Treatment of Hyperkinetic Movement Disorders

Huntington’s Disease  Tardive Dyskinesia  Tourette Syndrome
Forward Looking Statements

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# Experienced Management Team

<table>
<thead>
<tr>
<th>Name</th>
<th>Background</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pratik Shah, Ph.D.</strong></td>
<td>Formerly Chairman at Auspex Pharmaceuticals. Partner at Thomas, McNERney &amp; Partners, Board of Ocera Therapeutics, Cebix, Inc. and SGB, Inc., Formerly at McKinsey &amp; Company.</td>
</tr>
<tr>
<td><strong>John Schmid</strong></td>
<td>Former Chief Financial Officer, co-founder at Trius Therapeutics</td>
</tr>
<tr>
<td><strong>David Stamler, M.D.</strong></td>
<td>Responsible for FDA approval of Xenazine® as Head of Development for Prestwick. Over 20 years of development experience with Abbott, Fujisawa and XenoPort</td>
</tr>
<tr>
<td><strong>Samuel Saks, M.D.</strong></td>
<td>Former co-founder and CEO of Jazz Pharma, and leadership roles at ALZA Corporation</td>
</tr>
<tr>
<td><strong>Bharatt Chowrira, Ph.D., J.D.</strong></td>
<td>Former CEO of Addex, and various leadership roles at Nektar, Merck, Sirna</td>
</tr>
<tr>
<td><strong>Andreas Sommer, Ph.D</strong></td>
<td>Former CSO of Insmed, and various leadership roles at Celtrix</td>
</tr>
</tbody>
</table>
**Company Highlights**

**SD-809 NOVEL DRUG: DUTETRABENAZINE**
- Targeted Deuterium Chemical Modifications to an Approved Drug ($253M 2013 Revenues)
- Differentiated Profile without Changing Target Binding

**THREE INDICATION OPPORTUNITY**
- Not just Huntington’s disease but also Tardive Dyskinesia, Tourette Syndrome
- Issued Composition of Matter Patent Expected to Expire in 2031 in the US and 2029 in Europe

**LATE STAGE OPPORTUNITY**
- Orphan Indication (Huntington’s disease) in Phase 3
- Expected Phase 3 Huntington’s Data Q4 ’14
- Phase 2/3 Data in Tardive Dyskinesia Mid-2015
- Phase 1b trial in adolescents with Tourette’s
- Major independent catalysts

**FOCUSED EXECUTION STRATEGY**
- Efficient Go-to-Market Potential
- Promising Physician Feedback
# Anticipated Milestone Roadmap

<table>
<thead>
<tr>
<th>MILESTONES</th>
<th>Preclinical</th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
<th>Timeline</th>
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<tbody>
<tr>
<td><strong>Huntington’s Disease</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>Topline data in Q4’14</strong></td>
</tr>
<tr>
<td>- First-HD: Tetrabenazine Naïve,</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Primary Endpoint:</td>
</tr>
<tr>
<td>Double-Blinded, Placebo-Controlled</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Change in Total Maximal</td>
</tr>
<tr>
<td>- <strong>ARC-HD Switch</strong>: Switch Patients</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Chase in Total Maximal</td>
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<tr>
<td>Currently on Tetrabenazine, Open-Label</td>
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<td></td>
<td></td>
<td></td>
<td>Chorea Score (TMC)</td>
</tr>
<tr>
<td>- <strong>ARC-HD Rollover</strong>: Long-Term Safety</td>
<td></td>
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<td></td>
<td><strong>Topline data in Mid</strong></td>
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<tr>
<td>Study, Open-Label</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2015</td>
</tr>
<tr>
<td><strong>Tardive Dyskinesia</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>Topline data in Q4’14</strong></td>
</tr>
<tr>
<td>- n = 90</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Primary Endpoint:</td>
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<tr>
<td><strong>Tourette Syndrome</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Change in Abnormal Involuntary Movements Scale (AIMS)</td>
</tr>
<tr>
<td>- n = 12</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>Topline data in Q4’14</strong></td>
</tr>
<tr>
<td><strong>IPF &amp; Systemic Sclerosis (SD-560)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>Topline data in ‘15</strong></td>
</tr>
<tr>
<td>- n = 12</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Primary Endpoint:</td>
</tr>
<tr>
<td>8 Week Treatment Period</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Change in Yale Global Tic Severity Scale (YGTSS)</td>
</tr>
</tbody>
</table>

*Primary Endpoints were specified but may change based on evolving clinical data.*
SD-809: Deuterated Tetrabenazine

**XENAZINE® (Tetrabenazine)**

Only FDA-Approved Drug for Chorea Associated With Huntington’s Disease

**SD-809 (Dutetetabenazine)**

Targeted Deuterium Chemical Modifications in an Approved Drug

**What is it?**

A non-toxic, naturally occurring form of hydrogen (H) with twice the molecular weight.

