies in the flexibility that its dosing regimen provides to physicians and the potentially disruptive way it can change physician practice in the treatment of MRSA infections. Currently, a patient who presents at a hospital with a skin infection deemed severe enough for IV therapy is considered MRSA-suspect, typically admitted into hospital, and started on empiric IV vancomycin. Blood and abscess samples are routinely taken for bacterial culture and drug sensitivity studies (C&S), which may be helpful in guiding therapy. Vancomycin needs to be administered for at least 48-72 hours for an observable clinical response such as decline in body temperature or stabilization/decrease in the skin lesion size. At this point, C&S results usually become available, and drug therapy can be maintained or switched depending on the labs as well as the patient's clinical response. For patients who have improved within three days and are now clinically stable, discharge from hospital is possible, with arrangements made for the patient to return to the ER or an outpatient clinic to be infused or for a visiting nurse to continue treatment through to 14 days. A switch to BID oral Zyvox or QD IV Cubicin is an alternative, but compliance with a 2x/day Zyvox tablet is not guaranteed, and a Cubicin patient would still need to be seen once a day for the rest of the treatment course. Finally, a patient would typically come in for a follow-up visit at the end of therapy.

We believe that dalbavancin can change the way MRSA patients are treated at three separate points along the current paradigm. (See Exhibit 43.)

Some patients will be clinically stable and doctors may be comfortable using dalbavancin up-front, avoiding admission. If IV therapy •At least 48-72 •If stable, patient warranted and hours of inis discharged in MRSA-suspect. patient 3 days begin empiric vancomycin and •ED/OP or Discharge Patient w/ vancomycin. observation for visiting nurse to Admission response. abSSSI Send blood keep dosing follow-up through day 14 and/or abscess Maintain/switch of treatment. discharge for therapy based on culture and response and •Follow-up at end sensitivity labs of treatment. At some point between days 3 - 7, Patient discharged on dalbavancin won't need treatment can be switched to dalbavancin to be seen every day but rather have one and patient is discharged sooner. follow-up if a second dose is needed and/or a final check-up at end of treatment. HOSPITAL DAYS SAVED = 7 to 14 VISITS SAVED = 11 to 22

Exhibit 43: How Dalbavancin Can Change the MRSA Treatment Paradigm

Source: Credit Suisse analysis.



The most likely clinical scenario would be the continued usage of vancomycin up-front for at least the first 72 hours of treatment, since the patient needs to be admitted anyway and observed for clinical response. Assuming the patient improves, is stable after three days, and is clinically eligible for discharge, a doctor can decide to switch treatment to dalbavancin prior to sending the patient home, not only shortening length of stay but also ensuring that the patient gets appropriate antibiotic coverage for an entire week with full compliance "built-in." Once a patient is discharged on dalbavancin, s/he will not need to come back for repeated infusions nor take any pills. If the 500mg maintenance dose after eight days is necessary, the patient visit conveniently coincides with a timepoint at which a follow-up consult would be appropriate. In what will probably be a less common scenario, some patients may have a relatively less severe infection and are stable enough clinically that a physician will be comfortable using dalbavancin up-front when the patient first presents and, therefore, potentially avoid admission into hospital altogether.

# What Is the Pharmaco-Economic Argument for Dalbavancin?

While the clinical benefits of using dalbavancin are apparent, the ultimate hurdle to widespread adoption for any branded MRSA antibiotic is its cost efficiency versus vancomycin, because the drug costs for branded drugs are around two to three times higher. While the per-vial price tag for dalbavancin may cause sticker shock, we believe that comparing the *total* cost of treatment with dalbavancin (drug + medical costs) versus vancomycin, Zyvox, or Cubicin provides a compelling pharmaco-economic argument. (See Exhibit 44.)

