

**Jefferies 2013 Healthcare Conference** 

# **Forward Looking Statements**



This presentation contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this presentation, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make as a result of various important factors, including those discussed in the "Risk Factors" section of our most recent quarterly report on Form 10-K, which is on file with the SEC and is also available on our website. The forward-looking statements contained in this presentation reflect Durata's current views with respect to future events, and Durata assumes no obligation to update any forward-looking statements except as required by applicable law.

# **Durata Therapeutics**



We are a pharmaceutical company focused on the development and commercialization of novel therapeutics for patients with infectious diseases and acute illnesses. Our lead product candidate, dalbavancin, is in development for the treatment of patients with acute bacterial skin and skin structure infections, or ABSSSI.

# **Key Investment Highlights**



- Highly differentiated, late-stage product with documented efficacy, safety and tolerability
  - Previous Phase 3 program met all primary and secondary endpoints
  - Recently reported DISCOVER program studies met all primary and secondary endpoints
  - Clearly defined regulatory pathways with near term NDA & MAA filings planned
- Clinical focus is moving to opportunities beyond the primary ABSSSI indication
  - Osteomyelitis
  - Hospital Community Acquired Pneumonia
  - Diabetic Foot Infection
- A large and growing category
  - ~2.6 million patients admitted to hospitals for IV Antibiotic therapy annually
  - > ~35mm days of therapy annually: \$10B at branded prices
- Favorable capital structure
  - Recently added \$70M+ to balance sheet
  - Favorable corporate tax rate and no royalties (except single digit on Japan sales only)
  - Patent coverage/exclusivity through 2023 with possible extension; 5 years added (10 total) data exclusivity upon FDA approval with QIDP designation

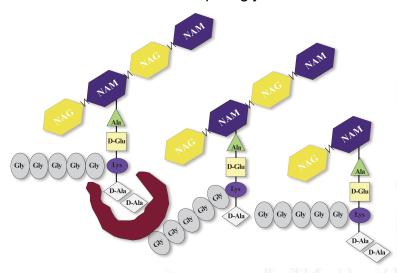
# Dalbavancin Differentiation

## **Dalbavancin: Mechanism of Action**



 Dalbavancin is a potent semisynthetic glycopeptide (lipoglycopeptide) which interferes with peptidoglycan cross-linking in the cell wall by binding to the D-ala-D-ala terminus of stem peptides.

Peptidoglycan of S. aureus



Glycopeptide binding

# Comparative MIC90 (µg/ml) of selected agents and dalbavancin tested against Worldwide clinical isolates (2002)\*

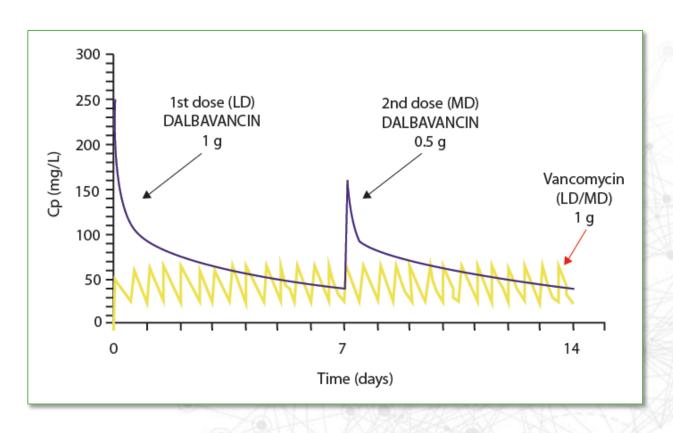
	S. aureus (1,815) OX-S	S. aureus (1,177) OX-R	β-hemolytic streptococci (234)	viridans group streptococci (30) PCN-R
Dalbavancin	0.06	0.06	0.06	0.03
Teicoplanin	1	2		
Vancomycin	1	2	0.5	0.5
Oxacillin	S	R	PCN = 0.06	R
Linezolid	2	2	1	1

<sup>\*</sup>Streit, et al. DMID 2004, p137





Dalbavancin dosed with 1000 mg IV on Day 1 and 500 mg IV on Day 8



Dalbavancin's pharmacokinetic profile enables:

- Broad tissue distribution
- Continuous cidality
- Once weekly dosing
- Maintenance of high plasma concentration