**Advantages of D Substitution:**

- No Change in Shape, Size, Charge, or Target Pharmacology of Small Molecules
- Can Improve PK: 8x stronger C-D bond attenuates metabolism and increases half life
  - Confers Several Potential Advantages
- Less frequent dosing
- Reduced interpatient variability in drug metabolism
- Improved tolerability
- Reduced drug interactions
- Reduced genotyping
**Tetrabenazine has limitations**

**A Successful Drug**

**XENAZINE® ACTUAL RUN-RATE**

- **$253M** in 2013 Revenues
- **Approximately 4,000** Patients Treated with XENAZINE®
- **$60 - $70K** Estimated Annual Cost of Treatment

**BUT**

**Significant Limitations**

**DOSE-LIMITING SIDE EFFECTS**

<table>
<thead>
<tr>
<th>Five Most Prevalent AEs</th>
<th>Xenazine®</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sedation/ Somnolence</td>
<td>31%</td>
<td>3%</td>
</tr>
<tr>
<td>Insomnia</td>
<td>22%</td>
<td>0%</td>
</tr>
<tr>
<td>Fatigue</td>
<td>22%</td>
<td>13%</td>
</tr>
<tr>
<td>Depression</td>
<td>19%</td>
<td>0%</td>
</tr>
<tr>
<td>Akathisia</td>
<td>19%</td>
<td>0%</td>
</tr>
</tbody>
</table>

- PK Profile with High Peak Concentration Makes It Difficult to Stay within Therapeutic Window
- Burdensome Dosing Schedule (TID) Due to Its Short Half-Life
- Highly Variable Metabolism
- Need to genotype at 50% maximal dose

Sources: ¹ Lundbeck Quarterly Earnings Reports, ² XENAZINE® FDA Label
Tetrabenazine Is Effective in Other Movement Indications

Efficacy Response Rates

75%+ of patients show marked or moderate reductions across all 3 indications.

- Chorea (n=98):
  - 60% in Marked Reduction
  - 21% in Excellent Improvement
  - 10% in Moderate Reduction
  - 4% in Poor or No Response

- Tardive dyskinesia (n=149):
  - 71% in Marked Reduction
  - 14% in Excellent Improvement
  - 4% in Moderate Reduction
  - 5% in Poor or No Response

- Tics (n=92):
  - 50% in Marked Reduction
  - 29% in Excellent Improvement
  - 16% in Moderate Reduction
  - 4% in Poor or No Response

Three Horizons for Growth for SD-809 – Unmet Needs in Movement Disorders

**Tourette Syndrome**
- Approved Neuroleptics Are Inadequate
- Risk of causing tardive dyskinesia
- Estimated 100,000 to 350,000 Patients Affected

**Tardive Dyskinesia**
- No Drugs Approved in the United States
- Tetrabenzine Effective in Treating Chorea, but Many Limitations
- Poorly Tolerated, Frequent Dosing, Need for Genotyping, etc.
- Estimated 500,000 Patients Affected

**Huntington’s Disease**
- Tetrabenzine 2013 Sales were $253M with approximately 4,000 patients on therapy in US (On and Off-Label)
- Estimated 30,000 Patients Affected

**Tetrabenzine**
- 2013 Sales were $253M with approximately 4,000 patients on therapy in US (On and Off-Label)
Deuterium Modification Attenuates Metabolism

SD-809 Dutetrabenazine

Active Metabolites

Deuterium Modification Attenuates Metabolic Breakdown of alpha and beta

- $\alpha$-dihydrodutetrabenazine (alpha)
- $\beta$-dihydrodutetrabenazine (beta)

O-desmethyl dihydrodutetrabenazine (ODM)
SD-809 Provides Doubling of AUC Compared to an Equal Dose of Tetrabenazine

Two-way Crossover Study comparing total alpha + beta with 25 mg SD-809 and 25 mg Tetrabenazine (N = 19)

Systemic Exposure or Plasma Concentration (ng*hr/mL or ng/mL)
Differentiated Pharmacokinetic Profile

SD-809 DEMONSTRATED
- Reduced Cmax
- A Lower Rate of Rise
- Comparable Drug Exposure with Half the Dose
- Less frequent dosing
- Improved tolerability
- Reduced interpatient variability
- Reduced drug interactions
- Reduced need for genotyping