Cost Comparison by Key Components \$14,000 \$12,676 ■ Drug Cost \$9,682 (Inpatient) \$12,000 \$8,408 ■Drug Cost (Outpatient) \$10,000 \$4,041 ■Inpatient medical **Medicare DRG** \$8,000 payment for ■ Outpatient medical MRSA skin infection \$6,000 \$4,000 \$2,000 \$0 Vancomycin + Linezolid Daptomycin

Exhibit 44: Total Treatment Cost of Using Dalbavancin Potentially Lower than Vancomycin

Chart compares the total costs of treating a MRSA abSSSI patient with dalbavancin x 14d outpatient vs. vancomycin x 3d inpatient + oral Zyvox x 11d outpatient, vancomycin x 3d inpatient + 11d outpatient, and Cubicin x 3d inpatient + 11d outpatient.

Source: Company data, Credit Suisse estimates.

As Exhibit 44 shows, branded drug costs are roughly similar across the MRSA space. However, inpatient medical costs (~\$2,000 per day of admission) make the total cost of dalbavancin treatment potentially much lower than using even vancomycin. While we acknowledge that some eyebrows will be raised to the up-front expense of dalbavancin, framing the value proposition as cost-savings on the back end should help get the drug on hospital and managed care formularies.

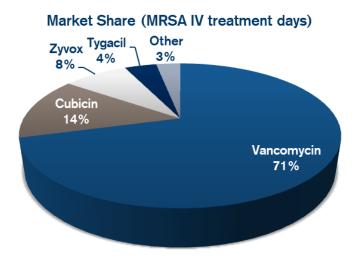


# **Appendix 4**

## What Is Dalbavancin's Commercial Opportunity?

It is estimated that there are 35M days of IV therapy annually for MRSA across all indications in the United States. At branded MRSA antibiotic pricing of ~\$300 per day of treatment, this market is worth ~\$10B per year. Of IV therapy for MRSA, ~26% is already taking place in the outpatient setting (dalbavancin's natural clinical niche), and we believe that this trend will only increase as the broad push for overall healthcare cost-efficiency continues in this country. At least 70% of IV therapy days for MRSA are still attributable to vancomycin (Exhibit 45), not surprising due to generic pricing as well as the vast amount of clinical experience with the drug, notwithstanding all the issues around its usage. Prior to the emergence of branded alternatives with significantly differentiated profiles such as Zyvox and Cubicin, vancomycin held as much as an 85% share.

Exhibit 45: MRSA Drug Market as Share of IV Treatment Days



Source: Company data, Credit Suisse estimates.

Our peak dalbavancin sales estimate of \$635M by 2024 is based upon what we believe is a conservative peak market share of ~6%. We also model dalbavancin to capture significantly more share in the outpatient treatment setting, given its dosing regimen, resulting in a larger proportion of revenues coming from outpatient toward the out-years. (See Exhibit 46.)



CS Estimated Dalbavancin Revenues in the U.S. 700,000 600,000 500,000 56.8% 57.2% 400,000 \$ 000 s 57.2% 56.1% 55.3% 300,000 53.8% 48.9% 45.6% 200,000 43.0% 41.1% 40.7% 40.7% 41.9% 42.6% 100.000 44.0% 48.6% 43.1% 51.8% 54.3% 54.2% 2014E 2020E 2024E 2015E 2016E 2017E 2018E 2019E 2021E 2022E 2023E Stocking ■ Non-MRSA ■ MRSA - US In-patient MRSA - US Out-patient

Exhibit 46: We Model Outpatient Revenues Providing the Majority of Dalbavancin Sales in the U.S.

Source: Company data, Credit Suisse estimates.

We would point out that, while we model a dalbavancin launch price at parity with current branded antibiotics (~\$3,000/14-day course), we are assuming equally conservative pricing growth of only 5% per year. As a reference, Cubicin has historically increased its price in the range of 8-10% annually.

We do not yet account for potential sales of dalbavancin in the EU. Because of the substantial resources needed to establish a separate commercial structure in that region, we think it is more likely that Durata will out-license the ex-U.S. rights to dalbavancin. In any case, the commercial opportunity for dalbavancin in the EU would be less than what we model for the U.S. due to a lower MRSA prevalence, less common outpatient therapy for serious MRSA infections, and significantly lower pricing as compared to what would be possible in this country.