# DURATA

# **DISCOVER Program Summary and Conclusions**

- Protocol designs were consistent with the U.S. FDA Draft Guidance for Developing Drugs for Treatment of ABSSSI (Acute Bacterial Skin & Skin Structure Infections).
- Each of the studies were conducted pursuant to a Special Protocol Agreement (SPA) with the FDA, as well as Scientific Advice provided by the European Medicines Agency (EMA).
- Based on preliminary top-line data, the trial objectives were achieved
  - Efficacy
    - Primary and key secondary endpoints were met
    - Additional secondary endpoints were supportive of the primary endpoint
    - MRSA data similar to comparator & number of isolates meets FDA/EMA requirements
  - ✓ Safety
    - Adverse event profile was encouraging and similar to prior studies
      - No unexpected adverse events
- Program demonstrates the reproducibility of dalbavancin's activity in the treatment of ABSSSI, including those caused by MRSA, at both early and late time points.

# **Commercial Thesis and Opportunity**

## **Dalbavancin Commercial Thesis**



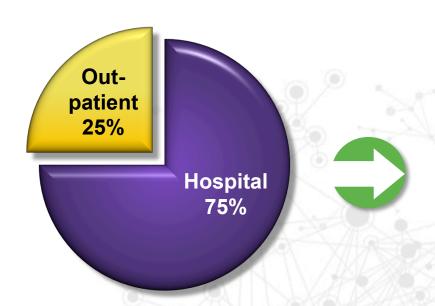
- US ABSSSI (at risk for MRSA) market is large;
  - > ~2.6 million patients admitted to hospitals for IV Antibiotic therapy annually
  - > ~35mm days of therapy annually, dominated by vancomycin
  - > High and growing prevalence of MRSA leads to empiric treatment
- Providers respond positively to the dalbavancin product profile
  - Well positioned to address providers' desire to deliver care in ambulatory settings more frequently
  - Presents opportunities in indications beyond ABSSSI
- Health economic and reimbursement dynamics are favorable
  - Reimbursement metrics are driving care to hospital ambulatory or out-patient settings
- Customer universe is highly targeted
  - Top 500 hospitals provide greater than 40% of our target market opportunity

# **US Market Opportunity**



We believe there are ~35 million days of treatment (DOT) annually, in the US, for ABSSSI patients at risk for MRSA utilizing intravenous antibiotics; this would represent a \$10 billion market at branded pricing\*

**ABSSSI Annual Days of Treatment – IV Antibiotics** 



Market is larger when expanded to include MSSA and oral step-down therapies

### Source: Stanford Group June 2007, Industry Sources 2010

### **Leading Products**

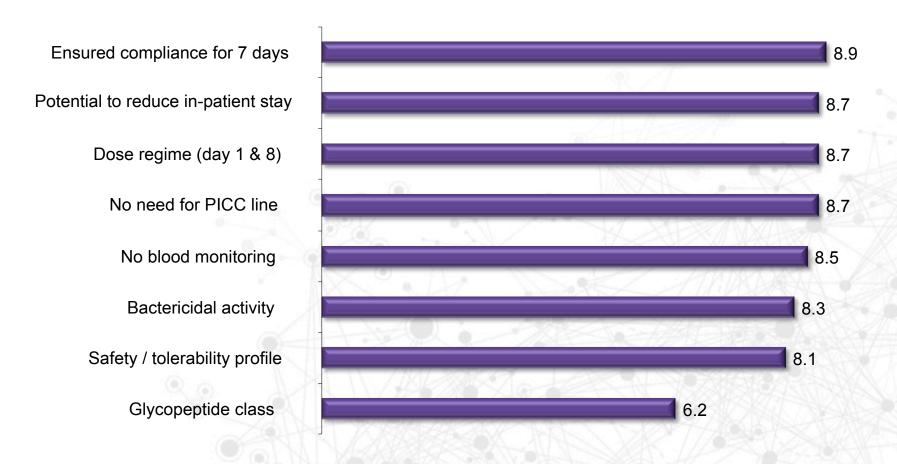
Product	DOT (Millions)
Vancomycin	7.2
Cefazolin	3.4
Piperacillin	3.4
Clindamycin	2.5
Ampicillin	1.6
Ceftriaxone	1.3
Levofloxacin	1.1
Gentamicin	0.7
Daptomycin	0.6
Tigecycline	0.4