Note: SD-809 AUC in Fasted State was comparable to SD-809 AUC in Fed State (within 15%). Tetrabenazine is given without regard to meals, per the FDA label.
Precedents: Differentiated Pharmacokinetics Leading to Improved Safety Profiles

**C-Max Reduction**

- **EFFEXOR XR**
  - Mood Disorder

- **AMPYRA**
  - Multiple Sclerosis

- **GRALISE**
  - Postherpetic Neuralgia

**Reduced Side Effects***

- **EFFEXOR XR**
  - Nausea: 26% vs. 19%
  - Somnolence: 14% vs. 9%
  - Dry Mouth: 11% vs. 6%
  - Asthenia: 6% vs. 1%

- **AMPYRA**
  - Dizziness: 46% vs. 3%
  - Gait Instability: 14% vs. 4%
  - Paresthesia: 6% vs. 1%
  - Seizures: 2% vs. 0%

- **GRALISE**
  - Nausea: 21% vs. 1%
  - Somnolence: 16% vs. 2%
  - Dizziness: 18% vs. 9%
  - Edema: 6% vs. 4%

* Cross Study Comparisons; All Values Placebo-Adjusted
Differentiated Profile for HD, TS and TD

POPULATION PHARMACOKINETIC MODEL OF TETRABENAZINE AND SD-809 FROM HUMAN STUDIES

Note: Population pharmacokinetic model derived from Auspex’s Phase 1 clinical studies to date.
Reduced Interpatient Variability with More Uniform Metabolism

TWO-WAY CROSSTOVER STUDY
N = 14

Ratio of ODM to Active Metabolites

Wide Spread in Rates of Metabolism

Reduced variability

Tetrabenazine

SD-809

Note: Two way cross-over study; 25 mg of SD-809 or 25 mg of tetrabenazine.
**Comparison of Maximal Dose Without Restriction**

From Tetrabenazine FDA-Approved label (09/12/12)

**WARNINGS AND PRECAUTIONS**

Do not exceed 50 mg/day and the maximum single dose should not exceed 25 mg if administered in conjunction with a strong CYP2D6 inhibitor (e.g., fluoxetine, paroxetine).

Sec. 5.2:

Doses above 50 mg should not be given without CYP2D6 genotyping patients to determine if they are poor metabolizers.

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% Maximal Daily Dose Without Restrictions is 50% for Tetrabenazine and 75% for SD-809

**SD-809**

- 48 mg

**Tetrabenazine**

- 100 mg

AUC Matched Doses:

- 50 mg

Maximum Daily Dose:

- 0 mg

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**From Tetrabenazine FDA-Approved label (09/12/12)**
Maximal Mean Change from Pre-Dose in Corrected QT Interval after Single Doses of SD-809 (15 mg) or Tetrabenazine (25 mg), N = 12

<table>
<thead>
<tr>
<th></th>
<th>SD-809 15 mg</th>
<th>Tetrabenazine 25 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximal Increase in</td>
<td>0.36 (7.68)</td>
<td>7.26 (6.12)</td>
</tr>
<tr>
<td>Corrected QT Interval</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(msec)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Values are Mean (SD)
VMAT-2 Is A Clinically Validated Mechanism

PIVOTAL STUDY RESULTS FOR TREATING CHOREA IN HD (XENAZINE® FDA LABEL)

- Tetrabenazine Inhibits Vesicular Monoamine Transporter 2 (VMAT-2)
- VMAT-2 Inhibition → Dopamine Depletion → Reduction in Involuntary Movements

Sources: Xenazine® FDA Label
SD-809 Has Target Product Profile Valued by Neurologists

**TARGET PRODUCT PROFILE**
- Significantly Less Interpatient Variability vs. Xenazine®
- Twice Daily Dosing
- 15% or 33% Reduction in AE Rates

**NEUROLOGIST PREFERENCE SHARES BASED ON TWO DIFFERENT SD-809 PROFILES**
(Huntington’s Disease)

<table>
<thead>
<tr>
<th>Patients:</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
<th>Untreated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current Xenazine®</td>
<td>17%</td>
<td>31%</td>
<td>37%</td>
<td></td>
</tr>
<tr>
<td>Xenazine®</td>
<td>83%</td>
<td>69%</td>
<td>63%</td>
<td></td>
</tr>
<tr>
<td>Untreated</td>
<td>11%</td>
<td>17%</td>
<td>23%</td>
<td></td>
</tr>
<tr>
<td>SD-809</td>
<td>70%</td>
<td>53%</td>
<td>41%</td>
<td></td>
</tr>
<tr>
<td>Xenazine®</td>
<td>18%</td>
<td>28%</td>
<td>34%</td>
<td></td>
</tr>
<tr>
<td>Untreated</td>
<td>12%</td>
<td>19%</td>
<td>22%</td>
<td></td>
</tr>
<tr>
<td>SD-809</td>
<td>15%</td>
<td>28%</td>
<td>34%</td>
<td></td>
</tr>
<tr>
<td>Xenazine®</td>
<td>18%</td>
<td>28%</td>
<td>37%</td>
<td></td>
</tr>
<tr>
<td>Untreated</td>
<td>18%</td>
<td>28%</td>
<td>37%</td>
<td></td>
</tr>
</tbody>
</table>

