Commercializing Your Ophthalmic Drug in North America

Ram Palanki
Senior Vice President
Commercial-Americas
Santen Inc
Acknowledgements

Bio Value Campaign

Dr. Ron Cohen

Dr. Pravin Dugel

Deloitte

McKinsey
It ain’t what you don’t know that gets you into trouble, its what you know for sure that just ain’t so

- Mark Twain (Attributed)
Hence, before we talk about commercialization......

some quick......
Most new drugs are invented in the US

By Inventing County in 2000
Small companies are the main driver behind the global pharma pipeline

Small companies drove 70% of the 5,923 clinical programs in 2015

Source: BIO Industry Analysis, BioMedTracker, June 2016
Less than 10% of US biotech companies are profitable.

Source: Factset, BIO Industry Analysis, January 2016
Biopharma had the highest rate of R&D reinvestment of any industry in 2015

<table>
<thead>
<tr>
<th>Rank</th>
<th>Industry</th>
<th>R&amp;D Spend</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1</td>
<td>US and Global Large BioPharma</td>
<td>18.5%</td>
</tr>
<tr>
<td>#2</td>
<td>Semiconductors</td>
<td>18.4%</td>
</tr>
<tr>
<td>#3</td>
<td>Electronic Production Equipment</td>
<td>17.6%</td>
</tr>
<tr>
<td>#4</td>
<td>Internet Software/Services</td>
<td>17.4%</td>
</tr>
<tr>
<td>#5</td>
<td>Packaged Software</td>
<td>14.3%</td>
</tr>
<tr>
<td>#6</td>
<td>Computer Communications</td>
<td>13.7%</td>
</tr>
<tr>
<td>#7</td>
<td>Computer Peripherals</td>
<td>11.7%</td>
</tr>
<tr>
<td>#8</td>
<td>Internet Retail</td>
<td>10.4%</td>
</tr>
<tr>
<td>#9</td>
<td>Electronic Equipment/Instruments</td>
<td>9.8%</td>
</tr>
<tr>
<td>#10</td>
<td>Medical Specialties</td>
<td>7.0%</td>
</tr>
</tbody>
</table>

Source: Factset, BIO Industry Analysis, June 2016
Developing a new medicine takes 10–15 years and over $2.5B*

Yet only 1 in 10 compounds reaching the clinic is approved.


*Actual range of compounds will vary by drug type and discovery technologies.
BioPharma industry ranks #45 in return on equity

<table>
<thead>
<tr>
<th>Rank</th>
<th>Industry</th>
<th>Return on Equity</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1</td>
<td>Tobacco</td>
<td>542.0%</td>
</tr>
<tr>
<td>#2</td>
<td>Financial Publishing/Services</td>
<td>90.2%</td>
</tr>
<tr>
<td>#3</td>
<td>Airlines</td>
<td>67.4%</td>
</tr>
<tr>
<td>#4</td>
<td>Casinos/Gaming</td>
<td>60.2%</td>
</tr>
<tr>
<td>#5</td>
<td>Home Improvement/Chains</td>
<td>41.2%</td>
</tr>
<tr>
<td>#6</td>
<td>Restaurants</td>
<td>37.9%</td>
</tr>
<tr>
<td>#7</td>
<td>Telecommunications Equipment</td>
<td>34.9%</td>
</tr>
<tr>
<td>#8</td>
<td>Office Equipment/Supplies</td>
<td>32.7%</td>
</tr>
<tr>
<td>#9</td>
<td>Beverages: Non-Alcoholic</td>
<td>29.9%</td>
</tr>
<tr>
<td>#10</td>
<td>Aerospace &amp; Defense</td>
<td>27.0%</td>
</tr>
<tr>
<td>#45</td>
<td>US and Global Large BioPharma</td>
<td>14.8%</td>
</tr>
</tbody>
</table>

Source: Factset, BIO Industry Analysis, June 2016
The Biopharmaceutical innovation ecosystem

The few winners must deliver significant returns on investment to incentivize ongoing investments across the ecosystem
Understanding the market segment is the essential to create a successful launch strategy.
2017: Three large growing Ophthalmic markets….

<table>
<thead>
<tr>
<th>Market</th>
<th>US*</th>
<th>Growth (2014-2025)</th>
<th>2025 %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retina</td>
<td></td>
<td>9.4%</td>
<td>39.2%</td>
</tr>
<tr>
<td>Glaucoma</td>
<td></td>
<td>0.3%</td>
<td>9.8%</td>
</tr>
<tr>
<td>Dry Eye</td>
<td></td>
<td>9.2%</td>
<td>17.3%</td>
</tr>
<tr>
<td>Allergy</td>
<td></td>
<td>5.8%</td>
<td>6.1%</td>
</tr>
<tr>
<td>Anti-Infectives</td>
<td></td>
<td>3.2%</td>
<td>3.5%</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td>11.3%</td>
<td>24.2%</td>
</tr>
</tbody>
</table>

Source: *IMS DataView; IMS MIDAS. IMS NPA
Retina: Frequent repeat Anti-VEGFs!
No new class of drug for Glaucoma in 21 Years!