<sup>\*</sup> If generic units were converted to branded daptomycin pricing

# Clinician Response to Dalbavancin Product Profile by Feature



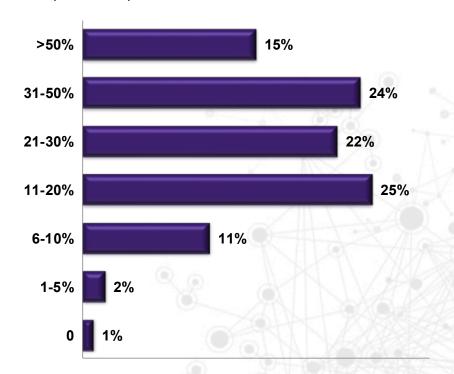
1 = Not favorable at all; 10 = Extremely favorable



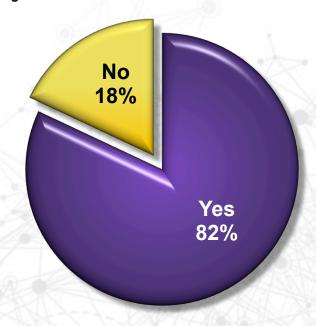
# Clinicians Response to Treatment Setting Using Dalbavancin



- 86% of respondents believe that >10% of SSSI patients, currently admitted to the hospital, could be treated as an outpatient with dalbavancin
- Q: What percent of SSSI patients currently admitted to the hospital could now be treated on an out-patient basis over the entire course of treatment due to this product's profile?



- Institutional burden is a factor for assessing benefit
- Q: Will your hospital/institution factor in the savings from administrative benefits, such as lower burden on nursing time, in assessing the cost/benefit of this drug?



# **Commercial Strategy: Selected Potential Patient Flow Examples**



	1 <sup>st</sup> Infusion	2 <sup>nd</sup> Infusion
1	Emergency Department (ED)	Hospital Outpatient Department (HOPD)
2	Inpatient	HOPD / Infusion center
3	Physician office	Physician office

### **Example 1**

- Patients who are released from the ER without being admitted to the hospital inpatient setting are an optimal target population for the drug
  - Infusion 1 performed in ED, separate payment for the drug
  - Infusion 2 performed in HOPD, separate payment for the drug

### Example 2

- While the inpatient setting is important for the drug, drug costs are bundled into a single payment
  - Infusion 1 in inpatient setting, no separate payment for the drug (bundled into DRG)
  - Infusion 2 performed in HOPD, separate payment for the drug

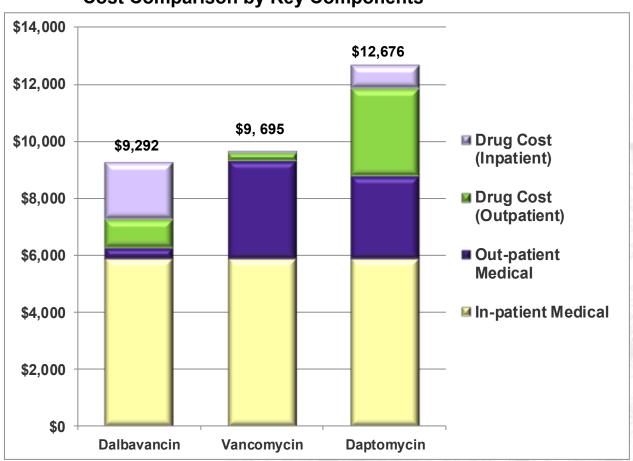
### **Example 3**

- Patients who receive infusions in physician offices are an optimal target population
  - Infusion 1 in the physician office, separate payment for the drug
  - Infusion 2 in the physician office, separate payment for the drug