## The Competitive Landscape in MRSA

While generic vancomycin is still the most commonly used MRSA drug (and should remain so for a significant amount of time), the last decade or so has shown that alternative antibiotics that provide equivalent efficacy and are significantly differentiated in terms of dosing convenience can take market share away from the generic incumbent, even at a 3x price premium. Therefore, in considering dalbavancin's positioning in MRSA, we highlight the advantages that dalbavancin has not only over vancomycin but over Zyvox and Cubicin as well. (See Exhibit 42.) As Exhibit 42 shows, dalbavancin has an arguably superior clinical profile to currently approved MRSA antibiotics. Dosing for the other drugs is at least 1x/day, and dalbavancin generally has a shorter infusion time as well. Most of the currently approved competitors, not just vancomycin, also have specific potentially serious safety issues and may need renal dose adjustments.

Note that Zyvox, while it has greatly benefitted from having an oral formulation, still leaves room for patient noncompliance. Patients with bacterial infections, in particular, are prone



to forget or discontinue taking their oral meds because the acute symptoms are usually unapparent after the first week of treatment (assuming the patient is responsive to the antibiotic). Incomplete treatment of a bacterial infection is a significant cause of not only readmission to hospital but also of bacterial resistance to antibiotics. Furthermore, a pill form is not necessarily always the best option for all patients, particularly patients who medically cannot take anything by mouth, older patients who may already be taking multiple pills on a daily basis, or patients who otherwise have poor or inadequate home support.

It is also worthwhile to contemplate what the MRSA space is going to look like in the coming years as Zyvox loses patent protection in 2015, as Cubist begins its U.S. Cubicin sales agreement with Teva in 2018, and as other MRSA antibiotics are potentially approved and launched (particularly tedizolid from Trius and oritavancin from The Medicines Co.; Exhibit 47).

Exhibit 47: Dalbavancin Is Better Differentiated than Other MRSA Antibiotics in Development

|                                      | Oritavancin                                                                                              | TR-700                                         | Taksta                                      | Omadad                         | cycline                                                                   | BC-3781                                    | Delafloxacin                                | RX-1741                                                                         |
|--------------------------------------|----------------------------------------------------------------------------------------------------------|------------------------------------------------|---------------------------------------------|--------------------------------|---------------------------------------------------------------------------|--------------------------------------------|---------------------------------------------|---------------------------------------------------------------------------------|
| Active ingredient                    | oritavancin                                                                                              | tedizolid                                      | fusidic acid                                | omadad                         | cycline                                                                   | BC-3781                                    | delafloxacin                                | radezolid                                                                       |
| Company                              | Medicines<br>Company                                                                                     | Trius                                          | Cempra                                      | Para                           | tek                                                                       | Nabriva/Forest Labs                        | Rib-X                                       | Rib-X                                                                           |
| Spectrum                             | Gram-positive                                                                                            | Gram-positive                                  | Gram-positive                               | Broad-sp                       | ectrum                                                                    | Broad-spectrum                             | Broad-spectrum                              | Gram-positive                                                                   |
| Dosing                               | Single Dose                                                                                              | QD x 6 days                                    | BID                                         | QI                             | )                                                                         | BID                                        | BID                                         | QD                                                                              |
| Form                                 | IV                                                                                                       | IV and Oral                                    | Oral                                        | IV and                         | Oral                                                                      | IV and Oral                                | IV                                          | Oral                                                                            |
| Infusion time                        | 3 Hours                                                                                                  | 60 minutes                                     | N/A                                         | Bolus in                       | jection                                                                   | Unknown                                    | Unknown                                     | N/A                                                                             |
| Indications                          | abSasi                                                                                                   | abSSSI, HAP                                    | abSSSI                                      | SSSI, (                        | CABP                                                                      | abSSSI, CABP                               | abSSSI                                      | abSSSI, CABP                                                                    |
| Cidality                             | Continuously<br>bactericidal                                                                             | Static                                         | Static                                      | Star                           | tic                                                                       | Bactericidal                               | Bactericidal                                | Static                                                                          |
| Development phase                    | Phase III                                                                                                | Phase III                                      | Phase II                                    | Phas                           | e II                                                                      | Phase II                                   | Phase II                                    | Phase II                                                                        |
| Possible launch date if approved     | Late 2014-early 2015                                                                                     | 2015                                           | Looking for partner to continue development | Novartis with partnership 2011 |                                                                           | Phase III to initiate in 2013              | Looking for partner to continue development | Looking for partner to continue development                                     |
| Safety                               | Infusion site phlebitis,<br>higher serious adverse<br>event rate than<br>comparator in previous<br>PIIIs |                                                |                                             | Adverse eve<br>similar to con  |                                                                           | Adverse events we're similar to comparator | Adverse events were similar to comparator   | Adverse events<br>were similar to<br>comparator<br>(modest data set to<br>date) |
| Receive                              | ed CRL in                                                                                                | 3-hour infusion time limits                    |                                             |                                | More frequent dosing regimens                                             |                                            |                                             |                                                                                 |
| 2008; efficacy and safety not shown. |                                                                                                          | utility in key segments of ER and out-patient. |                                             |                                | of vs. dalbavancin aren't differentiated and limit the value proposition. |                                            |                                             |                                                                                 |