**FP receptor agonists and alpha agonists were approved as new class of agents in 1996**

Persistence and Adherence With Topical Glaucoma Therapy

- Adherence Poor (< 50% by 6 months for most drops)
- 2x higher with once daily therapy (PG’s)

“Inflammatory Dry Eye”: What’s the true cause?

**International Dry Eye Workshop (DEWS) 2007**
- Decreased lacrimal tear secretion
- Tear Film and epithelial hyperosmolarity
- Stimulates a cascade of inflammatory events leading to decreased tear production and the generation of inflammatory cytokines
- Leading to
  - The need to treat with anti-inflammatory therapy

**The International Workshop on MGD 2011**
- Meibomian Gland Dysfunction (MGD)
- Increased evaporation leading to Hyperosmolarity
- Stimulates a cascade of inflammatory events leading to the generation of inflammatory cytokines
- Leading to
  - The need to first solve the MGD?
Define your market clearly: Optimize asset value proposition & price early

With only 8% of all new product forecasts being at on or near target, it is critical to identify the initial Target Market Early.

Ratio of actual sales at year of launch to forecast sales one year prior to launch

- Below forecast (66%)
  - 0-40%: 44
  - 40-80%: 22

- On or near forecast (8%)
  - 80-120%: 8

- Above forecast (26%)
  - 120-160%: 6
  - 160-200%: 7
  - >200%: 13

Source: EvaluatePharma, McKinsey analysis
If you forecast wrong in year 1, the trend will likely continue....

Launches that exceed forecasts

- Y1: 100%
- Y2: 65%
- Y3: 53%

Launches that lag forecasts

- Y1: 100%
- Y2: 78%
- Y3: 70%

Source: Evaluate; McKinsey
Start value proposition development during phase III

Value Based Care Payment Model

Enhance Patient Experience

Reimbursement from Payer

Improve Quality

Lower Overall Costs of Care
The U.S. pharmacy distribution and reimbursement system for patient-administered, outpatient prescription drugs

A Byzantine distribution & reimbursement system........
A Byzantine distribution & reimbursement system

Medical benefits that are physician administered

Physicians buy from Specialty Distributor or Specialty Pharmacy

Physicians outlay cash from their practice to inventory a product

Physicians bill patient’s health insurance after administration

Physicians are reimbursed for the product
Critical commercial operations for launch

1. **Transportation Management**
   - Leverage key carrier partnerships to ensure products are delivered to right location and on time

2. **Warehousing and Distribution**
   - Utilize network of warehouses and distribution facilities to hold products and materials

3. **Inventory Utilization**
   - Manage inventory levels to never have under-utilized product in the channel

4. **Reporting**
   - Leverage real-time views of sales, item movement, and inventory levels

5. **Order Management and Accounts Receivable**
   - Handle order management / verification, account reconciliation and invoice collection

6. **Contracts, Chargebacks, and Return Management**
   - Monitor contract obligations, eligibility, and chargeback processing

7. **HUB**
   - Streamlines access to products, providing resources to make treatment more affordable, and ensuring adherence
Strategic keys to introduce a product……

Develop a segmentation process where you are gathering feedback from KOLs & market research prior to establishing R&D model……

Gain rapid availability & access to all qualified customer channels; develop product champions to help fortify product need/distribution…..

Drive awareness of limitations of current therapies and position your product as innovative solution…..

Establish “Leadership Presence” by creating ‘product’ & ‘resource’ value that establishes a partnership with HCP & patient!
Monitoring performance in the first 6 months of launch

**Winning Launch Mindset**
- Is our organization sufficiently engaged and excited about launch?

**Launch Academy**
- Do we have pockets of excellence and capabilities we need to upgrade?

**“Five great decision”**
- What lessons have we learned from testing plans to secure price and access?
- How is the market responding to our key value messages?
- What feedback have we had on our project launch messages and activities?
- How has the market reacted to our go-to-market approach? Do we have an appropriately diversified and tailored mix?
- What positioning, access and commercial models do our competitor(s) adopt?
- How has the market responded?

**The Fundamentals**
- Are we executing according to plan, e.g., meeting targets for field force visits?
- What is the performance uptake in terms of prescriptions, sales, protocol inclusions, and so on?

Source: Insights into Pharmaceuticals and Medical Products, Beyond the storm, Launch excellence in the new world; McKinsey and company
Execution is everything!

If you’ve felt as if your struggling with execution, you’re not alone.

The Strategy to Execution Gap

According to Fortune Magazine less than 10% of strategies effectively formulated are implemented effectively.

“It’s rarely for lack of smarts or vision. Most unsuccessful CEOs stumble because of one simple, fatal shortcoming.”

Authors Ram Charan and Geoffrey Colvin’s in their June, 1999 Fortune cover story.