# **Hypothetical Dalbavancin Scenario 1**<sup>2</sup>: Same Treatment Protocol (hospital and out-patient days)



### **Cost Comparison by Key Components**



### Scenario 1:

Assumes first line treatment only, equal efficacy 88.9%<sup>1</sup>

# Comparators and Selected Assumptions:

### 1) Dalbavancin:

3 days in-patient 11 days out-patient

### 2) Vancomycin:

3 days in-patient 11 days out-patient

### 3) Daptomycin:

3 days in-patient 11 days out-patient

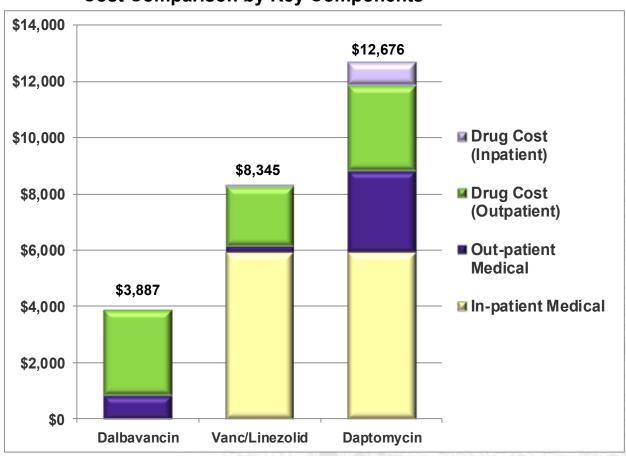
<sup>&</sup>lt;sup>1</sup>Jauregui, et al. Clin. Infect. Dis. 2005;41:1407-1415

<sup>&</sup>lt;sup>2</sup> Please see the appendix for additional information re: this data/cost scenario

# **Hypothetical Dalbavancin Scenario 2**<sup>2</sup>: Altered Treatment Protocol (avoiding hospital admission)



### **Cost Comparison by Key Components**



### Scenario 2:

Assumes 1<sup>st</sup> line treatment only, equal efficacy 88.9%<sup>1</sup>

# Comparators and Selected Assumptions:

### 1) Dalbavancin:

14 days out-patient (no in-patient admission)

### 2) Vancomycin:

3 days in-patient

### + Linezolid (oral):

11 days out-patient

### 3) Daptomycin:

3 days in-patient, 11 days out-patient

<sup>&</sup>lt;sup>1</sup>Jauregui, et al. Clin. Infect. Dis. 2005;41:1407-1415

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# Commercial Strategy: Target hospitals



 Approximately 1,900 hospitals account for 80% of the total opportunity based on our selected target market; the top 500 hospitals provide greater than 40% of our target market opportunity

Number of hospitals accounting for:

Deciles 3-10 of Target Market: 1,870

Deciles 3-10 of Branded Market: 1,594

Deciles 3-10 of both Target Market and Branded Market: 1,392

Deciles 6-10 of both Target Market and Branded Market: 459

Source: IMS: Durata - Account Based Targeting and Alignment, March, 2013

# Commercial Strategy: Launch Plans



- Current pre-launch efforts will focus on key stakeholders:
  - Mapping formulary submission processes and evidence requirements
  - Development and validation of value dossier, formulary submissions
  - Infectious disease and pharmacy education of key thought leaders
  - Develop key account plans and value proposition with payers and hospital administration
  - > Develop reimbursement support services and resources
- Target audiences:
  - > 1,500-2,000 hospitals
  - > 7,000 IDs
  - > 6,000 high volume (gram + utilization) IMs and surgeons
- Anticipate a commercial organization of ~140 personnel, including hospital specialists, key accounts, formulary, marketing, discharge and reimbursement support



# **Recent and Upcoming Events**

# **Key Milestones / Upcoming Events**



- Strong balance sheet
  - > \$46M cash, cash equivalents and short-term investments at Q1'13
  - \$20M debt funding received (low # warrants, interest only year 1)
  - \$54M additional capital from April 2013 follow on offering
- Controlled Operating Expenses
  - > \$11.1M R&D at 1Q13
  - > \$4.1M G&A at 1Q13
- Current shares outstanding: Approx. 26.6M (ex. 2.3M options)
- Actively seeking Ex-US Commercial Partners

# **Key Milestones / Upcoming Events**



- NDA filing for ABSSSI in mid-2013:
  - Anticipated approval: 1H 2014
  - Pre-launch activities ongoing
- MAA filing for ABSSSI end of 2013:
  - Anticipated Approval: end of 2014
  - Commercial planning beginning
- Data presentations at select 2013 scientific meetings:
  - 8-week dosing at ECCMID
  - Additional data from DISCOVER Programs at ICAAC and ID Week
- Other studies and indications:
  - Pediatric ABSSSI: As required by regulatory authorities
  - Osteomyelitis: Program to pursue a near term publication is underway (Phase I)
  - Hospitalized Community Acquired Pneumonia: Phase 1 to be initiated in 2H 2013
  - Diabetic Foot Infection: Program to pursue a near term publication TBD

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