Source: Company data, Credit Suisse estimates.

Tedizolid is in the same class as Zyvox, with the advantage of once-daily dosing and a shorter course of therapy (six days in abSSSI). In our view, tedizolid will come under more competitive pressure from a generic Zyvox than dalbavancin would because of the points that we highlighted above (i.e., dalbavancin's patient profile does not necessarily overlap with Zyvox's).

Oritavancin is also an extended half-life second-generation glycopeptide antibiotic, with the advantage of being dosed just once for a complete abSSSI treatment course. Its three-hour infusion time, however, could conceivably limit its use in settings where a high turnover of patients is necessary or desirable, such as in an ER or outpatient clinic. We



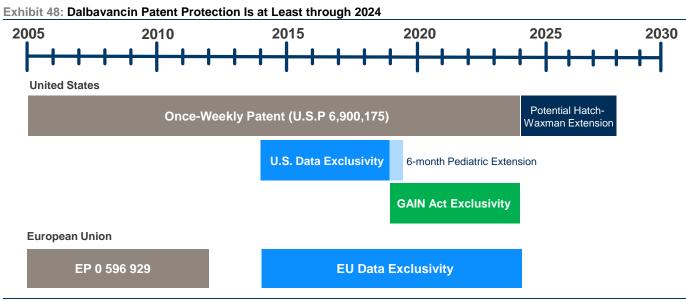
would also point out that oritavancin received a complete response letter from the FDA in 2008 after an overall negative opinion from an advisory committee panel. The previous two pivotal trials for oritavancin were not deemed to adequately show efficacy against MRSA. Furthermore, death, sepsis/septic shock, osteomyelitis, and discontinuations due to lack of efficacy were more common in patients who received oritavancin.

Lastly, as part of the settlement between Cubist and Teva over Teva's daptomycin ANDA, Cubist has granted Teva a license to sell Cubicin in the U.S. starting in 2018, with Teva buying its daptomycin supply exclusively from Cubist. This agreement between Cubist and Teva will likely keep Cubicin pricing at a higher level than it would have been otherwise. Overall, this has positive implications across the entire branded MRSA antibiotic space, although we cannot foresee at this point if Cubist will be able to fend off other ANDA challenges. (Hospira filed a daptomycin ANDA early this year.)

While the MRSA antibiotic space is undoubtedly very competitive, we believe that dalbavancin has such a differentiated clinical profile that it can successfully find a foothold in the market. In any case, we highlight that our conservative peak penetration rate of ~6% is enough to support our fundamental valuation for DRTX. Put another way, dalbavancin does NOT need to become the gold standard of care for the stock to work. It only needs to be used in 6 out of every 100 patients, and it is our view that the drug's clinical profile alone makes that target very achievable.