Sources: Healogix physician survey, ¹ Defined in survey as 15% or 33% reduction in adverse events
Strong Interest In Other Indications

**Percent of Physicians Who Have Prescribed Xenazine®**

- Tourette Syndrome:
  - Mild: 15%
  - Moderate: 26%
  - Severe: 32%
- Tardive Dyskinesia:
  - Mild: 18%
  - Moderate: 28%
  - Severe: 38%
- Huntington’s Disease:
  - Mild: 47%
  - Moderate: 66%
  - Severe: 74%

**Percent of Physicians That Suggested They Would Prescribe SD-809**

- Tourette Syndrome:
  - Mild: 73%
  - Moderate: 90%
  - Severe: 89%
- Tardive Dyskinesia:
  - Mild: 64%
  - Moderate: 94%
  - Severe: 85%
- Huntington’s Disease:
  - Mild: 81%
  - Moderate: 84%
  - Severe: 84%

**Significant Market Potential**

- Tourette Syndrome: ~100,000-350,000 Patients
- Tardive Dyskinesia: ~500,000 Patients
- Huntington’s Disease: ~30,000 Patients

Sources: Healogix physician survey
Attractive Reimbursement and Specialty Pharmacy Distribution

HIGH REIMBURSEMENT SPECIALTY DISTRIBUTION

Current Annual Pricing
- $60,000-$70,000

Current Distribution
- Special Form Rx ➔ Centralized Hub
- Distributed Through 3 Specialty Pharmacies in U.S.
- Direct-Shipped to Patient on Named Basis
- REMS Program (FDA-Mandated Restrictions)

REDUCED PRICE EROSION FOR SPECIALTY PHARMACY DISTRIBUTED DRUGS POST-GENERIC ENTRY

Percent Price Change: Generic vs. Branded

Drugs Distributed by Specialty Pharmacies Only (n = 21)

Less than 20%
(Median # of Generics = 3)

All Values Are Medians
Note: (1) Redbook for pricing data, (2) Retail drugs includes non-specialty immediate release CNS drugs with available pricing data and approved extended release versions, (3) Price reduction is at 4 years after 1st generic relative to pre-generic price, (4) Number of marketed generics as of Q1 2013 from Drugs@FDA.

Drug Makers Use Safety Rule to Block Generics

“...It is not clear under applicable laws and regulations that Lundbeck is permitted to sell tetrabenazine to any person or entity without prescription.”
- Lundbeck Spokeswoman
April 15, 2013

The New York Times
Tourette Syndrome and Tardive Dyskinesia: Significant Tetrabenazine Clinical Response Yet Limited Usage

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### TOURETTE SYNDROME: TETRABENAZINE STUDIES

<table>
<thead>
<tr>
<th>AUTHOR(S)</th>
<th>PUB.</th>
<th>DESIGN</th>
<th>N</th>
<th>TREATMENT LENGTH</th>
<th>RESPONSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jankovic, Beach</td>
<td>1997</td>
<td>Retro</td>
<td>47</td>
<td>Avg: 20 mo</td>
<td>36/47</td>
</tr>
<tr>
<td>Paleacu et al.</td>
<td>2004</td>
<td>Retro</td>
<td>9</td>
<td>Avg: 25 mo</td>
<td>3/6</td>
</tr>
<tr>
<td>Jain, Greene, Frucht</td>
<td>2006</td>
<td>Retro</td>
<td>8</td>
<td>Avg: 22 mo</td>
<td>6/8</td>
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<tr>
<td>Kenney et al.</td>
<td>2007</td>
<td>Retro</td>
<td>77</td>
<td>Avg: 24 mo</td>
<td>64/77</td>
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<tr>
<td>Porta, et al.</td>
<td>2008</td>
<td>Retro</td>
<td>120</td>
<td>Avg: 19 mo</td>
<td>91/120</td>
</tr>
</tbody>
</table>

