Strategic Market Analysis
for Early Stage Oncology Companies

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Presentation Outline

• Services overview
• Analysis simplifies the complex
• Analysis process
• Capabilities and experience
• Working together
• Discussion
Understanding of product, competition and path to market is key for successful new product development.
Services Overview

Market Analysis
- Treatment landscape
- Competition matrix
- Epidemiology
- Reimbursement and pricing
- Treatment drivers
- Barriers to entry
- Unmet medical need
- Primary and secondary market research

New Product Planning
- Target Product Profile
- Indication prioritization
- Forecasting
- Product positioning
- Medical communications
- Medical affairs support
- SWOT
- Landscape mapping

Business Development
- Licensing representation
- Business plan writing
- Corporate communications
- Start-up advisory
- Deal comparables analysis

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Analysis Simplifies the Complex

Oncology markets are more crowded, complex and challenging

- 4 fold increase in oncology compounds in Phase 1 at big pharma (32 vs. 130) past 10 years
- Shift to targeted therapies and more target overlap across mechanisms
- Few overlooked, indications, small indications are of interest
- More challenging regulatory environment, emphasis on overall survival, and economic benefit

Higher stakes for decisions around indications and path to market, need to be informed and data-driven
Market Analysis To Enhance R&D

Program Resource Allocation
- Global opportunity assessment

Compound Lead Selection
- Target Product Profile
- Competitive impact

Indication Prioritization
- Landscape analysis by indication
- SWOT
- Sales forecast
Market Analysis For Future Development

- Tailoring product positioning to support future partnering
- Designing studies to support product positioning
- Identifying patient segments of greatest promise
- Rationale for future investment and fundraising
- Rationale for timing and spending for development
Analysis Process

1. Target indication
2. Define the Patient Population
   - Epidemiology
   - Extrapolate segments
3. Pipeline
   - Clinical trial activity
   - Outcomes
4. Assess opportunity within and across indications
   - Target Product Profile
   - Expert input
5. Standard of care
   - Clinical outcomes by segments
   - Trends
   - Opportunities

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Market Research Resources

Secondary Data

- Clinical conferences and scientific literature
- SEC.gov
- NIH/NCHS
- clinicaltrials.gov
- Competitor websites
- Medical Associations
- Trade associations (BIO, AdvaMed, PMC)
- Trade publications (FierceBiotech, Signals)
- Patient advocacy groups (American Cancer Society)
- Foundations MMRF
- Public health (WHO, NICE, FDA, Globocan, CDC)
- USPTO.gov
- Google
- Wikipedia

Primary Data

- KOL’s • Interviews • Focus Group • SAB
- Stakeholders: Physician, Nurse, Patient, etc. • Interview • Focus groups • On-line survey • Convention survey
- Analyst reports
- Syndicated reports • Pharmacor • DaVinci
- Audit data • IMS • Synovate
- Conference competitive intelligence
## Assessment Metrics

<table>
<thead>
<tr>
<th>Subject</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current standard of care and outcomes</td>
<td>NCCN guidelines, clinical lit, NICE other govt. guidance</td>
</tr>
<tr>
<td>Competitive clinical activity, by stage, by pathway, by compound type</td>
<td>clinicaltrials.gov listing, identify key agents using clinical lit</td>
</tr>
<tr>
<td>Key compounds: features and benefits</td>
<td>Conferences and literature, analyst reports</td>
</tr>
<tr>
<td>Patient population</td>
<td>Prevalence and incidence, SEER and Globocan Trends and subsets from clinical lit</td>
</tr>
<tr>
<td>Clinical trial population availability</td>
<td>clinicaltrials.gov</td>
</tr>
<tr>
<td>Regulatory path</td>
<td>FDA website, Fast Track requirements</td>
</tr>
<tr>
<td>Pharmacoeconomics</td>
<td>QALY evaluations for competitive drugs/regimens, NICE Guidance's</td>
</tr>
<tr>
<td>Pharma interest</td>
<td>Licensing presentations, contacts</td>
</tr>
<tr>
<td>Intellectual property, freedom to operate, prior art</td>
<td>uspto.gov</td>
</tr>
<tr>
<td>Reimbursement and pricing</td>
<td>Medicare databases, DRG codes, RedBook, 3rd Party coverage statements (Aetna, Anthem)</td>
</tr>
</tbody>
</table>
Analysis Process

Target indication

Assess opportunity within and across indications
Target Product Profile
Expert input

Define the Patient Population
Epidemiology
Extrapolate segments

Pipeline
Clinical trial activity
Outcomes

Standard of care
Clinical outcomes by segments

Market Drivers and Barriers
Trends
Opportunities

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Defining the Patient Population

Myeloma 2007

By staging, by prior treatment, use of SCT, treatment response, biomarkers, cell types