## **Dalbavancin Intellectual Property**

We assume patent protection for dalbavancin through 2024. (See Exhibit 48.) The patent estate is based on a wide range of dosing intervals, dosage amounts, and dosage ratios. Assuming approval by 2014, dalbavancin will have data exclusivity in the U.S. for five years with a possible six-month extension based on pediatric data from the pivotal trials. Any potential ANDA filer would not be able to file with the FDA until the last year of data exclusivity and would not be able to use any of Durata's data until exclusivity expires. It is also highly likely that dalbavancin will be given an additional four years of Hatch-Waxman patent-term extension.



Source: Company data, Credit Suisse analysis.

As part of PDUFA V, a section called the Generating Antibiotic Incentives Now (GAIN) Act may have significant positive implications for dalbavancin's intellectual property rights.



Under the GAIN act, antibiotics being developed to treat a list of specified pathogens are considered "qualified infectious disease products" and are entitled, therefore, to receive an additional five years of data exclusivity if approved. MRSA is part of that list, thus making dalbavancin potentially qualified for GAIN Act exclusivity. PDUFA-V has been passed through both houses of Congress and is likely to be signed into law by the President soon, potentially coming into effect by October 1, 2012.



# **Appendix 5**

## **Previously Completed Dalbavancin Clinical Trials**

Three separate controlled Phase III trials have already established that dalbavancin is equally effective in abSSSI as three other relevant comparator antibiotics: cefazolin, vancomycin, and Zyvox. (See Exhibit 49.)

Exhibit 49: Previous Phase III Dalbavancin Trials Met Primary Efficacy Endpoints

|                             |              |           | Pe          | r-protocol Analys | sis          | Inter       | Non-<br>inferiority |               |        |
|-----------------------------|--------------|-----------|-------------|-------------------|--------------|-------------|---------------------|---------------|--------|
| Comparator Blindi           | Blinding     | N (ratio) | Patients    | cured [n (%) of   | patients]    | Patients    |                     |               |        |
|                             |              |           | Dalbavancin | Comparator        | 95% CI       | Dalbavancin | Comparator          | 95% CI        | margin |
| Cefazolin                   | Double-blind | 553 (2:1) | 237 (89.1%) | 131 (89.1%)       | (-6.8, 6.8)  | 279 (76.0%) | 141 (75.8%)         | (-7.7, 8.2)   | -12.5% |
| Vancomycin                  | Open-label   | 107 (2:1) | 71 (88.9%)  | 26 (86.7%)        | (-13.0, 9.4) | 92 (86.0%)  | 32 (65.3%)          | (4.3, 37.0)   | -20.0% |
| Linezolid                   | Double-blind | 571 (2:1) | 386 (88.9%) | 206 (91.2%)       | (-7.3, 2.9)  | 437 (76.5%) | 234 (82.7%)         | (-12.0, -0.3) | -12.5% |
| Linezolid<br>(FDA analysis) | Double-blind | 523 (2:1) | 346 (88.3%) | 189 (89.6%)       | (-6.9 4.3)   | 383 (73.2%) | 198 (75.3%)         | (-8.84.7)     | -12.5% |

Source: Company data.

In all three trials, the primary endpoint was noninferiority to the comparator in terms of clinical and microbiological response at a test-of-cure visit (i.e., @ day 28, 14 days after the end of a 14-day course of treatment). Equal efficacy of dalbavancin to the comparator drug was defined statistically with a prespecified noninferiority margin, the lower bound of the 95% confidence interval of the difference in cure rates. The primary endpoints in all three trials were calculated on a per-protocol basis, with intention-to-treat analysis as a secondary endpoint. Patient response at the end of treatment (day 14) was also a secondary endpoint. In all three trials, patients on comparator drug were given the option to switch to an oral formulation after the first week of IV therapy (in the case of vancomycin, the oral option was cephalexin).

As shown in Exhibit 49, dalbavancin met its primary endpoint in all three previous Phase III trials. As part of the previous NDA process in 2004, the FDA conducted its own analysis of the dalbavancin trial versus Zyvox (VER001-9). In this analysis, the FDA found that the noninferiority margin was actually higher than Pfizer's own calculation, both on a per-protocol and intention-to-treat analysis.