### TARDIVE DYSKINESIA: TETRABENAZINE STUDIES

<table>
<thead>
<tr>
<th>AUTHOR(S)</th>
<th>PUB.</th>
<th>DESIGN</th>
<th>N</th>
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<th>RESPONSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jankovic, Beach</td>
<td>1997</td>
<td>Retro</td>
<td>94</td>
<td>Avg: 35 mo</td>
<td>87/94</td>
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<tr>
<td>Ondo, Jankovic</td>
<td>1999</td>
<td>OL</td>
<td>20</td>
<td>Avg: 20 wk</td>
<td>54% ↓ in AIMS</td>
</tr>
<tr>
<td>Jankovic, Mejia, Vuong</td>
<td>2004</td>
<td>Retro</td>
<td>139</td>
<td>Avg: 30 mo</td>
<td>116/139</td>
</tr>
<tr>
<td>Paleacu</td>
<td>2004</td>
<td>Retro</td>
<td>15</td>
<td>Avg: 22 mo</td>
<td>10/15</td>
</tr>
<tr>
<td>Kenney</td>
<td>2007</td>
<td>Retro</td>
<td>149</td>
<td>Avg: 30 mo</td>
<td>128/149</td>
</tr>
</tbody>
</table>

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### CURRENT STATUS

- TS and TD **NOT** on FDA Label for Xenazine®
- Limited Usage in TS and TD possibly due to lack of patent protection

### PROMISING RESULTS

- Used FDA-Suggested Endpoints (AIMS Scale)
- 9.7 Point Reduction from a Baseline of 17.9

### OUTLOOK FOR SD-809

- Improved Profile Should Be Welcome in These Indications

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Sources:
Tardive Dyskinesia P2/3 Study Design

Phase 2/3, Double-Blind, Placebo-Controlled, Parallel Group Study at ~30 Enrolling Sites in US/Canada

MODERATE TO SEVERE DRUG-INDUCED TARDIVE DYSKINESIA

~45 Subjects (SD-809) ~45 Subjects (Placebo)

12 Week Treatment Period Titrated to Optimal Dose

Efficacy Endpoints
Primary: Change in AIMS Score from Baseline to Week 12 as Assessed by Central Video Rater
Key Secondary: Clinical Global Impression

Safety Endpoints
Adverse Events, Vital Signs, Physical/Neuro/Laboratory Examinations, ECGs During Dose Escalation
Tourette Syndrome Phase 1b Study

- Open label, preliminary efficacy and safety study to evaluate SD-809 in the treatment of tics associated with Tourette syndrome (TS)

- Objectives:
  - Evaluate safety and tolerability of SD-809 in TS
  - Evaluate preliminary efficacy of SD-809 to suppress tics associated with TS

- 12 adolescent subjects with moderate to severe tics associated with TS

- 8-weeks treatment, titrated to optimal dose

- Key Efficacy Parameters:
  - Total tic score (from Yale Global Tic Severity Scale)
  - TS- Clinical Global Impression

- Data Expected in Q4’14
SD-560: Deuterium-Containing Pirfenidone

- SD-560 is intended for the treatment of idiopathic pulmonary fibrosis (IPF), systemic sclerosis and other related orphan indications
- Auspex believes that SD-560 can potentially have benefits over pirfenidone in efficacy as well as safety and tolerability.
- SD-560 has issued composition of matter patents in the US and Europe that expire in 2028
- Phase 1 clinical study data expected in 2015
## Robust Global IP Portfolio

### Worldwide Coverage for SD-809

**Composition-of-Matter Claims**  
(US8,524,733; EP2326643B)

<table>
<thead>
<tr>
<th>Compound:</th>
<th>SD-809</th>
</tr>
</thead>
<tbody>
<tr>
<td>Priority Date:</td>
<td>September 2008</td>
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<tr>
<td>Expected Exclusivity:</td>
<td>2031 (Before any patent term extension)</td>
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</tbody>
</table>

### Additional IP Portfolio

- **41** Issued/Allowed Patents
- **51** Patent Applications
- **52** Drugs Covered
## Capitalization

<table>
<thead>
<tr>
<th>($ Millions)</th>
<th>Actual 3/31/14</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash and Cash Equivalents</td>
<td>$119.8</td>
</tr>
<tr>
<td>Long Term Debt*</td>
<td>$ 15.0</td>
</tr>
<tr>
<td>Runway</td>
<td>Q4 ‘15</td>
</tr>
<tr>
<td>Shares Outstanding</td>
<td>23.6MM</td>
</tr>
<tr>
<td>Fully Diluted Shares Outstanding</td>
<td>28.0MM</td>
</tr>
</tbody>
</table>

*Interest only loan through the end of Q2 ’15 and maturing in Q4 ‘17.*