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Analysis Process

1. **Target indication**
   - Define the Patient Population
   - Epidemiology
   - Extrapolate segments

2. **Assess opportunity within and across indications**
   - Target Product Profile
   - Expert input

3. **Pipeline**
   - Clinical trial activity
   - Outcomes

4. **Standard of care**
   - Clinical outcomes by segments
   - Trends
   - Opportunities
# Pipeline Analysis

## First Step: Data Capture

<table>
<thead>
<tr>
<th>MOA</th>
<th>Company</th>
<th>Dev. MM</th>
<th>Pop.</th>
<th>Current Studies</th>
<th>Efficacy</th>
<th>Safety</th>
<th>Dosing</th>
<th>Comp. Threat</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>NR-0052</td>
<td>PI</td>
<td>Nereus</td>
<td>I</td>
<td>Ref Ref. MTD, N=35, Start 3/07</td>
<td>In vivo n to bortezomib in MM xenograft, in vitro act. Against bortezomib resistant cell line</td>
<td>NA</td>
<td>IV. once weekly, possible oral</td>
<td>Low</td>
<td>Timing, More focus on solid tumors (3:4 Phase 1s)</td>
</tr>
<tr>
<td>Cep-18770</td>
<td>PI</td>
<td>Cephalon</td>
<td>PC</td>
<td>Not known</td>
<td>In vitro sign. Lower IC50 vs bortezomib in MM and other cell lines and in vivo longer survival vs bortezomib</td>
<td>NA</td>
<td>IV, orally active</td>
<td>Low</td>
<td>Timing, Emphasis on solid tumors, NHL (Ph1)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Generic (Brand)</th>
<th>Efficacy</th>
<th>Safety</th>
<th>Dosing/Ad administration</th>
<th>Current Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patupilone</td>
<td>High clinical activity against the MM cell line, improved over WBRT alone (57% vs 28% 90-day survival)</td>
<td>Overall low incidence, 8% disease free survival</td>
<td>IV initial dose, then weekly administration</td>
<td>Dosed in trial</td>
</tr>
<tr>
<td>Hyzena (Topotecan)</td>
<td>Concurrent w WBRT: 28% ORR, but no statistically significant benefit over WBRT alone, median PFS 79 days</td>
<td>Hypoactivity and treatment related death due to febrile neutropenia</td>
<td>IV. based on dose</td>
<td>Phase III completed but enrollment is due to dose limited further studies needed. Approved for IV.</td>
</tr>
<tr>
<td>Temodar (Temozolomide)</td>
<td>Concurrent w WBRT: studies did not demonstrate additional benefit of Temodar plus WBRT alone. NO. ORR was 14 vs 8%, P = 0.05</td>
<td>Grade 3 adverse events were neurological and dermatologic (22% vs 19%)</td>
<td>Dosed in trials</td>
<td>FDA approved for use in gliomas and glioblastomas.</td>
</tr>
<tr>
<td>Xytrin (mitotane)</td>
<td>Concurrent w WBRT: Phase II in NSCLC, no significant difference for survival (median, 5.3 vs 9.4 months, P = 0.48) or time to neurotoxic progression TNP. 9.5 vs 8.3 mo; P = 0.05</td>
<td>Grade 3 adverse events were neurological and dermatologic (22% vs 19%)</td>
<td>Dosed in trials</td>
<td>FDA approved for use in metastatic breast cancer.</td>
</tr>
<tr>
<td>Tarceva (erlotinib)</td>
<td>Concurrent w WBRT: In a handful of cases have shown encouraging results in combination with WBRT</td>
<td>Severe rash &amp; diarrhea in 10% and the dermatologic adverse event of lung damage</td>
<td>Dosed in trials</td>
<td>FDA approved for use in non-small cell lung cancer.</td>
</tr>
<tr>
<td>Gemzar (gemcitabine)</td>
<td>Boost the activity of response to standard chemotherapy and decrease the mortality of patients with advanced MM. Phase I did not show any efficacy reported. Phase II in conjunction with WBRT is being considered withesar</td>
<td>Severe hematologic toxicity +</td>
<td>Dosed in trials</td>
<td>Abstracts refer to Phase II studies to follow-up, but found no further data on ongoing studies in brain metastases</td>
</tr>
</tbody>
</table>

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Pipeline Analysis

Slice and Dice

By segment indication

<table>
<thead>
<tr>
<th>Product</th>
<th>1st line adult</th>
<th>2nd line adult</th>
<th>1st line elderly</th>
<th>2nd line peds</th>
<th>Maintenance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product A</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product B</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product C</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product D</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product E</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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Analysis Process

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  - Expert input
- Standard of care
  - Clinical outcomes by segments
  - Trends
  - Opportunities