A recent retrospective analysis (company-sponsored) of VER001-9 was presented at ECCMID 2011. This study applied the 2010 FDA guidelines, specifically the inclusion criteria of lesion size (≥75cm²) and signs of systemic infection (fever, increased WBCs, or increased band-forms), as well as the day 3/4 timepoint for measuring the FDA-preferred primary endpoint (cessation of skin lesion spread and/or absence of fever). This analysis suggests that the difference in cure rates between dalbavancin and Zyvox are similar regardless of whether the early timepoint or late timepoint (test-of-cure @ day 28) is used when evaluating response. (See Exhibit 50.)



Exhibit 50: Retrospective Analysis of VER001-9 Suggests Dalbavancin Is Noninferior at Early or Late Timepoints

| Timepoint | Analysis Population                     | Endpoint                          | Dalbavancin, n/N (%) | Linezolid, n/N (%) | Difference | 95% Cl       |
|-----------|-----------------------------------------|-----------------------------------|----------------------|--------------------|------------|--------------|
| Day 3/4   | Clinically evaluable                    | Cessation of spread + afebrile    | 283/340 (83.2%)      | 155/178 (87.1%)    | -3.8       | (-10.6, 2.9) |
|           |                                         | Cessation of spread               | 312/340 (91.8%)      | 165/178 (92.7%)    | -0.9       | (-6.2, 4.3)  |
|           | + >75cm2 lesions                        | Cessation of spread + afebrile    | 212/258 (82.2%)      | 109/135 (80.7%)    | 1.4        | (-7.3, 10.1) |
|           | *************************************** | Cessation of spread               | 237/258 (91.9%)      | 121/135 (89.6%)    | 2.2        | (-4.5, 8.9)  |
|           | + >75cm2 lesions + one systemic sign    | Cessation of spread + afebrile    | 103/135 (76.3%)      | 67/85 (78.8%)      | -2.5       | (-14.8, 9.7) |
|           | *************************************** | Cessation of spread               | 120/135 (88.9&)      | 76/85 (89.4%)      | -0.5       | (-9.9, 8.9)  |
| Day 28    | Clinically evaluable                    | Clinical response at test-of-cure | 386/434 (88.9%)      | 206/226 (91.2%)    | -2.2       | (-7.3, 2.9)  |

Source: Dunne, MW et al. Poster presented at ECCMID 2011.

## **Dalbavancin's Safety Profile**

The integrated safety database from all completed Phase II and Phase III programs shows that dalbavancin has comparable, if not slightly better, safety versus all the tested comparators. Specifically, the database suggests that dalbavancin exposure causes fewer adverse events on a percentage basis and that the duration of adverse events tends to be shorter for dalbavancin as well. (See Exhibit 51 and Exhibit 52.)

Exhibit 51: Less Frequent/Severe AEs on Dalbavancin

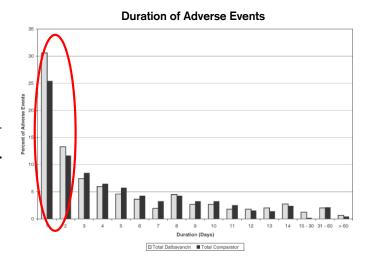
| Overview of Adverse Event Incidence |                   |                  |  |  |  |  |  |  |
|-------------------------------------|-------------------|------------------|--|--|--|--|--|--|
|                                     | Total Dalbavancin | Total Comparator |  |  |  |  |  |  |
| Preferred Term                      | (N=1126)          | (N=573)          |  |  |  |  |  |  |
| ≥1 AE                               | 585 (52.0)        | 326 (56.9)       |  |  |  |  |  |  |
| ≥1 treatment-related AE             | 248 (22.0)        | 157 (27.4)       |  |  |  |  |  |  |
| ≥1 SAE                              | 92 (8.2)          | 54 (9.4)         |  |  |  |  |  |  |
| ≥1 treatment-related SAE            | 2 (0.2)           | 5 (0.9)          |  |  |  |  |  |  |
| ≥1 AE leading to discontinuation    | 39 (3.5)          | 22 (3.8)         |  |  |  |  |  |  |
| Number (%) deaths                   | 9 (0.8)           | 7 (1.2)          |  |  |  |  |  |  |
| Number (%) of deaths due to TAE     | 0                 | 0                |  |  |  |  |  |  |

AEs Occurring in >2% of Patients Receiving Dalbavancin

| Dueformed Torres            | Total Dalbavancin | Total Comparator |
|-----------------------------|-------------------|------------------|
| Preferred Term              | (N=1126)          | (N=573)          |
| Patients with at least 1 AE | 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)          | 19 (3.3)         |
| Vomiting NOS                | 34 (3.0)          | 26 (4.5)         |
| Urinary tract infection NOS | 31(3.0)           | 12 (2.1)         |
| Anemia NOS                  | 31 (2.8)          | 12 (2.1)         |
| Rash NOS                    | 29 (2.6)          | 13 (2.3)         |
| Puritus                     | 25 (2.2)          | 14 (2.4)         |

Source: Company data.

Exhibit 52: Shorter Duration of AEs on Dalbavancin



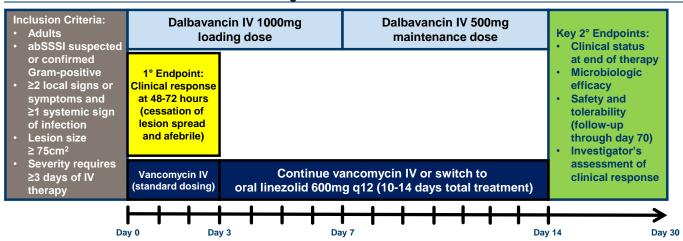
Source: Company data.

## The DISCOVER Phase III Program

Dalbavancin is currently being studied in two pivotal Phase III trials, DISCOVER-1 and DISCOVER-2. Both trials are being run under Special Protocol Assessments and incorporate the FDA's 2010 draft guidance on designing clinical trials in abSSSI. The clinical trial design is diagrammed in Exhibit 53.



Exhibit 53: DISCOVER-1 and -2 Phase III Trial Design



Source: Company data, www.clinicaltrials.gov, Credit Suisse analysis.

DISCOVER-1 and -2 are multicenter, double-blind, double-dummied, randomized, controlled trials. Patients will be randomized into a dalbavancin or vancomycin arm. Patients on dalbavancin will receive a 1000mg loading dose at the beginning of treatment and a 500mg maintenance dose seven days later. Patients on vancomycin will receive the standard weight-based dose infused 2x/day for the first three days of therapy with an option to continue IV vancomycin or switch to 600mg oral Zyvox BID through to the end of treatment. Each DISCOVER trial will enroll 556 patients, and the whole program will be run across as much as 150 different global sites. DISCOVER-1 is currently >75% enrolled, while DISCOVER-2 is >40% enrolled. Top-line results are expected within 4Q12.

Important inclusion criteria for the DISCOVER studies include minimum baseline lesion size of ≥75cm² and signs and symptoms of systemic infection (e.g., elevated WBCs/neutrophils or fever). These criteria were not required previous to the FDA draft guidelines and were established to ensure that trial patients actually needed IV antibiotic therapy and ostensibly to improve patient population comparability across trials. The measurement of lesion size could prove challenging in terms of limiting inter- and intra-rater variability. The measurement technique prescribed in the DISCOVER studies is by hand using a ruler. Durata has opted to supplement ruler measurements with ancillary techniques: digital photography with a specialized wound imaging camera and wound tracings. The company has also completed a lesion size assessment study (DUR000-201) in order to optimize the reliability of its measurement methods.

The primary efficacy endpoint for the DISCOVER studies is clinical response at 48-72 hours based on the cessation of lesion spread and loss of fever. Secondary endpoints include clinical status at the end of therapy (i.e., @ day 14), microbiological efficacy, as well as safety and tolerability through the complete follow-up period of 70 days. While the early assessment timepoint is mandated by the FDA, the EMA will consider the end-of-therapy timepoint as its primary outcome measure.