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Compare Product Attributes

### Product Rankings

<table>
<thead>
<tr>
<th>Time to Market</th>
<th>Convenience</th>
<th>Indication</th>
<th>Response</th>
<th>Safety</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product A</td>
<td>1</td>
<td>3.0</td>
<td>4.0</td>
<td>5.0</td>
<td>3.0</td>
</tr>
<tr>
<td>Product B</td>
<td>2</td>
<td>2.0</td>
<td>2.0</td>
<td>5.0</td>
<td>4.0</td>
</tr>
</tbody>
</table>

### Standard of Care

<table>
<thead>
<tr>
<th>Scale Definition</th>
<th>Consequence</th>
<th>Indication(s)</th>
<th>Response</th>
<th>Safety</th>
</tr>
</thead>
<tbody>
<tr>
<td>IV</td>
<td></td>
<td>Refractory=60, not FLT3 targeted</td>
<td>Hematological only</td>
<td>≥30% grade 3/4</td>
</tr>
</tbody>
</table>

### Compound Comparison

<table>
<thead>
<tr>
<th>Compound</th>
<th>Efficacy</th>
<th>Safety</th>
<th>Dosing</th>
<th>QOL</th>
</tr>
</thead>
<tbody>
<tr>
<td>DRUG A</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DRUG B</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DRUG C</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DRUG D</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A + B</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A+ C</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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Translate to Impact

- Map products against market attributes
Forecast Assumptions

**REVENUE**
- Prevalence and/or Incidence
- Treatment Population by Segment
- Market launch dates and indications
- On label and off label market shares
- Peak penetration rates
- Competitor drug shares, pipeline order entry
- Patent expiration impact
- Alternate scenarios
- Translation to vials, tablets
- Price per unit
- Sales revenue

**INCOME**
- Cost of goods
- SG&A expense
- R&D expense
- Tax credit or payment
- Royalty rates
- Discount rates
- Probability adjustments
- Partnering impacts
Capabilities and Experience

Consultant since 2005

- Start-up executive with breadth of knowledge in new product development
  - President, Janus Pharmaceuticals
  - SVP, Business Development Cell-Matrix
  - VP, Business Development Xencor
  - VP, Product Development, Alpha Therapeutic

- Industry expertise in-depth analytic and new product planning experience
  - Marketing research, Roche
  - R&D portfolio planning, Pfizer
  - New product marketing, Pfizer

- Passion for drug development focused on unmet medical needs
  - MS Public Health UCLA
  - Epidemiology
  - BS Physical Anthropology UC Berkeley
  - Genetic basis of behavior

Past Clients:
- AEMF
- LARTA
- IMMURX
- STRATINOVA
- XOMA
- NEREUS
- TRANSMEMBRANE
- MOLECULAR EXPRESS
- PROTEOLIX
- ABRAXIS BIO
- CHIOME BIO
- XENCOR
- SPECTRUM
- NOVARTIS
- AMI-USC
- NISSAN CHEMICAL
- ARIGEN
## Completed Consulting Projects

<table>
<thead>
<tr>
<th>Type</th>
<th>Therapeutic Area</th>
</tr>
</thead>
<tbody>
<tr>
<td>Competitive intelligence, conference coverage</td>
<td>Oncology</td>
</tr>
<tr>
<td>Market analysis</td>
<td>Peripheral neuropathies</td>
</tr>
<tr>
<td>Landscape and situational analysis</td>
<td>Oncology</td>
</tr>
<tr>
<td>KOL interviews, primary market research, in-licensing opportunity</td>
<td>Oncology</td>
</tr>
<tr>
<td>Income forecast and NPV analysis</td>
<td>Oncology</td>
</tr>
<tr>
<td>Competitive clinical assessment</td>
<td>Oncology</td>
</tr>
<tr>
<td>Business Plan Rewrite</td>
<td>Antibody library generation</td>
</tr>
<tr>
<td>Commercialization Plan</td>
<td>POC rapid diagnostic test, infectious disease</td>
</tr>
<tr>
<td>Pipeline; resource allocation/prioritization</td>
<td>Rheumatoid arthritis</td>
</tr>
<tr>
<td>Out-licensing strategic partner assessment, identification</td>
<td>Oncology</td>
</tr>
<tr>
<td>Pricing analysis</td>
<td>Oncology</td>
</tr>
<tr>
<td>Market analysis</td>
<td>Rare ophthalmic diseases</td>
</tr>
<tr>
<td>Commercial Assessment and Sales Forecast</td>
<td>Rheumatoid arthritis</td>
</tr>
<tr>
<td>Commercialization opportunity summary</td>
<td>Oncology</td>
</tr>
</tbody>
</table>
Working Together

- Analysis
- Solution
- Process
- Objectives
- Teamwork
- Vision
- Sales