As per the FDA guidelines, the non-inferiority margin of the primary endpoint has been set at -10%. This is the lower bound of the 95% confidence interval of the difference in cure rates between dalbavancin and vancomycin. The studies assume an 85% point estimate of effect and an n=556 provides 90% power reliably to detect a difference between treatment groups. The trial protocols allow Durata to increase the sample size to maintain 90% powering if the point estimate is calculated to be <85%. The point estimate calculation is performed once a trial reaches 60% enrollment. This preliminary analysis was recently performed for DISCOVER-1, and it was determined that the sample size did not need adjustment.



Companies Mentioned (Price as of 13 Aug 12)
Cempra Holdings LLC (CEMP, \$7.77, NOT RATED)
Cubist Pharmaceuticals (CBST, \$43.67, NOT RATED)
Durata Therapeutics (DRTX, \$7.86, OUTPERFORM, TP \$13.00)
Medicines Company (MDCO, \$25.35, NOT RATED)
Pfizer, Inc. (PFE, \$23.72, RESTRICTED)
Trius Therapeutics (TSRX, \$5.40, NOT RATED)

## **Disclosure Appendix**

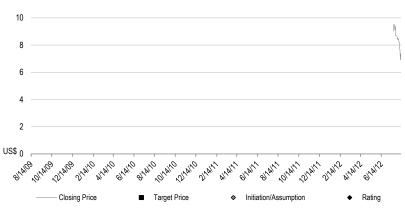
### **Important Global Disclosures**

I, Ravi Mehrotra PhD, certify that (1) the views expressed in this report accurately reflect my personal views about all of the subject companies and securities and (2) no part of my compensation was, is or will be directly or indirectly related to the specific recommendations or views expressed in this report.

See the Companies Mentioned section for full company names.

### 3-Year Price, Target Price and Rating Change History Chart for DRTX

| DRTX | Closing | Target      |               |
|------|---------|-------------|---------------|
|      | Price   | Price       | Initiation/   |
| Date | (US\$)  | (US\$) Rati | ng Assumption |



O=Outperform; N=Neutral; U=Underperform; R=Restricted; NR=Not Rated; NC=Not Covered

The analyst(s) responsible for preparing this research report received compensation that is based upon various factors including Credit Suisse's total revenues, a portion of which are generated by Credit Suisse's investment banking activities.

#### Analysts' stock ratings are defined as follows:

Outperform (O): The stock's total return is expected to outperform the relevant benchmark\* by at least 10-15% (or more, depending on perceived risk) over the next 12 months.

Neutral (N): The stock's total return is expected to be in line with the relevant benchmark\* (range of ±10-15%) over the next 12 months.

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\*\*An analyst's coverage universe consists of all companies covered by the analyst within the relevant sector.

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Overweight: Industry expected to outperform the relevant broad market benchmark over the next 12 months.

Market Weight: Industry expected to perform in-line with the relevant broad market benchmark over the next 12 months.



Underweight: Industry expected to underperform the relevant broad market benchmark over the next 12 months.

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Restricted 2%

\*For purposes of the NYSE and NASD ratings distribution disclosure requirements, our stock ratings of Outperform, Neutral, and Underperform most closely correspond to Buy, Hold, and Sell, respectively; however, the meanings are not the same, as our stock ratings are determined on a relative basis. (Please refer to definitions above.) An investor's decision to buy or sell a security should be based on investment objectives, current holdings, and other individual factors.

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Price Target: (12 months) for (DRTX)

**Method:** Our \$13 TP for DRTX is derived from a DCF analysis of dalbavancin revenues through 2024, risk-weighted at 60% to reflect Durata's execution risk. We use a standard 10% discount rate with no terminal value.

Risks: Key risk factors to our \$13 TP include: 1) dalbavancin does not meet clinical trial endpoints, 2) dalbavancin is not approved or launch is significantly delayed, 3) dalbavancin launch ramp and/or peak sales underperforms our estimates, and 4) dalbavancin is not adopted for other MRSA indications.

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See the Companies Mentioned section for full company names.

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